Date: 11-29-2023

IRB #: IRB-2020-27
Title: Direct Scheduling Platform for CC COAP
Creation Date: 1-7-2020
End Date:
Status: Approved
Principal Investigator: NICOLE ADAMS
Review Board: Exempt Reviewer and Admin Office Actions FY23
Sponsor: In Family & Social Services Admin

Study History

Submission Type Initial	Review Type Expedited	Decision Approved
Submission Type Modification	Review Type Expedited	Decision Approved
Submission Type Modification	Review Type Exempt	Decision Exempt
Submission Type Modification	Review Type Exempt	Decision Approved
Submission Type Modification	Review Type Exempt	Decision Approved
Submission Type Modification	Review Type Exempt	Decision Exempt
Submission Type Renewal	Review Type Exempt	Decision Exempt

Key Study Contacts

Member NICOLE ADAMS	Role Principal Investigator	Contact adams417@purdue.edu
Member NICOLE ADAMS	Role Primary Contact	Contact adams417@purdue.edu
Member Cathy Carby	Role Co-Principal Investigator	Contact ccarby@purdue.edu
Member PI JU LIU	Role Co-Principal Investigator	Contact liu2572@purdue.edu

Initial Submission

Study Personnel

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact

and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: LAURA REESE
Organization: PWL HEALTH & KINESIOLOGY
Address: 800 W. Stadium Avenue , West Lafayette, IN 47907-0000
Phone:
Email: lschwabr@purdue.edu

Name: WILLIAM FELIX
Organization: PWL HEALTH & KINESIOLOGY
Address:
Phone:
Email: wfelix@purdue.edu

Name: LAUREN MURFREE
Organization: PWL HEALTH & KINESIOLOGY
Address: 700 W. State Street , West Lafayette, IN 47907-0000
Phone:
Email: lmurfree@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Dr. Schwab Reese will be overseeing the qualitative portion of the study and participating in evaluation. Will Felix and Lauren Murfree and graduate students in Health and Kinesiology and will be conducting interviews, coding, and analysis.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

3

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC that work directly with the COAP program. Eligible participants must be employees of CC and must work directly with the COAP program. This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC or that does not work directly with the COAP program is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

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*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.)

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*required

What type of change(s) would you like to make?

IMPORTANT:

All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

Personnel

Study Procedures

Change to the recruitment and/or data collection status.

✓ *(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)*

*required

Please briefly describe the change in status.

We would like to interview all of the community corrections staff, not just pre-trial early release staff. With this we would like to interview a total of 15 people instead of 3.

Something else

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: LAURA REESE
Organization: PWL HEALTH & KINESIOLOGY
Address: 800 W. Stadium Avenue , West Lafayette, IN 47907-0000
Phone:
Email: lschwabr@purdue.edu

Name: WILLIAM FELIX
Organization: PWL HEALTH & KINESIOLOGY
Address:

Phone:
Email: wfelix@purdue.edu

Name: LAUREN MURFREE
Organization: PWL HEALTH & KINESIOLOGY
Address: 700 W. State Street , West Lafayette, IN 47907-0000
Phone:
Email: lmurfree@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.
Dr. Schwab Reese will be overseeing the qualitative portion of the study and participating in evaluation. Will Felix and Lauren Murfree and graduate students in Health and Kinesiology and will be conducting interviews, coding, and analysis.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

15

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC. Eligible participants must be employees of CC and must work directly with the clients or the COAP program This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

---

*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.) Also, see www.irb.purdue.edu for additional changes not requiring modification during the COVID-19 pandemic.

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*required

What type of change(s) would you like to make?

IMPORTANT:
All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

Something else (e.g. participant compensation amounts)

(For resuming on-campus in-person research)- COVID-19 Research Space Standard Operating Procedure approval.

(For resuming off-campus in-person research)- COVID-19 off-campus research certification of practices outlined in the EVPRP Guidance for Off-Campus Research Activities

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Dr. Reese, Will Felix, and Lauren Murfree have been removed from the project as of 8/11/2020.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

---

*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.
The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

15

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC. Eligible participants must be employees of CC and must work directly with the clients or the COAP program This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.) Also, see www.irb.purdue.edu for additional changes not requiring modification during the COVID-19 pandemic.

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*required

What type of change(s) would you like to make?

IMPORTANT:
All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

Something else (e.g. participant compensation amounts)

(For resuming on-campus in-person research)- COVID-19 Research Space Standard Operating Procedure approval.

(For resuming off-campus in-person research)- COVID-19 off-campus research certification of practices outlined in the EVPRP Guidance for Off-Campus Research Activities

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Yixun Ke
Organization: PWL HHS ADMIN
Address:
Phone:
Email: ke21@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Dr. Reese, Will Felix, and Lauren Murfree have been removed from the project as of 8/11/2020.

Yixun Ke is a senior public health student who will be conducting data analysis and project evaluation.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

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Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC. Eligible participants must be employees of CC and must work directly with the clients or the COAP program This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

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*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.)

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*required

What type of change(s) would you like to make?

IMPORTANT:

All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

Don't forget to add the person's name to the Personnel section of the form.
If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button in t please have the person submit this electronic form to the HRPP. All new users will need first-time access granted to be in the Cayuse system.

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

New site for off-campus recruitment and/or data collection.

Something else (e.g. participant compensation amounts)

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Cathy Carby
Organization: PWL NURSING
Address:
Phone:
Email: ccarby@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Dr. Reese, Will Felix, and Lauren Murfree have been removed from the project as of 8/11/2020.

Ms. Ke has been removed from the project as of 9/7/2022.

Ms. Carby is a DNP student and will be conducting data collection and analysis.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

15

Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC. Eligible participants must be employees of CC and must work directly with the clients or the COAP program This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

---

*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

---

*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

---

*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

---

*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Modification Submission

Modification/Amendment to a Protocol

Changes to a study must be approved by the HRPP/IRB.

Examples include (but are not limited to) changes in:

- Recruitment methods
- Screening materials
- Intended study population
- Inclusion/Exclusion criteria

For a list of minor changes that do not require IRB review, please see Purdue HRPP Standard Operating Procedure 305. (Link appears in the "?" button above.)

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*required

What type of change(s) would you like to make?

IMPORTANT:

All revisions to the protocol must be made to the relevant sections of your study in the sidebar. Please note, that more than one section may require change. For non-exempt protocols, please review your current consent form and edit language as needed.

Remember to review any advertisements, scripts, information sheets and consent forms. Attach them to the relevant sections of your protocol. Please title any attachments with dates or version control numbering in the file name to assist with review.

✓ Personnel

Don't forget to add the person's name to the Personnel section of the form.
If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button in t please have the person submit this electronic form to the HRPP. All new users will need first-time access granted to be in the Cayuse system.

*required

Are you changing the Principal Investigator?

Yes

✓ No

Study Procedures

Change to the recruitment and/or data collection status.
(For example, click here if you are finished with data collection and would like to notify the IRB that the study will only analyze the collected data.)

New site for off-campus recruitment and/or data collection.

Something else (e.g. participant compensation amounts)

*required

Study Personnel

In this section you will name all staff who will participate in the study.

*required

A Principal Investigator (PI) is responsible for all aspects of a research study.
STUDENTS ARE NOT AUTHORIZED TO BE PRINCIPAL INVESTIGATORS

Provide the name of the Principal Investigator of this study.
All faculty (tenured, tenure-track, research and clinical) are eligible to be Principal Investigators. Others requesting to submit proposals as the Principal Investigator for the first time must obtain special approval.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.
Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

*required

Primary Contact

Provide the name of the Primary Contact of this study. The Primary Contact will be copied on all correspondence regarding the IRB review. Note that the Primary Contact and the Principal Investigator may be the same. The Primary Contact must be a current Purdue University faculty, staff, postdoc, or student and must have a role as Key Personnel on the study.

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

Name: NICOLE ADAMS
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000
Phone:
Email: adams417@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. We will need to verify their information and load into the system.

(First Name: Last Name: Purdue e-mail address)

If you wish to provide a campus phone number for the Primary Contact, you may list it here.

This field is optional. Most correspondences from the IRB will arrive via the Cayuse system.

*required

Key Personnel

Below is a definition of Key Personnel. Please read the definition and decide who will need to be listed as Key Personnel on the study.

Key personnel: The Principal Investigator and any project staff, students, postdoctoral staff, internal or external to Purdue University who contribute in a substantive way to the scientific development or execution of a project (including, but not limited to, consent, data collection or analysis).

*required

Does your study have additional Key Personnel besides the PI and Point of Contact?

Once the name is selected, training courses from the CITI system should appear. If the courses are not appearing. Click the "?" on the top of this question to find out how to sync your accounts.

✓ Yes

*required

Where are the Key Personnel from?

Check all that apply.

✓ I have key personnel from Purdue University.

I have key personnel from another external site (outside of Purdue).

No, the only personnel on the project are the PI and Point of Contact.

Key Personnel From Purdue University

- *The Principal Investigator and Primary Contact are considered Key Personnel. You do not need to list these names again.*
  Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.
  If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.
- *Provide the name(s) of any other key personnel from Purdue University for this study using the "find people" button below.*
- *If your collaborating key personnel are not affiliated with Purdue University, please indicate this in the next section.*

Name: Cathy Carby
Organization: PWL NURSING
Address:
Phone:
Email: ccarby@purdue.edu

Name: PI JU LIU
Organization: PWL NURSING
Address: 502 N. University Street , West Lafayette, IN 47907-0000

Phone:
Email: liu2572@purdue.edu

If you cannot find the name of the Purdue University personnel that you are looking for using the "Find People" button above, please list them here. For researchers outside of Purdue university, please use the next section and click "external investigators".

(First Name: Last Name: Purdue e-mail address)

*required

Provide a brief description of each person's position at Purdue (e.g. student, staff, faculty) and their role in the study.

Examples:
Prof. Principal (faculty) will oversee all aspects of the study design and conduct
John Researcher (graduate student) will recruit and consent participants and collect data
Purdue Pete (staff) will analyze collected study data.

Dr. Reese, Will Felix, and Lauren Murfree have been removed from the project as of 8/11/2020.

Ms. Ke has been removed from the project as of 9/7/2022.

Dr. Adams (faculty) will oversee all aspects of the study including design, data collection, analysis, and dissemination.
Ms. Carby is a DNP student and will be conducting data collection and analysis.
Dr. Liu (faculty) is advising Ms. Carby on her DNP project and will be assisting with data analysis support.

Research Sites

*required

Where will the study take place?

Purdue University

✓ External Site (non Purdue University)

*required

Please list the external sites. Keep in mind that later in the application process, you will be asked for appropriate permission letters to document the site's agreement to allow your team to conduct research.

Tippecanoe County Community Corrections

SPS Contracting assistance has been requested for a Data Use Agreement.

*required

Are any of the sites outside of the United States?

The IRB may need to make special considerations when reviewing international research.

Yes

✓ No

Getting started with your submission

*required

Welcome to the submission system for the Purdue HRPP/IRB. Before you begin, you should be familiar with the framework of human research protections and how they relate to your proposed study. The materials to help you appear on our website.

Be certain that all personnel have completed online training prior to submitting the protocol.

The choices you make on the first two sections will help populate the required sections for your submission. Please look through the options and make the choice closest to your research. You can always seek assistance by scheduling an appointment with the HRPP Office or reviewing the materials at www.irb.purdue.edu.

Exempt study

Please look at the list of studies below. Determine if your proposed study design might fit into one of these descriptions.

Exempt research still requires review by the Human Research Protection Program. Choose this option if you believe your study is:

- Research in a common educational setting (e.g. school, daycare) about normal educational practices.
- Educational Test, Survey, Interview, or Observation of Public Behavior
- A benign intervention involving short puzzles, games and their outcomes on human behavior conducted during a single day.
- Secondary Analysis of data, documents, records, pathological or diagnostic specimens that are publicly available or properly deidentified.
- Taste and Food Quality Evaluation or Consumer Acceptance Studies.

Non-exempt study

✓ *Research that does not fit into an exempt category typically involves the collection of new data from a participant.*

Just-in-time

I have been contacted by a sponsor (often NSF or NIFA/USDA) to provide documentation of IRB approval, (such as Just-in-Time or JIT) but my application to the IRB is dependent on other factors such as:

- *completion of instruments*
- *prior animal studies*
- *purification of compounds*

Note: This category should be utilized ONLY if the above criteria apply. If study procedures are discernible at the time of the sponsor request, please do not select this option. The research team should affirm that their sponsor will accept documentation for a development protocol.

If you request this study type, the title of the IRB protocol must exactly match the title of the grant proposal. Most funding agencies will not accept protocols with different titles.

Quality Improvement

My research involves activities without a plan to conduct research (Case Report or Quality Improvement project)

I need to know if my project is considered "Human Subjects Research"

I would like to request that another IRB Review this study. (Request for Purdue IRB to defer to another site).

When Purdue University will be engaged in human subject research with one or more institutions, investigators may submit a Request for Deferral asking that the review be deferred to one institution's Institutional Review Board (IRB).

Research Classification and Special Considerations

Would you determine that this research is predominately social or biomedical in nature

When you provide an answer to this question, a series of additional questions will display, and checking on each of these questions will generate a new form to the left that you will need to complete. These forms will ask the questions we used to ask, but in a clearer and more organized way, which will help the reviewer, as well as the investigator.

Biomedical
My research typically went to the old biomedical review board and/or is more biomedical in nature.

Social / Behavioral
✓ *My research typically went to the old social sciences review board and/or is more social or behavioral in nature.*

A combination of social science and biomedical, or I'm not sure.

*required

Please check any of the following that apply to the proposed research.

Each of these involves special considerations in the IRB review. If none of these items apply, click on "None of These" and continue forward in the application.

Clinical Trial
PLEASE READ THIS DEFINITION CLOSELY.

NIH defines a Clinical Trial as "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."

If this determination applies, please check this box.

Nursing or Study Physician Resources
This protocol will have Nursing or Study Physician Resources

International Research

This protocol includes research that is conducted at a non US location.

Data Controlled Under HIPAA and/or FERPA

Health Insurance Portability and Accountability Act (HIPAA) covers individually identifiable health information held or transmitted by a covered entity. This often involves healthcare providers and insurance companies.

AND/OR

Family Educational Rights and Privacy Act (FERPA) protects the privacy of student education records.

Community-engaged research

✓ *This is community-engaged research. For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.*

Incidental Findings

Incidental findings are discoveries of individual-level findings that are unrelated to the goals of the study. (e.g. genetic data, MRI or test results).

Data repository

This protocol involves the establishment of a data repository. Repositories are defined as prospective collections of data that are processed, stored and distributed to multiple investigators for use in research.

Deception or incomplete disclosure

Deception occurs when an investigator intentionally gives research participants misleading or false information about some aspect of the research.

Incomplete Disclosure occurs when an investigator intentionally withholds information from participants about the true purpose or nature of the research.

Potentially Vulnerable Populations

None of the above apply.

Protocol Description

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

Tell the IRB what specific trait(s), function(s) or behavior(s) you would like to study. Give a brief summary of your study in simple terms.

Describe why you are conducting the study. Identify the research question(s).

The COAP program, which is operated by Tippecanoe County Community Corrections (CC), is a pre-trial early release program which connects low level offenders to services upon their release. The case managers are responsible for making connections to services. Many of the participants have mental health or substance use issues for which they require specialized treatment. Through a collaborative partnership between CC, local behavioral health and substance use treatment providers, and the North Central Quick Response Team, an online scheduling platform is being created to allow case managers to view appointments at multiple providers in one place and then direct schedule the client without the burden of making multiple phone calls.

In order to evaluate the impact of this program we ask: Is the direct scheduling platform a benefit to Community Corrections for their COAP population?

*required

Specific Aims/Objectives

Give the IRB an example of potential discoveries you hope to make or insight you hope to share. For example, outline a disease state, social characteristic or behavior that might benefit from the study results.

Specific Aim 1: Improve the work of the case managers.
Using qualitative data analysis we will assess how the case managers feel about their work flow, efficiency, and quality of referrals before and after implementation of the system.

Specific Aim 2: Increase the number of participants that have appointments within one week of release.

Using aggregate facility level data provided by CC to compare the number of appointments within one week of release before and after the implementation of the scheduling platform.

Specific Aim 3: Improve the outcomes of the COAP program
Based on the data that is required to be reported to the COAP funders, improve rates of appointment schedules, appointment attendance, and [reduced sentence time]

*required

Background and Significance

Include how previous research studies and their results support your study or how you will build upon existing information.

This is an innovative scheduling platform that has not been previously studied. It is the first platform of its kind that can bring appointments from disparate providers together in one place and allow for a person outside of the provider organization to book an appointment.

*required

Research Hypotheses

Please list any relevant study hypothesis/hypotheses. If this does not apply, type "Not Applicable".

We hypothesize that the implementation of the direct scheduling platform will improve the efficiency and work flow for the case managers, increase the number of participants with appointments within a week, and improve the overall outcomes of the COAP program.

*required

How long will participants be asked to be in the study?

List the approximate duration in the fashion below.

- *Number of Visits =*

- *Minutes or Hours per visit =*
- *Single Day or Multiple Days?*
- *Total number of months until all data are collected =*

The case managers will be asked to participate in an interview prior to the implementation of the system and then again 6 months post implementation.

CC will provide facility level data (not at the person level) at 3 month increments for the duration of their program ([years]).

*required

Specific Study Procedures

Describe in detail what a research participant will be asked to do.

The interview participants will participate in one-on-one interviews with the researchers. Researchers will follow a semi-structured interview guide and ask about the case managers work with this program.

In long term studies, a visual representation of a timeline is helpful. You may upload a visual representation as a Word (.docx) or PDF file here.

Attach any surveys, questionnaires, assessments

COAP Interview guide.docx

Flow charts, schemas

References

Participant Information

*required

Total Study Enrollment

*Please enter the number of subjects that will be enrolled at **all sites,** that are required to complete data analysis. Include the rationale for this number (e.g. statistical analyses, population composition). If at a later time it becomes apparent you need to increase your sample size, you will need to submit a Revision Request.*

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Attrition Considerations

If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through Purdue University. Please describe the rationale.

Consider:

- *Whether the withdrawal of the subjects might result from a decision by the subject or by the investigator, and the reasons for the withdrawal, if known; and*
- *Whether the withdrawal might occur from all components of the research study or just the primary interventional component.*

*required

Age(s) of Participants in Study Population

Please include an age range for subjects, if relevant. If the research has multiple subject groups, describe the requirements for each separately.

Newborn to less than 10 years old

10 years old and less than 18 years old

✓ 18 to 65 years old

Enter specific age range if the target population age is if target population is less than 65.

18-65

65 years and older

Unknown- Data are deidentified of any age or date of birth

*required

Inclusion criteria - Please identify the population that you would like to study.

Your study should only include those who are able to participate and those who represent the population where your study is relevant. List the criteria that make someone eligible for your study.

The interviews will include the case managers and staff of CC. Eligible participants must be employees of CC and must work directly with the clients or the COAP program This includes supervisory and director level participation.

*required

Exclusion criteria - Please identify the characteristics that do not represent your intended study population.

Exclusion criteria are not simply the inverse of inclusion criteria. There might be individuals who should not participate in your study because it could be too risky or interfere with a condition. Please provide information about why the group will need to be excluded.

For NIH funded protocols: If you do not include women, minorities and children in your subject pool, you must include a justification for their exclusion. The justification must meet the exclusionary criteria established by the NIH.

Anyone not employed by CC is excluded from participating.

Please consider the population being studied. Are there any other safeguards that you are putting in place to address participant protections?

Information provided in interviews will not be shared directly with supervisors or management at CC and will only be provided in thematic aggregate form to protect participants from negative consequences of participation.

Community-Engaged Research

*required

Is this community-engaged research?

For the purposes of IRB at Purdue University, community-engaged research is defined as research that includes the meaningful involvement of community partners in the research process, including but not limited to topic development, need identification, research design, conduct of research, and/or sharing of results.

✓ Yes

How are/were the community partner(s) involved in the research? Choose all that apply:

Topic development, need identification, and/or development of research questions

✓ Research design and/or selection of appropriate measures and data collection methods

Contribution to consensus about findings, conclusions, and/or recommendations for implementing findings

✓ Dissemination of findings and actions taken based upon results

Only provided access to study subjects or project sites, and not involved with study design, subject recruitment, data collection, data analysis, or dissemination of results

No

*required

Please describe how the study uses community-based participatory research design.

Although this is community -engaged research, it is not CBPR. The data collection is influenced by the community partner as they are collecting and sharing their facility level aggregate data. The knowledge gained from this study will be shared with the partner and the community at large.

Please attach any relevant permission letters or letters of support from community partner(s).

Recruitment

*required

Recruitment Processes

How will people find out about your study? It's common for studies to be advertised on flyers, social media, or ads. The IRB must know what language and materials are used to recruit participants.

*required

Does your study use a known group of participants or records to recruit up-front? Check any of the following sources of information which will be used to identify potential subjects

- ✓ Yes, a known group or subject pool.
- No, only the general population
- Both a known group AND also the general population.

*required

Please identify any known groups, participant pools, or records that will be used for recruitment purposes.

- Health or Education Records
- Purdue University student subject pool
- ✓ Other methods to recruit from a pre-defined population or pool

*required

Please describe the recruitment methods.

Describe the other method used to pre-identify a study population.
If the study involves an educator/student, employer/employee relationship, please explain the methods used to eliminate coercion.

The employees of CC that work with the COAP program directly will be asked to participate in interviews about their work. The director of CC will provide names, time, and a physical location on site for employees to participate in the interviews.

*required

Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).

Examples of issues:
Potential subjects may not want to be approached for research purposes by someone they do not know.
Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.

Include the provisions for ensuring privacy in the event that an interest to participate in a study could reveal a condition, disability, experience, mental health condition, etc.
Interviews will occur in a private room and be recorded for later transcription. Participants will not be discussing personal health matters, only their work experiences.

*required

Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?

Yes

✓ No

*required

Check any of the following recruitment materials which will be used to contact potential subjects.

Direct mail/email

Flyers/Brochures

Published Advertisements

Verbal Scripts

Website

Social Media

Other

✓ None of the above

Risks and Benefit

Helpful links and relevant guidance can be found by clicking the question mark in the top-right corner of each question.

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*required

List and describe (in lay terms) the potential risks to which subjects may be exposed as a result of their participation in the research. Describe the likelihood and seriousness of each risk.

Participation in research is voluntary. Consider the risks that a participant might encounter if they participate in the study. Risks may be physical, psychological, social, legal, etc. Please note that all research exposes to subjects to some risk.

For example, if the only foreseeable risk is breach of confidentiality, please describe the potential consequences to the participant's reputation, lifestyle, employability, or legal status that might occur if it became known that they participated in the study.

Potential risks to subjects includes psychological distress over recounting their work experiences. Negative comments made about their employers may place them at risk for retaliation from their employer.

*required

Describe how risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.

Points to Consider

- *Are there adequate preliminary data and is there appropriate justification for the research?*
- *Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question?*
- *Are there qualified staff and resources to conduct the research?*
- *Is there appropriate monitoring of the subject during and after the research?*

- *Are medical or psychological resources available that participants might require as a consequence of the research?*

The risks are minimized through providing information about accessing the employee assistance program for anyone experiencing distress over recounting their work experiences. Information from interviews will not be shared directly with supervisors or the director to protect employees from any harm in their work place.

*required

Please provide the risk level that you believe applies to the study.

In addition to the population being studied, consider the this definition:

Minimal Risk: *Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.*

✓ The researchers believe the study is no greater than minimal risk.

The researchers believe the study is greater than minimal risk.

*required

Are there potential direct benefits to a participant or benefits to society from your research?

The IRB must consider the risk/benefit ratio of each study.
Please note that payment for participation is not considered a benefit. If there are no direct benefits, please state this fact.

Yes, there are potential benefit(s) to be gained by the individual subject/participant.

✓ Yes, there are potential benefits to be gained by society.

*required

Please list the potential benefit(s) to society.

This project seeks to prove the value of a collaborative on-line scheduling system. The COAP program employees are the first to use this system. Validation of the system allows for increased use in other venues and may increase access to mental health and substance use treatment.

No, there are no benefits.

*required

How does the investigator evaluate the probability and magnitude of the possible harms, when compared to the probability and value of the possible direct benefits to the subjects?

Please provide an assessment of the risk:benefit ratio associated with your study. The HRPP/IRB must assess that the risks and benefits are appropriate . This is a crucial consideration for your study.

While participants are unlikely to directly benefit from participating in this study, there are several likely benefits to society. If the evaluation suggests that the collaborative on-line scheduling system is an efficient, effective way to schedule appointment, other venues may be able to adopt the system, resulting in increased efficiency of their program. In addition, individuals in need of services would have increased access to mental health and substance use treatment. If the evaluation does not support the scheduling system, demonstrating the need for changes will prevent unnecessary financial and non-financial costs for other venues. We are taking steps to reduce the risks to participants, including providing information about accessing their employee assistance program (to address possible psychological discomfort associated with recounting work experiences) and taking steps to prevent loss of confidentiality (to address possible issues associated with making negative comments about their employer). As such, the risks associated with participating in this study are minimal while the potential benefit to society is substantial.

Privacy and Confidentiality

*required

Privacy

Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant?s ability to privately provide information used for your study.

Privacy refers to a person's desire to control access of others to themselves.Participants must be able to control their right to participate in research (such as the timing and location of data collection. Describe the methods you will use to ensure that only information necessary to the research is collected and that the location does not jeopardize the participant's ability to privately provide information used for your study. Subjects may not want to be seen in areas that may stigmatize them or at times when they are working or competing other tasks).

All employees of the division will be invited to participate in the interviews and the supervisor has given permission to use work time for the interviews. The supervisor has also given permission to a private area in the work space for the interviews, but we will also offer to meet participants at another location, if that is their preference. To ensure only necessary information is collected, we will follow the semi-structured interview guide, which permits the flexibility to gain additional context to information shared by participants but focuses the interview around the necessary information.

*required

Confidentiality

Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the general coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.

- *For identifiable data in electronic format, describe the system that will be used.*
- *For identifiable data in hard copy or tangible format, describe methods on how to secure the data*

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once

transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The electronic transcripts will be stored on a password protected computer on Purdue campus until analysis is complete. Once analysis is complete, the transcripts and qualitative coding will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete. The transcripts will be retained for 10 years.

*required

Provide a plan to protect the identifiers from improper use and disclosure.

The informed consent document will be the only research documentation that includes participants' names. These documents will be stored separately from the audio files and transcripts. The informed consent documents will be retained for 3 years after closure of the study. The audio files will be stored on a password protected computer on Purdue campus while being transcribed. Once transcription is complete, the audio files will be moved to an encrypted external hard drive stored in a locked file cabinet in a secure office. The audio files will be destroyed with the research is complete.

*required

Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers.

Describe if the research records, data, specimens, etc. will be de-identified and/or destroyed at a certain time. If records, data, specimens, etc. will be de-identified, address if a code key will be maintained and when, if ever, it will be destroyed. Additionally, address if they may be used for future research purposes. For protocols that may be subject to future continuing and secondary data analysis, the IRB needs to have the justification for not destroying identifiers permanently.

The informed consent documents will be retained for 3 years after closure of the study. The audio files will be destroyed with the research is complete. The transcripts will not contain identifiable information so they will be retained for 10 years. The informed consent documents, audio files, and transcripts will be stored separately.

*required

Will a Certificate of Confidentiality be obtained from NIH for this research?

What is a Certificate of Confidentiality?

Certificates of Confidentiality (CoCs) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

CoCs are automatically granted for NIH-funded research (as of 2017). The IRB may request that the investigator seek a CoC if disclosure of identifiable sensitive information.

Consider this option if your study may place participants at risk due to the potential to identify situations such as disease state or criminal activity.

Please note that if a CoC applies, the consent form must have appropriate language (found in our template).

Yes, the study is funded by an NIH grant or subaward and therefore automatically has CoC protections.

Yes, our team will seek a CoC from NIH if approval is granted for this IRB application. I will amend the study if this CoC is granted by attaching the document here.

✓ No, this study will not require a CoC.

Compensation for Research Participation

Describe any compensation that subjects will receive when they participate in your study. Consider what happens to the compensation amount if the participant withdraws or is disqualified from the study. If course credit will be offered, please provide the amount and the percentage of the total grade.

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*required

Will subjects be compensated for their participation in the study?

Will the study provide (money/gift cards/inducements/discounts/entry into a drawing/course credit) in exchange for a person's participation in the study? Please note that Purdue University policies might affect how you can compensate subjects. Please contact your department's business office to ensure your compensation procedures are allowable by these policies.

- Yes
- ✓ No

Informed Consent Process Section title

Informed consent is more than a form; it's a process and a responsibility.

Please answer all questions regarding the ways that participants will provide informed consent to participate in your study.

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*required

Identify which subjects will consent to participate in the research.

- ✓ All subjects (or their legally authorized representative) will consent to participate in the research.
- Some subjects (or their legally authorized representative) will consent to participate in the research, and some subjects will not.
- No subjects (or their legally authorized representative) will consent to participate in the research.

*required

For subjects who will consent to participate, choose whether the consent process will be documented by a **signature** from subjects.

Please note that you may request a waiver of the signature requirement if this study is minimal risk OR if the only record linking the subject and the research would be the consent document and the principal risk of the study is potential harm resulting from a breach of confidentiality.

- ✓ All consented subjects will provide a signature as documentation of consent
- Some subjects will provide a signature as documentation of consent, and some subjects will not.
- No subjects will provide a signature as documentation of consent.

*required

Indicate in what language(s) the consent conversation will be conducted.

✓ English

Language(s) other than English

*required

Will subjects participate in any study activity prior to signing a consent document?

For example, some studies require subjects to fast, to refrain from drinking or smoking, pass a phone screening process or keep a journal/log prior to enrollment in the study.

Yes

✓ No

*required

Will any other materials (videos, brochure, drug/device information, etc) be used to present information to potential subjects?

Yes

✓ No

*required

Describe the timing of the informed consent process, including how you will ensure potential subjects have sufficient opportunity to discuss and consider participation before agreeing to participate in the research.

Participants will have the consent explained to them at the beginning of the interview. They will be offered an opportunity to ask questions and then sign the consent prior to the beginning of the interview.

*required

Consent form Elements

The following components are required for informed consent forms. If any of these elements are missing, you must provide justification for the reasoning.
Please confirm that all elements of informed consent are present. Use the Purdue IRB template found on the Purdue HRPP/IRB website

BASIC REQUIRED ELEMENTS OF INFORMED CONSENT
Please confirm that all elements of informed consent are present.

- Key Information at the beginning of the consent form
- A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- A description of any reasonably foreseeable risks or discomforts
- A description of any benefits to the subject or to others that may reasonably be expected
- A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained
- A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

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*required

Please confirm that all basic elements of consent appear in your draft consent form.

✓ The research team has drafted a consent form and affirmed that it contains all of these basic considerations of informed consent.

Our research team is omitting an basic section from the consent form.

SPECIAL REQUIRED ELEMENTS OF INFORMED CONSENT

Please check if these items apply and are addressed in the draft consent form.

If any of these elements apply, but are missing, you must provide justification for the reason(s) to omit this information.

- *A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.*
- *A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.*
- *Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.*
- *Any additional costs to the subject that may result from participation in the research.*
- *The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.*
- *A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.*
- *A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.*

- *For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).*
- *A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.*
- *Disclosure of any conflicts of interest.*
- *Registration of the trial on Clinicaltrials.gov*
- *NIH Certificate of Confidentiality coverage.*
- *Future uses of identifiable or deidentified data.*

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*required

Please confirm that all items that apply to your study have been addressed in the consent form.

You must review the study-specific parameters that were discussed within your application in previous sections. Please refer to the sections on the left for any items that may apply.

✓ The research team has drafted a consent form and affirmed that it contains all special considerations of informed consent applicable to our study.

Our research team is omitting an applicable section from the consent form.

*required

Please attach all versions of your consent form here.

Consent forms should follow the structure of the template on the IRB website.
Consent form COAP.doc

Funding Source(s)

*required

CURRENT Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI's responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

Please list any sources of funding that are **confirmed** by contract, agreement, or other support of a sponsor.
You will list any pending sources in the next question.

✓ Externally sponsored (federal, state, corporate, foundations, industry, donor)

Please search for the sponsor(s) here. Be certain to include any funding that originates or includes US federal sources.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

In Family & Social Services Admin

If you do not see the name of the funding source using the "Find Sponsors" button above, please enter the full sponsor name in the text box below.

Please use the full name of the sponsor and include any subcontracted efforts.

Internal Purdue University Funds (Includes departmental funds, start-up funds.)
(Note, this does not include Purdue Research Foundation or Purdue Research Park companies-please list as external sponsor above).

None - There are no confirmed funding sources at this time.

*required

ANTICIPATED Funding Source(s)

To review your protocol appropriately with differing sponsor standards, the HRPP must have the accurate funding source. It is a PI responsibility to update funding sources as a modification to the protocol and associated forms when funding changes.

If you are a student or staff member filling this out on behalf of a Principal Investigator (PI), please be certain to affirm with the PI that this information is accurate.

Please list any sources of funding where sponsorship is **anticipated** or pending a final decision.

Externally sponsored (federal, state, corporate, foundations, industry, donor)

✓ There are no pending funding sources at this time.

If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

Conflict of Interest and/or Outside Activities Disclosure

Conflicts of Interest or outside activities must be disclosed and managed prior to IRB approval. For more information about these policies, please consult the resources listed in the question marks in each section.

The IRB may request confirmation of proper disclosures.

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*required

Does this IRB protocol involve any work, advice, or service for an entity other than Purdue University?

For example, if this activity is done as an outside consulting activity, or employee's start-up company, this activity will not qualify for review by the Purdue IRB and an outside IRB or service must be sought.

✓ I attest that I understand the outside activities policy and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University.

*required

Do you or any investigator(s) participating in this study have a significant financial interest (SFI) related to this research project?

Receiving more than $5,000 in compensation from, or having ownership interests in, outside entities, constitute Significant Financial Interests that need to be disclosed. Definitions of SFI, Investigator and Institutional Responsibilities, can be found at https://www.purdue.edu/policies/ethics/iiib2.html#definitions.

Yes

✓ No

*required

Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?

Yes

✓ No

*required

Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?

Yes

✓ No

Other attachments

*required

Do you have any other supporting documents to attach?

Investigators are invited to submit reference lists, study instruments, supporting information, training data, device pictures, or other relevant items for their study that were not addressed in the application.

Yes

Attach any other documents. Please use a file name that describes the document.

You may attach multiple files to this entry.

PLEASE DO NOT UPLOAD PARTICIPANT DATA OR IDENTIFIABLE RESEARCH DATA.

✓ No

Renewal Submission

Renewal of Protocol - For Studies Enrolling Participants, or Analyzing Data

Please choose the option that describes the renewal need for your study

If you've been contacted by the IRB Office to submit this renewal, please see the instructions in the request.

Continuing Review for Full-Board
I need to submit a **continuing review** for IRB renewal of an expiration.

Administrative Check-in Only
✓ I am requesting a new approval letter to update my study records because data collection and/or data analyses of the original research purpose continues without change.

Study Closure
I need to request closure of this study.

*required

Please confirm the following statements by clicking the checkbox below.

I understand that by certification of this study, I affirm its accuracy. Amendments, post-approval monitoring visits, and renewals remain the responsibility of the Principal Investigator.

✓ I understand the outside activities and Individual Financial Conflict of Interest policies and that all members of the research team are conducting this project on behalf of Purdue University. (See here for more information.)

Certification of the submission is required by the PI and is completed in the next step of the Cayuse submission process.