Purdue IRB Protocol Guidance Document

Before submitting a protocol to the IRB for review, please be sure all the below elements are included in the submission. Incomplete submissions will be returned to the PI for further edit before being review.

1) Study Personnel

a) Anyone who will have interactions with participants including collecting data, engaging in the consent process, or analyzing identifiable data need to be listed as Key Personnel. If Purdue personnel are not primarily engaged in participant interactions (including data collection and consent) and study materials are not being maintained by Purdue researchers, the protocol is likely *not* reviewable by the Purdue IRB. The protocol should be reviewed by the site where the research is occurring. The site of grant funding is not necessarily the site of IRB review.

b) When conducting international research, the use of in-country surveyors to collect data needs to be outlined, including the exact interactions surveyors will have with participants. For example, will surveyors be primarily responsible for the recruitment and consent of participants? What level of oversight will the PI and Key Personnel have over the surveyors as data is collected? Will any of the Purdue research team be in the country to supervise data collection, participant interactions, and data storage? How will study documents, including data and consent, be stored by the surveyors, and transferred to Purdue research personnel. Are there contractual agreements (e.g., consulting, subcontracts) that outline the role of the in-country personnel? Attach any documents to show these relationships.

c) The qualifications of all study team members and their roles in the study need to be detailed. If the research involves the administration of clinical tests, the study must contain personnel who are certified to administer the tests. Please also consider study risks when assembling a research team. For example, if study procedures may result in emotional distress, ensure personnel trained to deal with individuals under distress are present during data collection. These risks and how they will be mitigated need to also be outlined in the risks and benefits section of the Cayuse application.

d) Indiana is a mandatory reporting state; anyone who suspects a child has been neglected or abused must by state law make a report. If the study will involve children or the site of research is participants' homes or other locations in which researchers could witness child abuse or neglect, describe the training that investigators have taken pertaining to mandatory reporting for Title IX violations or suspected child abuse or neglect. Also, please be sure all risks related to mandatory reporting requirements are disclosed in the risks section of this document and disclosed to the parents in the consent document (see consent form template).

e) If the PI will be absent or lack oversight for any part of the research (e.g., on sabbatical), a plan on how study oversight will be maintained needs to be included. PIs are responsible for overseeing all aspects of the study, including supervising study personnel, maintaining study documents, participating in post approval monitoring visits, and submitting any noncompliance or incidence reports to the IRB when required (typically five business days) within the time lines specified here .

f) External Collaborators outside of Purdue – Determining the role of the external collaborator, please see here.

   i) Use this form if you will be receiving fully coded/deidentified human subjects research data from another investigator's study.

   ii) If you are proposing exempt human subjects research or non-exempt research that is not part of a federally-sponsored project with another individual who does not have an IRB overseeing research, complete this form. Note: the application should include the skills or specialization of the proposed independent investigator, and documentation of training in human subjects research through CITI or equivalent means.

iii) If you are proposing non-exempt human subjects research on a federally sponsored project with another individual who does not have an IRB overseeing research, complete this form. Note: the application should include the skills or specialization of the proposed independent investigator, and documentation of training in human subjects research through CITI or equivalent means.

iv) A confidentiality agreement transcription and/or translated services agreement form is required if any part of the IRB data or documents must be translated or transcribed by an outside party. Please note: if any participant data will be transferred to a third party, the detail of what information will be sent to the third party must be detailed in the consent form. Participants have the right to know if how their data will be treated and if any of their data will be given to non-Purdue personnel.

2) Research Sites

a) List all locations where any aspects of the study will take place, including where data will be analyzed. Include a name and description of each research site. The IRB would like to understand where data are being stored or what sites participants will visit. Keep in mind that in event of a data breach, adverse event, or other incident, the IRB will want to know where data should be or what rooms/locations participants visit.

b) If any component of the research project will be conducted at a location external to Purdue, a letter of collaboration written and signed by a person who has appropriate authority to allow researchers to use the site must be included in the application. The support letter should adhere to the letter of collaboration guidance posted on the Purdue IRB webpage. The name role of the person at the site should be included. Signed letters of collaboration are needed even if the site is only being used for recruitment.

c) If Purdue is not the only institution with study involvement, include all information about the other sites and investigators that are involved. Please see here for guidance about site permission versus site engagement.

d) If there are locations outside of the US, please check international research in the research classification section and include all required information. More guidance on international research can be found here. Studies taking place in countries with enhanced privacy laws (e.g., General Data Protection Regulation [GDPR] must have proper considerations embedded within the consent documents.)

3) Getting started with your submission

a) Correctly check the type of research that is being proposed. Please note: Many studies submitted as exempt do not qualify for exempt. Common mistakes often made with Exempt Category 1, 2, and 3 submissions.

i) Exempt Category 1 is reserved for studies that will be done in a typical classroom/educational setting. If the research will in any way alter the class or event, such as giving students an extra worksheet or survey that only exists for research purposes, the study does not qualify as exempt category 1. These extra non-curricular activities are either Exempt Category 2 or Non-exempt.

ii) Exempt Category 2 is generally only appropriate for research that uses surveys, focus groups, or interviews. studies where participants participate in workshops or an intervention as part of the research protocol do not qualify as exempt cat 2, even if they are only filling out surveys or interviews before and after the conclusion of the workshop. Not all questionnaire and survey activities qualify as exempt cat 2. For example, Exempt Category 2 is not appropriate If participants need to respond to any experimental stimuli such as stimuli that asks them to consider a specific situation or intervention and then give a response (e.g., pre- post- surveys with an experimental intervention or manipulation in between.)

iii) Exempt Category 2 for observational research is generally reserved for public spaces. If entrance involves membership or other entry arrangements, the observation is typically not public.
iv) Exempt Category 3 is reserved for benign behavioral interventions that are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Data cannot be collected via physical procedures, such as blood pressure monitoring, Virtual Reality, EEG, activity trackers, wearable eye trackers, and blood draws under this exempt category. In addition, any studies using deception do not qualify at Category 3 Exempt.
v) Note that in Categories 2 and 3, identifiable data may be collected. However, enhanced storage, privacy, and confidentiality protections will need to be described. This is essential for the "Limited" designation in the regulations applicable for Exempt protocols.

b) Any reliance with other institutions can be initiated in this section by following this guidance.

4) **Research Classification** - Ensure all appropriate boxes are checked. Below is guidance for the most common submissions.
   a) International Research
      i) Purdue researchers should be significantly involved in the study. If the study is primarily being conducted by international researchers, at international locations, the study is likely not reviewable by the Purdue IRB and international collaborators should obtain IRB approval from their home institution. Data can then be transferred in some situations to the investigator by submitting a category 4 exempt application and / or a data transfer agreement through SPS.
      ii) Please read the specific guidance for international research before submitting the application.
   b) FERPA
      i) FERPA must be checked if researchers will get any student information that is collected as part of the school curriculum. FERPA guidance can be found here. If the information collected in the classroom is not FERPA protected, this means it will be collected as part of the experimental procedures. All procedures for implementing experimental methods in a classroom must be followed and described in the protocol description section. In essence, information collected in a classroom is either curricular in nature, meaning it is FERPA protected or experimental in nature. It cannot be both. If it is experimental, all requirements for using minors in research, including (but not limited to) parental consent and voluntary participation must be followed. Additionally, a student's educational instruction should in no way be altered for experimental procedures if a parent or guardian does not explicitly consent to their child being used as a research participant. Thus, a child cannot be exposed to experimental educational procedures in the classroom if consent is not obtained. The application will walk you through the steps required. However, you should understand if the educational institution considers the data to be part of a student record. Please have this determination in hand before submitting the IRB protocol.
   c) HIPAA
      i) For additional guidance on Protected Health Information (PHI) in research applications, click here.
      ii) See here for required content for researchers to give participants prior to requesting release of Personal Health Information from a physician or other covered entity under HIPAA. *Note, many hospitals and clinics will have their own version of this form to use. If you are collaborating with an outside health care provider, please check with their HIPAA Privacy Office or Privacy Officer. The Purdue IRB does not waive release of PHI on behalf of Covered Entities.

iii) Guidance to complete the Authorization for Release or Use of PHI Template can be found here. Utilize if your research will involve data protected under HIPAA.
iv) A determination about the PHI disclosure or release (from the patient or from the facility/Covered Entity) must be understood before submitting the IRB protocol. No study can be approved if the release and storage of PHI is unclear.

d) Deception
i) Use this template as guidance if your study proposes to use deception or incomplete disclosure. All studies proposing deception or incomplete disclosure must meet criteria described by the IRB in Purdue HRPP Standard Operating Procedure(s) (SOP) 301 and/or 321. Please note: if the participant is not informed about the specific nature and details of the study and what they are being asked to do, this study likely involves deception or incomplete disclosure. Any vague language in either the recruitment documents or consent forms should be considered a form of deception or incomplete disclosure.

5) Protocol Description

a) Background and Significance
i) Provide evidence to support the objectives of the study. Discuss the need for the study, the gap in the literature your research will fill. Summarize how your research will tie into relevant literature, and ongoing studies. Ensure references are provided in the last text box of protocol description section.
ii) A description of the study significance should include the reason why this study is being performed. For example, how may this study improve public health or benefit society.
iii) Briefly describe the purpose of the proposed research. For example, is this research for publication, a dissertation, program evaluation, etc.

b) Research questions and hypotheses
i) Based off the background you describe above, discuss the specific research questions and aims that will be examined. Also, list anticipated results and dependent variables that will be used to assess study outcomes.

c) How long will participants be asked to be in the study
i) Include how many data collections will occur during the study. Each non-continuous occasion where a participant interacts with or is engaged with any aspect of the research is considered a study occasion.
ii) List the total time of each study occurrence.
iii) State if the study occurs on one day or multiple days.
iv) List the total amount of time it will take for a *single participant* to complete the study. This should focus on a single subject, not the total time you think it will take to complete the entire study.

d) Specific Study Procedures
i) This section should be written with the perspective of the research participant in mind. Write this in a way that is understandable to the general or non-scientific public. The protocol description should detail all the specific step-by-step procedures that will be followed, including any experimental or evaluation activities that will be conducted. If the study includes a workshop or class, please provide a copy of the curriculum, and clearly identify what parts of the project occur independent of the research and what components of the curriculum are done as part of research. If the standard curriculum is altered in anyway because of the research, these details should be disclosed.
ii) Please note: umbrella protocols – defined as a generic application designed to encompass multiple studies including future research studies that are not yet finalized - are generally not allowed. Protocols will be returned if study procedures are written in a vague manner. State explicitly what will be done, not what may be done.

iii) All details of the experimental design, including the various experimental groups, how participants are randomized into different groups, the details and numbers of the experimental conditions and trials performed must be included. The research design should be appropriate to address the research questions that are identified in the "research questions and hypothesis text box."
iv) Any questionnaires and experimental stimuli (including any video or audio) that are used need to be fully explained. The finalized versions of all experimental stimuli need to be uploaded as file attachments. Links to files should not be attached in lieu of the actual study files because links can be changed or removed. Finalized non-link attachments are needed so that the study becomes part of the permanent record. All attachments should be referenced in the protocol description box using intext citations. For example, detailed experimental procedures such as the implementation of a questionnaire should be described in the text box and then cited using an intext citation such as (See Attachment 1). This will allow the reviewer to better follow your experimental procedures and better recognize the attachment that accompanies specific procedures. Avoid embedding multiple study stimuli into a single large document as this can also impede review.
v) Variables of interest and study endpoints should be identified. This includes specifying analytical and statistical techniques the research will use to answer study questions. For qualitative data, specify the proposed analytic approaches.
vi) If your study is designed to be implemented in phases and the specific methodology of future phases has yet to be determined, please briefly outline what in general will be done in these future phases and how these phases align with current research objectives and hypotheses. Clearly affirm that no data collection will begin for these future phases until a protocol modification is submitted and approved. Also, include a brief plan describing the timeline when future phases will be implemented. Protocol modifications where new studies are being added to an existing protocol are generally not allowed and will require a new submission.
vii) Describe how eligibility screening will be conducted and if it will be before or after consent. Any materials used to screen participants for eligibility must be attached in the protocol description section and should be congruent with the stated inclusion and exclusion criteria that are listed in the participant information section. If any information is collected for screening or other purposes prior to consent, a waiver of informed consent must be requested and justified for these pre-consent activities in the informed consent section.
viii) In cases where classroom activities are also the topic of research, investigators must clarify the activities that are being done for research purposes and therefore distinct from required classroom activities. The distinction between typical classroom activities and activities that exist only for research purposes must also be made clear to the parents or guardians. When accesses to students educational records, or school facilities are needed for recruitment and/or research activities, a letter of support from an individual authorized to speak on behalf of the school/district (e.g., principal or superintendent) is generally required. The IRB is looking for the determination of legitimate educational interest under FERPA regulations which should be determined by the educational institution. Please ensure that all letters or validations come from officials responsible for FERPA protections at the site. Certain additional protections for students and parents are provided by federal regulations.
ix) The proposed use of student education records for research must comply with the requirements of the Family Educational and Rights Privacy Act (FERPA). Research involving surveys with students must comply with the Protection of Pupil Rights Amendment (PPRA) which applies to Department of Education funded research and is also mirrored in Indiana State Law. If the research is limited to an ongoing curriculum being implemented at the school, FERPA and potentially PPRA regulations apply since students

engaging in the curriculum are performing a school activity and any records generated as part of this activity become part of the student's educational record. If the investigator is altering the normal class curriculum as part of the research, FERPA may not apply if no educational records are being accessed or generated. However, the activities in the classroom children will do must now be considered experimental and not part of the normal curriculum, and PPRA regulations may still apply. Parents must therefore be told both in the recruitment and consent exactly what is being altered for experimental purposes. What new procedures their child will do if they agree to enroll their child in the study (i.e., how the typical instruction will be altered) and what will happen if they choose not to enroll their child in the study? For example, if the experiment is being embedded in the class, what options are available for the child whose parents don't agree to the experimental procedures? Will the standard teaching procedures be offered to these children? Will alternative procedures be offered in a way where it is not obvious the child is not part of the study? The IRB does not have the authority to waive any part of this requirement. In essence, research done in a classroom is either done on the standard curriculum and is therefore under FERPA or it is something that is done in addition to typical classroom activities and is therefore experimental. It cannot be both.

x) **Research with an existing camp, program, vocational training seminar, or conference** – Even if only adults are recruited as participants, it needs to be clear exactly how the research is fitting into existing activities. Detail must outline how participants are being recruited into the research. All recruitment and consent material needs to clearly inform participants that the research is independent of the program and that choosing not to participate in the research will in no way influence the individual's relationship with the program. Participants must also be told how the research may influence their participation in the program. For example, will participants miss out on curricular material while engaging in study activities? A support letter of the manager running the program needs to be included with the application. A PDF of the camp program, or activities should be attached.

xi) **Research in clinics** - It is critical to avoid therapeutic misconception, a situation that can occur when a patient fails to understand differences between procedures being done for their treatment and those being done for research purposes. The potential for therapeutic misconception is enhanced when the individual treating the patient is also involved in collecting research data. These situations are also an inherent conflict of interest since a clinician is supposed to focus on treatment of the patient, not collection of research data. To avoid therapeutic misconception the following procedures should be implemented; 1) the patient should be told if any medical procedures will be done for research purposes and / or analyzed for research purposes. 2) the patient should be recruited and consented by someone who is not involved in their treatment. 3) Patient needs to clearly be told how their treatment or their interactions with their clinical team will be altered if they agree to participate in the research. 4) Patients need to be clearly told during both recruitment and the consent process that the research is in no way related to their treatment and choosing not to be in the study will in no way influence their treatment or relationship with their clinical provider.

xii) **Research in the workplace** – Recruitment must minimize all any potential or perceived coercion or undue influence. Participants should not be selected for a specific worksite simply because the site provides a sample of convenience for the PI due to an existing relationship with the employer. Rather, potential participants should be solicited from a broad base of individuals who meet the inclusion criteria needed to address the research questions. Anyone in a position of authority, such as a supervisor, cannot be involved in the recruitment of an employee. Recruitment in general should be passive, where employees respond to research fliers. Any active recruitment, has the potential for employees to perceive participation in the study as part of their job duties. Participating in research

cannot be a condition of employment. All recruitment material should have highly visible text to inform employees that the research activity is in no way related to their employment. It should also be stated that choosing not to participate will have no impact on their job or employment. Similar language should appear in the consent form. If any employee research data, especially data related to job performance, will be shared with the employer, the employee should be told in both the recruitment material and consent exactly what data will be shared with their employer, and again be reminded that agree to participate or share their data is completely voluntary. Any risks to the employee need to be carefully outlined in the risks section of cayuse and in the consent form. For example, if an employee is surveilled for research purposes while performing their work duties, is there a risk that the data will capture the quality of the work they are performing? If so, there is likely a risk of jeopardy to employment. When collecting data in the workplace, the protocol description section should describe in detail where all research activities will take place. If the activities occur during work hours, describe the potential impact to the employee of being diverted from their normal job duties to perform research. Also, include a statement should be included in the support / collaboration letter from the employer that the employee has permission to perform non-employment research activities during typical work hours. When collecting data in the workspace, maintaining privacy and confidentiality can be challenging. Detail of the work environment, including where data will be collected and what other non-research personnel will be around and possibly witnessing the data collection must be provided. In essence, the IRB needs to know the unique challenges to privacy and confidentiality that emerge when collecting data in the specific work environment and how these challenges will be mitigated.

6) Participant Information

a) The total number of participants that will be enrolled needs to be stated and justified. The number should be appropriate to address the research questions and should be clearly justified. A good way to justify the number of participants is to reference papers in the literature that have used similar methodology or perform a sample size estimation. Umbrella protocols that attempt to request large numbers of participants to encompass potential data collections of future studies are generally not accepted. The IRB understands attrition, those considerations should be made with the number of participants requested by the research team.

b) The ages of all participants need to be listed. In the case where minors or individuals of advanced age are included in the study population, please check Target Recruitment of Potentially Vulnerable or Special Populations in the Research classification section and fill out all necessary information. When elderly will be used, methods should be incorporated into the protocol description that outlines how capacity to consent will be obtained.

c) It is important to consider that exclusion criteria are simply not the inverse of inclusion criteria. The inclusion criteria should list all the characteristics that make a person eligible for the study. These characteristics should be considered in relation to the research aims and questions. For example, a study that is investigating mobility issues in Parkinson's patients would have diagnosis of PD as inclusion criteria. The exclusion criteria are the characteristics that will invalidate the potential participants who qualify based on the inclusion criteria. For example, participants with the onset of dementia may be excluded from the hypothetical example given above. Consider the participants' perspective and any safety that an included population would need to know if they are at risk of participating. This could also relate to mental health or employment concerns. Protocols where the exclusion criteria are simply the inverse of the inclusion criteria will be returned to the PI for edit.

7) Recruitment

a) Using instructors or TAs to recruit students and recruiting students during class time is not permitted. Students enroll in classes for education, not to be research participants. PIs should carefully consider power differentials that exist between students and course instructors and professors. One possible method is to have the instructor dismiss class and give students who are not interested in the research the opportunity to leave. Once everyone associated with the class (e.g., instructor, TAs) has left the room, the researcher can begin recruitment. Instructors who are also members of the research team cannot recruit his/her own students due to the potential for undue influence. A 3rd party listed as key personnel (and CITI trained) on the application who does not have authority over the participants must conduct recruitment.

b) Recruiting samples of convenience is generally not allowed. Samples of convenience include, but are not limited to, using departmental email lists, and recruiting a known group of participants from a workplace or organization that is familiar to the PI. Convenience sampling selects a particular group of people based on aspects of the potential participant's situation which renders them more easily accessed by the investigator or more likely to complete research participation without regard for the representativeness of the sample. Convenience sampling fails to sample all a population and therefore may unfairly expose a population to research related risks. Participants in general should not simply be recruited because it is a convenience pool for the researchers. Rather, recruitment strategies should clearly align with the stated aims and research questions of the study such that the population recruited will provide a diverse participant pool needed to produce generalizable results relevant to the questions. If answering specific research questions requires recruitment from specific participant pools, this must be justified both here and in the protocol description section.

c) If students will be offered extra credit a non-research alternative that allows students to earn equivalent extra credit over an equivalent amount of time must be offered. Instructors cannot recruit students from their own class. The alternative assignment that will be provided to participants must be listed and attached to the cayuse application.

d) To mitigate undue influence, students should not be offered extra credit that exceeds 3% of their final grade. If it is possible for students to earn extra credit in multiple classes, the 3% rule must still be maintained, meaning students cannot earn 3% in multiple different courses. The total that can be earned is 3% across all possible classes. A plan to ensure students are not getting extra credit in multiple courses for participating in the same study must be described in the Cayuse application. Please see more information here.

e) When recruiting employees, special care must be taken to mitigate any potential of coercion or undue influence. Employees should never be recruited or asked to participate by a supervisor or anyone in authority over their employment. Employees should not be encouraged to take place in workshops or career training that is part of a research project as a condition of their employment. Research activities or results should never be used by employers to aid with performance evaluations or other employment related decisions. Recruitment of potential participants who are employees must be designed to minimize coercion or undue influence. Employees should not be selected solely based on convenience. Please see more information here.

f) PIs are not allowed to maintain or recruit from a participant database unless that pool has been approved by the IRB. If a participant database will be used for recruitment, please provide the approved IRB number in the application.

g) For snowball sampling, or similar procedures, please see here for the guidelines about justification of this method. Include these items in the application. Protocols that do not include the justification for snowball-style sampling will be returned to the PI for edit.

8) Risks and Benefits

a) Many risks can be mitigated by thorough inclusion/exclusion criteria. Please consider the population-based risks in the sections above to mitigate risks in those who qualify.
b) All potential risks should be clearly listed, including any mental health, financial, legal, social/reputational, etc. that may result from participation. It should not be stated that risks are "minimal" without specifically describing these minimal risks.
c) In most cases breach of confidentiality is a risk.
d) If deception is used, please list any risks that may emerge during the debriefing process, such as negative participant responses when participants are debriefed or dehoaxed.
e) In studies requiring participants to perform any physical tasks such as lifting, walking, running, or movement in the virtual environment there is a risk of injury. This risk in enhanced when using certain populations such as elderly adults are used.
f) Studies that will be done in non-controlled environments such as outside, in public places, or at the worksite may have enhanced risks such as risks to employee productivity or confidentiality that need to be carefully considered and described. Will individuals be excused to take time from their work day to participate in the research study? What mechanisms will be established to keep participation confidential from supervisors or coworkers?
g) Any risks of this study to groups of individuals such as lower socioeconomic groups or ethnic groups must be detailed.
h) If the study is greater than minimal risk include; 1) how an adverse event will be defined; 2) what adverse events are expected; 3) how adverse events will be managed; 3) rules for stopping the study; and 4) who is responsible for reporting adverse events and how that person will monitor the study to ensure adverse events are properly handled. The IRB wants to know how the research team will handle trends or adverse events should they occur.
i) A Data Safety Monitoring Plan (see an example from NIH here) should be included in all applications where studies are Greater than Minimal Risk. Studies may also need a Data Safety Monitoring Board who serves to evaluate the risks routinely.
j) Any potential benefits to the individual or society should be described. Investigators are also required to give a risk / benefit ratio assessment. This assessment should be specific and related to the study. Please avoid generic statements like "the benefits of the study outweigh the risks". The benefits must specifically relate to the significance statement listed in the protocol description section and be discussed relative to the risks described in the risk section above. A well written risks / benefit statement will clearly articulate why the benefit for doing this research outweighs any risks to the participants or groups of people.

9) Privacy and Confidentiality

a) The collection of any directly or indirectly identifying information should be detailed. Video and audio are considered identifiable data.
b) Include a plan for how all data will be stored and transferred. This plan should include Purdue approved mechanisms such as Box and File Locker. Storing any data on personal computers, portable storage drives, or mobile devices is not allowed.
c) Affirm that data will be kept for a minimum of three years after study is formally closed with the IRB. List any paper, electronic, video, audio, or photographic data that will be collected as part of the study and how this data will be securely stored. In the event that Personal Health Information (PHI) is used, the retention of the documentation is six years following study closure.
d) Include a statement that affirms the PI is responsible for ensuring all data is stored according to the procedures outlined above and that PI will monitor and have continuous access to all study data. Co-investigators should not have exclusive access to study records and data. If students graduate or leave the university, data must be retained with the PI. Any future use of the data at a different institution must be approved by that institutions' IRB.

e) Indicate if any direct or indirect identifiers such as names, telephone numbers, or social security numbers will be collected and justify why this information is needed to address the research questions, outcomes, or hypotheses of the study. If information is needed for participant reimbursement and will be transferred to non-study personnel, such as people in a business office, please include exactly what information is given to the business office, how they store that information, and how they reimburse the participant. The participant must also be told in the consent form what information will be given to a departmental business office for reimbursement purposes and how the business office will store their personal information and the duration it will be kept. In some cases, the title of the study and connection to a participant's name could jeopardize privacy. Ensure that these items are known before applying to the IRB.

f) When using a coding system to protect confidentiality of participants, describe the coding system that will be used and how you will protect against disclosure of participant identities. If participant codes or identities are given to anyone not explicitly listed as key personnel, the names of the people / researchers receiving the identity codes and how they will receive the codes needs to be listed. Use a coding system that is not easily traceable (e.g., initials, address, date of birth, etc.)

10) Compensation for Research Participation

a) The total compensation participants will receive needs to listed. Including plans for partial payment. The IRB discourages balloon payments where study completion is required. Consider a fair compensation plan relative to the time spent in a study.

b) Course credit is considered compensation.

c) Any products participants will receive such as toys or books is compensation

d) If drawings will be used to compensate participants, the odds of winning must be listed. Please see Purdue Tax guidelines here.

e) If no compensation will be offered, please include a detailed statement describing how the researcher plans get individuals to agree to be research participants without offering compensation for their time. This is particularly important when recruiting from a class or from a known group such as employees. The IRB needs to ensure that there is no potential for coercion or undue influence in the recruitment process.

11) Informed Consent Process

a) A standard consent process must be completed for all non-exempt studies. This consent process must include a consent document and signature that strictly adheres to the Purdue consent template. If the data is being collected remotely (e.g., via Zoom) signatures can be obtained using the signature field in Qualtrics, or signature software such as DocuSign or Adobe signature.

b) Waiver of Documentation of Informed Consent (45 CFR 46.117) For some research projects, the IRB may approve a request to waive the *documentation* of informed consent. This means that the study team must provide a subject with the required consent information, but the study team is not required to obtain the subject's signature on the informed consent document.

Subjects should be offered a copy of the consent information for their records even when a signed document is not required for the project.

A waiver of documentation is **permissible** when:

- The signature on the informed consent document would be the only record linking the subject to the research and the principal risk of harm to the subject would be a breach of

confidentiality. For example, for research on sensitive topics, such as domestic violence or illegal activities; **OR**

- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context. For example, minimal risk research that involves surveys/interviews conducted via telephone or online.

c) The purpose of the study and the details of what participants will do if they choose to be part of the study needs to be clearly written in a language that is understandable to the general public.

d) If any details are being withheld from participants during the consent process or if participants are being misled about the true research purpose, procedures for deception or incomplete disclosure need to be followed, including adding a debriefing consent. Participants have a right to know exactly what they will be doing if they agree to participate and the details of the purpose of the study.

e) Participants should be told if there are any costs associated with participating. For example, does participating in the research involve a medical visit that may be billed to the participant or their insurance?

f) If children will be used, please follow all parental consent and child assent procedures.

g) If non-English speakers will be recruited, translated consent forms must be attached. Please ensure that the translation and back-translation is included.

12) Conflict of Interest

a) It must be disclosed in the application and in the consent document if anyone on the research team has a stake in technology (e.g., a device, app etc.) that is being utilized in the research. Consider all potential conflicts, real or perceived. Under Purdue policy, the Purdue IRB does not review activities that are reportable outside activities.

13) Protocol Modification

a) Modifications are reserved for minor changes to existing protocols. Extensive modification that significantly change the procedures, address new research questions and hypotheses, or append new studies are generally not modifications and should be submitted as a new study.