TMP24-0026 | Sarah Mumford
Study - Pre-Submitted [New | Unsubmitted]

1. All comments, notes, and examples are highlighted in yellow throughout the application.

2. The application is a "Smart Form" and only applicable, required questions will be available based on previous answers. In this sample, all questions are included for educational purposes.

Annotated Guidance for New Study Application

Section 1: Study Title

1.1) Title of Study

Annotated Guidance for New Study Application

1.2) Study Purposes and Objectives

This response should be 1-3 sentences and specifically state the research question you are attempting to answer with this project. If there is no research question, this might be the objective or aim. You should be explaining the point of this project such that the IRB can determine whether or not the study design is appropriate to accomplish what you are setting out to do. The objectives should be stated in such a way that the reader can determine the appropriateness of the study design. If appropriate, state the specific hypotheses being tested and/or study aims. Use lay language.

1.3) Background and Introduction

The background and literature review is needed to help the IRB understand the context and importance of your research. This section should be as detailed as necessary to justify your project and the risks involved. The length of the response may vary depending on how much information is needed to justify those risks. The riskier the research, the more justification may be needed to ensure the IRB understands the context of the project. If this is a funded project, this section can be similar the grant.

1.4) Was this project previously approved by the University of Illinois Urbana-Champaign IRB as part of an earlier application?

◉ Yes

If yes, list the previous IRB number:

Only meant for transitioning from "paper" applications - or if your study gets closed out prematurely in the future.

○ No

Section 2: Research Team

2.1) Research Team Members

If other researchers have their own IRB approval, this should be stated in Section 12, #12.3. If other researchers need UIUC to act as the IRB, submit a Reliance Consultation Request to discuss.

Name
Jennifer Ford

Email
jnford2@illinois.edu

Department
1-344: Protection of Research Subject

Access Level
Research Team Contact

Campus Status
Academic Professional/Staff

Role on the Research Team (check all that apply)
Recruiting, Consenting, Administering study procedures, Handling identifiable data

2.2) Select the Position of the Principal Investigator:

Note: Students are not permitted to be Principal Investigator. Additional documentation may be required to ensure eligibility to act as PI https://oprs.research.illinois.edu/faqs/who-can-be-principal-investigator-pi

- (●) Faculty
- ( ) Academic Professional
- ( ) Civil Service Employee
- ( ) Other Non-Student Position

2.3) Is this a student-led research project?

- (●) Yes

  Please list student's name

  i.e. If Thesis/Dissertation - helps OPRS link grad student to project (PI is faculty advisor legally responsible for all research activities).

- ( ) No

2.4) Does any investigator (or any of their immediate family members) have a financial interest or fiduciary relationship with the research sponsor?

For example, the investigator is a consultant for the research sponsor. If yes, submit the University of Illinois approved conflict management plan in Section 23: Documents in the "Other Documents" area.

- ( ) Yes
- (●) No

2.5) Does any investigator (or any of their immediate family members) have a financial interest or fiduciary relationship that is related to the research?

For example, an investigator owns a startup company, and the intellectual property developed in this protocol may be useful to the company.If yes, submit the University of Illinois approved conflict management plan in Section 23: Documents in the "Other Documents" area.

- ( ) Yes
- (●) No

2.6) Are two or more members of the same family are acting as research team members on this protocol?

If yes, submit the University of Illinois approved conflict management plan in Section 23: Documents in the "Other Documents" area.

- ( ) Yes
- (●) No

Section 3: Funding

3.1) Is the research funded?

- ( ) Research is not funded and is not pending a funding decision
- (●) Research is funded (funding decision has been made).
- ( ) Funding decision is pending.

3.2) Add any funding sources you have initiated a proposal for.

Indicate the source of the funding.
University of Illinois Department, College or Campus

Please describe the specific fund source.
PI's startup funds

Funding Contact Name
Department Business or Grant Administrator

Funding Contact Agency
Department

Funding Contact E-mail
Email

Funding Contact Phone
Phone

Section 4: Subjects

4.1) Ages of Subjects

- ☐ Less than 7 (Parental Permission Needed)
- ☐ 7-17 (Parental Permission and Assent Needed)
- ☑ 18 and older (Consent form needed)

4.2) Specific age range of subjects (e.g. 7-12 years old, 60+, etc.):

18+

4.3) Indicate any vulnerable population groups that will be included:

- ☑ Children
- ☐ Pregnant women and fetuses (CFR Part 46, Subpart B)
- ☐ Neonates (45 CFR Part 46, Subpart B)
- ☐ Prisoners (45 CFR Part 46, Subpart C)
- ☐ Individuals with Cognitive or Decisional Impairment
- ☐ Students, staff, and faculty of the research institution
- ☐ Mentally Disabled
- ☐ Economically or Educationally disadvantaged persons
- ☐ Other

OR

- ☐ No vulnerable populations included

4.5) Number of subjects to be enrolled in this entire study:

4.5.1) Total Subjects enrolled by UIUC researchers:

This question is blank.

4.5.2) Total Subjects enrolled by all sites participating in study:

If this project is a single-center study, you can either use the same number as in 4.5.1 or you can enter "N/A".

4.6) Participant Inclusion Criteria:

In some cases, your experiments may have specific requirements. Those applications will each list the requirements. If it really doesn't matter, then you can just include "Ages 18 and over" as your inclusion criteria. It is not necessary to state "willing to provide consent" as that is assumed. If, for example, you are going to use a criteria, question, or make a decision on how well a participant speaks English, provide that information.

4.7) Participant Exclusion Criteria:

Often - exclusion is just the opposite of the inclusion criteria; however, in some cases there may be specifics. This question is just asking for a list of any conditions that would exclude someone from participation. For example, "Unable to understand or read English" might be an exclusion criteria. The higher the risk of the study, the more important these exclusion criteria are.

Section 5: Vulnerable Populations

5.1) How does the nature of the research require or justify using the the proposed subject population?

The IRB is required to document that there is a research purpose to justify the targeting and inclusion of any "vulnerable population". IRB policy and federal guidance include "Students, Staff, and Faculty" of the research institution as a vulnerable population. In order to target a vulnerable population (i.e. students, staff, and faculty) which you are doing by specifically recruiting on campus, you must justify the inclusion of these individuals in the study. The inclusion of a vulnerable population cannot be approved under these policies and regulations if the justification is for the convenience of the researcher.

5.2) Would it be possible to conduct the study with other, less vulnerable subjects?

- ○ Yes
- ◉ No

5.3) Is this population being included primarily for the convenience of the researcher?

- ◉ Yes

  Explain:

  Institutional policy and federal regulations do not permit the inclusion of defined vulnerable populations if the only reason for their inclusion is for the convenience of the researcher.
- ○ No

5.4) Does the scientific merit of the study warrant the inclusion of subjects who may either be susceptible to pressure or who are already burdened?

- ◉ Yes
- ○ No

Section 6: Study Information

Design of Study (Select all that apply)

6.1) Non-Experimental and/or Descriptive Research Design

Collection and assessment of the participant's data and information without prospective manipulation of the participant's body, environment, or treatment.

- ☑ Secondary/Archival Data Analysis or Retrospective Chart Review 

- [x] Survey/Questionnaire Research

List the name of any validated surveys that will be used in the project:

Validated surveys are those that have been scientifically validated and are available publicly. For example, a validated survey can searched online by name of the survey and the IRB easily obtain a full copy of the survey and scoring. For validated surveys, you can list the name of the survey in this box and do not need to attach the survey itself because the IRB can look up the survey themselves. For unvalidated surveys, or surveys created specifically for the project, you will attach them in 23.3, you do not list the name of them here.

- [ ] Interviews and Focus Groups
- [ ] Oral History
- [ ] Observational Research (e.g. ethnographic field work)

6.2) Experimental and/or Interventional Research Design

Prospectively manipulating the participant's body, environment, treatment, or strategies for receiving information in order to observe a resulting effect or outcome.

- [x] Prospective Social/Behavioral Intervention or Experiment
- [ ] Prospective Biomedical Intervention or Experiment
- [ ] Randomized Design
- [ ] Placebo or Sham Controlled Design
- [ ] Phase I Clinical Trial
- [ ] Phase II Clinical Trial
- [ ] Phase III Clinical Trial
- [ ] Phase IV Clinical Trial or Post-Approval Monitoring
- [ ] Open Label Trial

6.3) This project is Community Based Participatory Research https://oprs.research.illinois.edu/research-topics/community-engaged-research

- ○ Yes
- ◉ No

6.4) Study includes creating research resources such as repositories, databases, etc.

- ○ Yes
- ◉ No

6.5) Study will include a research design that is not listed in the previous questions.

- ○ Yes
- ◉ No

6.6) Length of entire study from initiation to closeout (including data analysis):

This should be a timeframe that covers the data collection and analysis of the activities described in this IRB application., not a date. (e.g. 2 years)

6.7) Length of individual subject's participation:

Enter the length of the subject's participation below (e.g. one-time visit for 2 hours, 4 weeks, 15 minutes, etc.)

The length of time a participant will be doing research-related activities is a specific requirement for consent documents and part of the criteria that determine if a project is exempt or not. If you cannot answer this question very specifically, it may be a hint that the project should be split into multiple IRB applications.

6.8) How will subjects be recruited or identified for inclusion in the study?

See more guidance on all types of advertising at: https://oprs.research.illinois.edu/forms-templates/guidance/guidance-advertisements.

Select all methods that will be used:

- [x] In-person contact (e.g. students in class, patients in clinic, etc)
- [ ] Referrals from other individuals
- [ ] Written or electronic record review
- [ ] Written advertising (flyers, brochures, website postings, newspaper ads, etc.)
- [ ] Audio/Video advertising (radio and television advertisements, etc.)
- [x] From a database or participant pool, for which participants have given prior permission to be contacted for future research studies

  Please list the name(s) of the database(s) or participant pool(s):

  e.g. SONA Psychology Pool
- [x] Specific online population such as MTurk, Qualtrics Panel or similar

  Please list the name(s) of the Online Population(s):

  e.g. Prolific
- [ ] Other

6.9) Describe the recruitment/participant identification process in detail.

Please detail the recruitment and participant identification process below.

For example: who will review records, who can refer subjects to the study , where will flyers be posted, how often recruitment letters will be sent, when will follow-up phone calls be made, etc. Attach additional pages if needed.

How will participants be identified for this research? How will you ask people to participate in the research? All studies "recruit" participants, this is not related to actually communicating with people, it means how will you identify/select/ask people to be in your study. Do not detail the research procedures in this response.

6.10) How will consent be obtained? Select all that apply.

- [x] Informed Consent Process (with or without a document).
- [x] Waiver of Informed Consent Process

6.11) Describe all procedures chronologically, from screening/enrollment through study closeout, which will be completed in the research project.

1. All research procedures should be clearly and concisely explained. If it works with your study, a list format is always useful. 2. How you are finding participants is described in 6.9, so everything from that point on should be described here. 3. In projects where randomization will occur, this response must provide details on how the randomization is determined, how it is handled, who will conduct the randomization. 4. In experiments (for example) where there may be multiple options or scenarios or the "path" a participant goes down may be pre-determined or determined by their responses, or random, you must provide all of the possibilities and then explain how that path is determined. 5. (Example) In one study participants have to read and react to different words that

appear on the screen. The researcher uses a bank of 60 words but a participant only gets 15-20 words. This must be explained in this section and all 60 words have to be attached for review and approval by the IRB. If the project were exempt, words could be replaced with similar words (i.e. non-offensive or sensitive in any way) without IRB approval for the change; however, if the study were determined to be minimal risk, the words could not be changed without IRB approval.

6.12) Are all procedures for research purposes only (non-standard or non-standard of care procedures, or occurring only related to participation in the research)?

Note: “Non-standard” refers to procedures that are only occurring because the participant agrees to participate in the research.

○ Yes, all procedures are for research purposes only.

◉ No, not all of the procedures are for research purposes only.

Please list the procedures that are performed for research purposes only (non-standard or non -standard of care procedures or only occurring as part of the research):

(Example) Professional development seminars are conducted as standard procedures for this population, but the surveys evaluating the seminars are for research purposes only. It is important to be clear about what activities are happening regardless of the research. Confusion about this can lead to multiple sets of revisions and higher risk determinations than necessary.

6.13) Provide a summary of the statistical methods, data analysis, or data interpretation planned for this study.

Please enter your summary below. Factors for determining the proposed sample size (e.g. power) should be stated.

This question is applicable regardless of whether it is quantitative or qualitative research. You must explain your plans for analyzing the data. The IRB is required to confirm that the data analysis plan will result in valid data. The regulations state that participants are not allowed to be put at any level of risk (including minimal risk) if the data being collected will not result in analyzable data. Qualitative research data is analyzed even if it is not done using statistical methods.

Section 7: Consent Process

7.1) Describe the location(s) where consent will be obtained:

Possible answers may include: - Researcher lab location - Classroom - Online (participant consent occurs as part of online survey they take at any location)

7.2) Describe whether there is a waiting period between the consent process and obtaining consent from the subject (i.e. any time between informing subjects and actually obtaining consent):

Sometimes there is no waiting period, this is OK. It is not necessary to justify it, just clearly answer the question based upon your plans for consent. Do not repeat the same responses in 7.2, 7.3, and 7.4, these are different questions.

7.3) Describe what measures will be taken to minimize the possibility of coercion or undue influence:

For studies that include students, appropriate responses/plans may be to make sure that instructors are not conducting the consent process, instructors (or those responsible for grading) do not know which participants agreed to participate until after grades have been given, or not enrolling participants who are in the courses taught by the researchers or research team members. For greater than minimal risk research, students, staff, or faculty members cannot be enrolled in research being conducted by their instructors or anyone within their direct reporting line. Please see research guidance document related to university employees in research.

7.4) Describe the provisions that are made to allow adequate time to exchange information and questions between the investigator and subject:

For a simple, online survey it may be appropriate to require participants to contact the researcher with questions; however, for a more complex or risky study, the onus should not be on the participant to reach out to the researcher. It may be necessary for the research team to reach out to participants or conduct a "live" consent process discussion. For studies that require the participant to agree to the

basics of the study before the first visit is scheduled due to the cost and logisitics involved in scheduling a visit, it may be acceptable to provide the consent electronically to the participant before the visit. However, the consent process should be conducted in-person when the participant comes to that visit allowing the researcher to review all of the information from the consent document and allow time for questions and further discussion as needed without requiring the participant to contact the research team.

7.5) Will a legally authorized representative (LAR) be used?

- (●) Yes
- ( ) No

7.6) Describe when the use of an LAR might arise in this study population and what the frequency of an LAR will be during the enrollment period:

A Legally Authorized Representative is only used for adult participants who do not have the legal ability to provide consent for themselves. Parents/guardians of children under the age of 18 (where the children are the participants) are not legally authorized representatives as this only refers to adult participants.

7.7) Will a language other than English be used to obtain consent?

- ( ) Yes
- (●) No

7.10) Are you requesting that documentation of informed consent be waived by the IRB (a consent process is in place, but no documentation of consent, e.g. questionnaire cover letter, web-based consent, consent without signature, etc.)?
If the study is subject to FDA regulation, a waiver of the requirement to obtain documentation of consent is not allowed.

- (●) Yes
- ( ) No

7.11) Waiver of Documentation of Consent

7.11.1) Explain why the waiver of documentation of consent is being requested.

A waiver of documentation of consent is only used when a participant has the choice to participate in research and they are being provided with all of the required elements of consent, the participant is just not signing a document in a way that could be considered a legal signature. Please review https://oprs.research.illinois.edu/research-topics/electronic-signatures-and-waivers-documentation-consent on the Research Topics page of the OPRS website.

7.11.2) Justification for the waiver is one of the following:

- ( ) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether he/she wants documentation linking the participant with the research and the participant's wishes will govern.
- ( ) Participants in this study are members of a distinct cultural group or community in which signing forms is not the norm. The research presents no more than minimal risk of harm to subjects and the study team has an alternative mechanism for documenting that informed consent was obtained.
- ( ) The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Section 8: Request for Waiver of Consent

8.1) Add requests

Purpose of the Waiver Request
A Waiver of Informed Consent means that participants do not have a choice to participate and likely don't even know research is occurring. You should explain what you are requesting the waiver for - one aspect of the project, the whole project, etc. Example: We are requesting a waiver of consent to observe how people interact with the museum exhibits.

Type of Request
Waiver of Informed Consent

List of identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or University record numbers)
If you will not collect or keep a link to identifying information, state that. Retrospective chart reviews of medical records will likely include a subject ID#, date of birth, date of service, etc.

Explain why the research could not be practicably conducted without using identifiable information.
If no identifiable information will be collected, state that.

Explain why the research could not practicably be conducted without the waiver or alteration.
If I had to obtain consent, the research could not be conducted because the research is meant to study how people interact with the exhibits and notifying them might alter their behaviors.

Explain why the research and privacy risk of the research are no more than minimal:
Example: Observed participants will have no contact with the research team and be unidentifiable by anyone related to the research project. Additionally, participants will be observed in a public setting, so any actions that are observed by the research team may also be observed by others.

Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the subjects:
All information collected is not sensitive and a reasonable person who is in the participant's position would not consider the waiver as adversely affecting his/her rights.

Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information after they have participated in the study, or indicate "Not Applicable":
Some studies may include a "de-brief" to provide information afterwards, but in many cases, it is not appropriate to tell participants about it, in those cases "N/A" is an acceptable response.

Purpose of the Waiver Request
An Alteration of Consent is when participants are given the choice to participate, but you have removed some of the elements of consent. This is most often see with "deception" or "incomplete disclosure" where the researcher may not want to explain the full purpose behind the research (for example). Explain what the alteration is for here. Example: The Alteration of Consent is needed to not inform participants of the full purpose of the study.

Type of Request
Alteration of Informed Consentof consent template be removed or altered e.g. use of deception in consent)

List of identifying information you plan to collect or keep a link to (e.g. names, dates, or identification numbers such as social security numbers or University record numbers)
Names of participants (If participants are signing consent documents, the data would include names). If no identifying information is being collected, state that.

Explain why the research could not be practicably conducted without using identifiable information.
Example: We are obtaining consent just withholding some of the information about the project. Names are being collected on the consent documents because consent is still being provided by participants. Example: N/A - no identifiable information is being collected.

Explain why the research could not practicably be conducted without the waiver or alteration.
If I had to obtain consent the research could not be conducted because providing the full details of the experimental procedure could alter how participants behave in the study and provide inaccurate or biased data.

Explain why the research and privacy risk of the research are no more than minimal:
Example: Identifiable information will not be collected and no attempt will be made to re-identify the data. The research procedures include surveys which are minimal risk.

Describe the measures you will take to ensure the waiver or alteration will not adversely affect the rights and welfare of the subjects:
Example: By ensuring no identifiable information is collected there is no risk to participants that anyone will discover their responses and no physical, financial, legal, or reputational harm could occur.

Explain how you will, if applicable and appropriate, provide the subjects with additional pertinent information after they have participated in the study, or indicate "Not Applicable":
Example: Following participation, we will provide participants with a de-brief document that will explain the true purpose of the study and explain why we could not provide the full information upfront. Once they have been told the true purpose of the project participants will be given the option to withdraw and not have their data included in the study. (Providing an opt-out is not always required, but is not uncommon.)

Section 9: Data Monitoring

https://oprs.research.illinois.edu/research-topics/data-safety-monitoring

9.1) Privacy Protections – What precautions will be used to ensure subject privacy is protected? Select all that apply:
Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Privacy refers to persons and to their interest in controlling access of others to themselves. Privacy can be defined in terms of having control over the extent, timing and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

- [x] The research intervention/interaction is conducted in a private place.
- [ ] Discussing the study with participants individually instead of in front of a group.

- ☐ The collection of information about participants is limited to the amount necessary to achieve the goals of the research, so that no unneeded information is being collected (can be used for research with no participant contact, e.g. secondary data analysis or chart reviews)
- ☐ De-identification of photos, audio tapes, or video tapes of the participant that will be made during the study
- ☐ Allowing for anonymous submission of surveys and questionnaires
- ☐ Other or additional details (specify):

9.2) Confidentiality Precautions – What precautions will be used to maintain the confidentiality of identifiable information? Select all that apply:

Confidentiality is an extension of the concept of privacy; it refers to the subject's understanding of, and agreement to, the waits identifiable information will be stored and shared. Identifiable information can be printed information, electronic information or visual information such as photographs.

- ☑ Storing research data on password protected computers or in locked cabinets or offices
- ☐ Participant identifiers will be stored separately from the coded, participant data
- ☐ Complete de-identification of study data
- ☐ All data that will be transferred or transported outside of the institution will be encrypted
- ☐ Destroying photos, audio recordings, or video recordings at the end of the study
- ☐ A Certificate of Confidentiality (from the NIH) will be used
- ☐ Other or additional details

9.3) Will photos, audio recording, video recordings, or medical images of subjects be made during the study?

- ○ Yes
- ◉ No

9.4) How will study data and documentation be monitored throughout the study? Select all that apply:

OPRS has self-assessment forms available for biomedical and social/behavioral studies to guide you through the monitoring process**:** https://oprs.research.illinois.edu/forms-guidance-resources/post-approval-monitoring

- ☑ Periodic review and confirmation of participant eligibility
- ☐ Periodic review of informed consent documentation
- ☐ Periodic review of the transfer/transcription of data from the original source to the research record
- ☐ Confirmation that all appropriate information has been reported to the sponsor, oversight agencies such as the FDA), and/or IRB
- ☐ Other or additional details

9.5) Who will be the primary monitor of the study data and documentation?

Select all that apply:

- ☑ Principal Investigator
- ☐ Research Assistant
- ☐ Study Coordinator or Research Nurse
- ☐ Study Monitor or Contract Research Organization (CRO)
- ☐ Independent Faculty or Staff member, Physician

☐ Data Monitoring Board or Committee

☐ Other or additional details

9.6) How often is study data and documentation monitoring planned?

(e.g. monthly, twice a year, annually, after N subjects are enrolled, etc.)

Data monitoring should occur as frequently as necessary to ensure the validity of data in the study. The frequency should relate to the risk of the study and the risk of finding errors and what that would mean to the validity of the data. At the approved frequency, a data monitoring report should be created and saved in the research record showing what was reviewed, what the results were, and what corrective and preventive actions were taken, if applicable.

9.7) Is there a SAFETY monitoring plan for this study?

A safety monitoring plan is required for all studies determined by the IRB to be greater than minimal risk.

◉ Yes

○ No

Section 10: Risks and Benefits

10.1) Describe the reasonable foreseeable risks or discomforts to the subjects:

Only include the risks of research-related procedures

List and describe the risks here. It is not necessary to justify the risks, clear and concise descriptions should be listed here and should be the same as those listed in the consent document.

10.2) Describe the potential direct benefits to subjects:

Do not include compensation. If there is no potential direct benefit to subjects, please state that.

Theoretical benefits should not be listed, only potential direct benefits. Many studies that do not include a direct intervention or treatment do not have any potential direct benefit to the individual participants, these should state "No potential direct benefits to participants". In order for something to be considered a direct benefit it should be directly related to the objective of the study.

10.3) Describe the potential benefits to society:

If there are no potential direct benefits to individual participants, there must be a benefit to society. This may include an advancement in the scientific knowledge of a certain area.

10.4) Using lay language, please describe the significance of this research and what you hope to show with the results of the project.

This should not be grant or publication language, but how you would explain the importance of this research to a lay person.

10.5) Are there any costs to the subjects from participating in the research?

○ Yes

◉ No

10.6) Is there any compensation to subjects (including monetary or class credit)?

◉ Yes

○ No

10.7) Compensation Details

Please answer the following questions related to subject compensation:

10.7.1) Specify overall amount:

Describe the amount and method by which participants will be paid. Extra credit for a course is considered compensation. For information about course credit, please review the research guidance document "Research Conducted in Post Secondary Schools". https://oprs.research.illinois.edu/sites/default/files/documents/RGD%20-%20Research%20Conducted%20in%20Post%20Secondary%20Schools%20B1324.pdf

10.7.2) Specify when participants will be paid (e.g. at each visit, at end of study, etc):

This is the time points for payment.

10.7.3) If applicable, please specify payment by visit or other time interval (e.g. $10 per visit, etc.):

If there is a payment per visit or payment schedule, detail here.

10.7.4) If applicable, explain plan for prorating payments if subject does not complete the study:

Detail pro-rating of payments here.

Section 11: Safety Monitoring Plan

11.1) Describe the safety monitoring entity for this study:

Select all that apply

- ☐ Principal Investigator
- ☐ Independent Physician or Faculty Member
- ☑ Safety Monitor
- ☐ Data and Safety Monitoring Board or Committee
- ☐ Other

11.2) Describe the expertise and affiliation of the individual(s) selected above who will monitor the study:

The person or people conducting the safety monitoring must have the expertise in the medical or psychological risks of this study to act as the safety monitor(s). Students are not acceptable safety monitors. Some studies may require medical professionals (MD, DO, PharmD) depending on risks of the project.

11.3) Describe the data and events that will be monitored and reviewed:

e.g. vital signs, safety blood labs, depression scales, neurological exams, types of adverse events, etc.

Adverse events Blood glucose levels

11.4) Describe the types of reports that will be produced by the monitoring entity:

e.g. study progress, interim analysis, safety, etc.

Quarterly study progress and safety reports

11.5) Describe the specific triggers or stopping rules for the study:

11.5.1) Under what conditions will a participant be withdrawn from the study?

This should include a test result or at what point something occurs with an individual participant where they will have to be removed from the study because continuing may no longer be safe.

11.5.2) Under what conditions will the study be modified or stopped?

This could be if a large number of unanticipated problems, or if the safety monitoring entity determines the potential benefits no longer outweigh the risks.

11.6) How often will the data and events be reviewed by the monitoring entity:

e.g., after every 5 subjects, monthly, quarterly, etc.

How often will aggregate data be reviewed to look for trends of adverse events across participants. This should be often enough to not put future participants at risk if new events are discovered, but should be too often that does not allow for review in the aggregate and ability to identify unexpected trends. A monitoring report should be created and reviewed by the monitoring entity at the stated frequency.

Section 12: Resources and Responsibilities

12.1) State and justify the qualifications of the study staff:

This response should justify that the PI, investigators and study staff are qualified to conduct human subject research. This may include their overall experience working in this field of study or with research in general.

12.2) Describe the training that study staff and investigators will receive in order to be informed about the protocol and understand their research-related duties and functions:

This response should explain how you as the PI will ensure that anyone working on this project will be trained and understand their duties related to this specific project. CITI training is not a sufficient answer as that is the basic training required for anyone working on any project, this response should provide information related to this specific project or working for this specific researcher. Monthly or weekly lab meetings may be an appropriate response that include protocol review and training.

12.3) Describe the facilities where the research activities will be performed (e.g. hospitals, clinics, laboratories, classrooms/schools, offices, tissues banks, etc.):

Specific locations on campus should be listed if participants will be meeting researchers in-person. For online research, the response might be "online and in the researchers' offices at Mumford Hall". If you are working with investigators at another institution who have their own IRB approval, list the name of the institution here and explain how you are working together. We do not need the individual names of the other researchers. Please specifically state if they will have their own IRB approval. If research is conducted at other locations, a letter of support may be required to be included as part of your submission. Please review the research guidance document: https://oprs.research.illinois.edu/forms-templates/guidance/guidance-letter-support

12.4) Describe the medical or psychological resources available at this site (and other participating sites, if applicable) that participants might require as a consequence of the research:

If not applicable, please state.

In many studies, this question is not applicable. However, if you are providing resources to participants in case of psychological distress (for example) they must be listed here.

Section 13: Additional Information

13.1) Does this study involve any of the following:

- [x] Sharing data with researchers outside of UIUC?
- [x] Sharing data with researchers from UIUC?
- [x] Planning, or is it possible, some research procedures or participants will be outside of the U.S.?
- [x] Creating or sending data and/or samples to a repository or database to be saved for future research uses?
- [x] Collecting, analyzing, or banking human cells, tissue, fluid, DNA, or other human biological samples (whether prospectively or retrospectively taken)?
- [x] Exposure to radioisotopes or ionizing radiation?
- [x] Genetic testing and/or analysis of genetic data?
- [x] Studying the safety, effectiveness, or outcomes of a drug, dietary supplement, biologic product, or cosmetic?
- [x] Studying the safety, effectiveness, or outcomes of any type of device, algorithm, or mobile application (medical or non-medical)?
- [x] Obtaining data/information from a medical record or entering data/information into a medical record? This includes deidentified health information or Protected Health Information (PHI).
- [x] Using the MRI at the Beckman Institute Biomedical Imaging Center (BIC)?

OR

- [ ] None of the above

Section 14: Data Sharing

14.1) Who will you be sharing data with?

This question refers to sharing raw data for specific research purposes either now or in the future. Scenario 1: Multi-center study or multiple researchers working together, UIUC is one site and all sites share data together for analysis of this specific project Scenario 2: A researcher outside of UIUC has a similar study and you intend to share your data with them for analysis of their specific project Scenario 3: A researcher in your department at UIUC is doing a related study and you share your data with them to provide more complete data This question refers to sharing raw data for analysis for a specific project (not future unspecified use, i.e. a registry or repository). Presenting or publishing the results of results of the project do not constitute data sharing. If you will be sharing data for the purposes of this study. If other researchers at UIUC will be using this data as part of their IRB-approved project, both PIs must list the other IRB# as sending/receiving data.

14.2) What data will you be sharing?

- ○ All data including identifiable data
- ◉ All data but no identifiable data
- ○ Some data, including some identifiable data
- ○ Some data, but no identifiable data

14.3) Explain what data you will be sharing:

This question is blank.

14.4) Are you sharing the data for purposes related to this project?

- ○ Yes
- ◉ No

14.5) Are you sharing the data for a specific project, but not this one?

- (●) Yes
- ( ) No

14.6) Is the data sharing for the purpose of future, unspecified research?

- (●) Yes
- ( ) No

14.7) Do you have some type of agreement that includes data sharing? This may include a federal multi-center grant, an industry-sponsor agreement, a data transfer agreement, or data use agreement.

- (●) Yes
- ( ) No
- ( ) Other

Section 15: International

15.1) Will UIUC researchers be located outside the US while conducting the research?

- (●) Yes

  Will the PI be present where the research is being conducted?

  - ( ) Yes
  - (●) No

  Describe the PI's ongoing oversight of the research activities conducted outside the U.S.

  For example, a student researcher is conducting research in a different country but the faculty advisor who is the PI remains in the U.S. The faculty advisor/PI is required to be providing ongoing oversight of the research activities that are occurring, describe what that process and communication will look like.

- ( ) No

15.2) Will UIUC researchers be interacting with participants who are outside the US? (e.g. Zoom interviews, phone call)

- (●) Yes
- ( ) No

15.3) Will participants be outside the US, but no direct interaction with UIUC researchers is occurring? (e.g. Online survey, secondary analysis of existing data)

- (●) Yes
- ( ) No

15.4) Countries Involved

List the country(ies) in which study activities will occur.

This question is blank.

15.5) Site Details

List the specific sites (e.g. name of clinic, hospital, school) at which study activities will occur in the countries listed above.

This question is blank.

15.6) Ethics Committee or IRB-equivalent Approval

For each of the countries/sites listed above, is there an ethics committee or other IRB equivalent that requires review of research? Please review the OHRP list of international human research standards https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html to inform your response.

Ensure you have reviewed the information provided at the link. If there is any suggestion that the country requires some type of oversight, you will be required to provide it or documentation from an official source that it is not needed.

15.7) Privacy Laws

For more information review https://www.vpaa.uillinois.edu/cms/one.aspx?portalId=420456&pageId=1050462

15.7.1) Will participants be physically located in the European Economic Area (European Union, Iceland, Liechtenstein, & Norway) and/or the United Kingdom?

- ◉ Yes

  If yes, you must complete the GDPR Research Tool found at https://flowsmart.research.illinois.edu/GDPR and attach your report. Attach the file in the Documents Section under “Other Documents”.

- ○ No

15.7.2) Will participants be physically located in Mainland China?

- ◉ Yes

  If yes, you must complete the PIPL Research Tool found at https://flowsmart.research.illinois.edu/pipl and attach your report. Attach the file in the Documents Section under “Other Documents”.

- ○ No

15.8) Local Knowledge

Describe the research team’s knowledge of the local culture and community.

This question is blank.

15.9) Location Justification

Describe why the particular location(s) has been selected to conduct the research.

This question is blank.

15.10) Potential Risks

Describe whether the culture, economic, or political conditions of the country or countries would alter the risk for participants compared to the same research conducted within the U.S.

This question is blank.

15.11) Communication Considerations

Describe any special considerations for communicating with participants during the course of the study (e.g. access to a local researcher/coordinator, access to telephone or other methods of communication, etc.).

This question is blank.

15.12) Consent Considerations

Describe any special cultural considerations for obtaining informed consent (e.g. community consent, presence of elders, etc.).

This question is blank.

Letters of Support or Approval(s) – Attach letters of support or approval for this study from relevant officials or collaborators at these sites. Attach the file in the Documents Section under "Other Documents".

Section 16: Databases and Repositories

16.1) Select the items that will be banked:

- [x] Data
- [ ] Audio/Video recordings or Images
- [ ] Biological Samples

16.2) What type(s) of future research will be allowed on the data/samples?

This may be related to the original purpose of the project or specific conditions and depends on what participants agreed to as part of the consent.

16.3) Who manages the repository and where will the data/samples be stored?

If this is a national or federal repository, state the name of it if known. Often, researchers are unsure of the specific database that they will need to submit their data to because it might depend on the journal or publisher, it is acceptable to state that you will submit it to whomever is required as part of the publication. Many funding agencies have specific requirements that are known in advance. If the repository is owned/managed by a specific researcher, specific institution, or specific company, the name and specific location are required.

16.4) Indicate whether the data/samples in the repository will be identifiable directly or through a code/link.
Identifiable means that the participant can be identified by the repository using information kept with or linked to the data/sample. The local PI and study team may not be managing the repository associated with this study; for example, the PI may send data/samples to the sponsor and the sponsor manages the repository. Answer these questions from the perspective of those who manage the repository.

- [x] OPTION 1: All data/samples will be identifiable to one or more individuals who have responsibilities to manage or oversee the repository.
- [x] OPTION 2: Some data/samples will be identifiable and some data/samples will be de-identified to one or more individuals who have responsibilities to manage or oversee the repository.
- [x] OPTION 3: All data/samples will de-identified to all individuals who have responsibilities to manage or oversee the repository. No link or code will be accessible to or maintained by the repository.

16.5) Information on Managing Identifiable Data

16.5.1) Who will manage and have access to the identifiable data?

This question is blank.

16.5.2) Where will the data be kept?

This question is blank.

16.5.3) How will the data be kept confidential?

This question is blank.

16.6) Information on De-identifying data/samples

16.6.1) Describe the process for de-identifying the data/samples:

This question is blank.

16.6.2) Who will de-identify the data/samples?

This question is blank.

16.6.3) When will the data/samples be de-identified?

This question is blank.

16.7) Describe the procedures for participants to withdraw their data/samples from the repository.

If participants will not be able to withdraw their samples, please provide an explanation:

If data is fully de-identified, it is usually not possible for participants to withdraw their data. However, if the PI is maintaining a link or key to the data, it would be possible for participants to request withdrawal of their data in the future and this process must be explained here and in the consent document.

16.8) Will future results or findings be communicated to the participants?

- ◉ Yes

  Please describe the process for providing these results to participants:

  This is meant to describe future individual results for that participant, not general results of the research. If a study does not include a genetic component, future results or findings are generally not communicated.

- ○ No

16.9) Describe the procedures for other researchers to obtain data/samples from the repository for use in future research.

Note: Future research projects using repositories may require IRB approval before data/samples are used.

Who can request to use the data for future studies and how do they do it?

Section 17: Biological Materials

17.1) Describe each material that will collected, analyzed, or banked for this protocol. Include the amount collected (e.g. mL of blood) and/or the frequency of collection (e.g. 2x per week for 4 weeks).

This question is blank.

17.2) Describe how samples are being obtained.

This question is blank.

17.3) Are blood samples being collected for this research?

- ○ Yes
- ○ No

17.4) Is this project registered with the Institutional Biosafety Committee (IBC)?
https://www.drs.illinois.edu/

○ Yes

○ No

17.5) Please list all IBC registration numbers.

This question is blank.

Section 18: Radiation

A "Physician Approval of Radiation Use Form" is required to be signed by a physician. Attach the signed form in Section 23: Documents in the "Other Documents" area. Obtain form here: https://oprs.research.illinois.edu/forms/physician-approval-radiation-use

State radiation safety regulations require that all radiation administered to humans must be "authorized by a licensed practitioner of the healing arts." This includes research as well as medical care.

Section 19: Genetic Research

19.1) Describe the risks to participants in regards to genetic testing, including applicable risks to privacy and confidentiality, as well as psychological and social risks.

If you have already specifically addressed these risks in the application, please note this.

This should include the risks specific to the genetic testing, not the general risks of the research. If you have already included the specific risks of the genetic testing in 10.1, you can state that.

19.2) Describe the privacy protections in place for participants in regard to genetic testing. This includes how family member privacy will be protected.

If you have already specifically addressed these protections in the application, please note this.

This question is blank.

19.3) Are you performing whole genome or whole exome sequencing?

○ Yes

○ No

19.4) Describe the confidentiality protections in place for participants' genetic information. Discuss if and how data will be shared and protected outside the local study team.

If you have already specifically addressed these protections in the application, please note this.

This question is blank.

19.5) Will genetic information or samples be submitted to a national or international database because of this research?

For example, any NIH-funded study that involves genomic data asks investigators to submit to a genomic database, such as dbGaP, as a requirement of the funding.

○ Yes

○ No

19.6) Will incidental findings relevant to individuals or families be communicated to the participants?

- ○ Yes
- ○ No

Section 20: Drugs, Supplements, etc

20.1) Please list the product(s) involved

Name of product
Vitamin D

Please briefly explain the product's use and purpose in the study.
How is the product being used and why is it being used in the study.

Is the intent of the product to affect the structure or function of the human body?
Yes

Are you studying the effectiveness of the product in humans?
Yes

Are you studying the outcomes on a person's health after using the product?
Yes

Are you comparing the product to another product?
Yes

Are you requesting IRB to issue an IND Exemption?
Yes

Describe the plan to control, store, and dispense the investigational product. This plan should ensure that the product is only used by qualified investigator(s) for the participants enrolled in this research project.
How will you make sure that only the researcher has access to the drug product? If it requires specific storage conditions, how will you ensure that occurs?

List the location of the product supply
Provide specific location

Emergency Drug Product Information (include name and phone number)
This should be the person that should be contacted if a participant is having an emergency related to the drug product and more information about the drug product is needed.

Section 21: Devices

21.1) List every device, algorithm, or mobile application where this project is studying the safety, effectiveness, or outcomes of the device, algorithm, or mobile application:

Name of device
Sample Device

Please describe the device, algorithm, or mobile application that is being used:
Explain the device, algorithm, or mobile application that is being studied in this project to determine its safety, effectiveness, or outcomes based on its use. The IRB will utilize this information to determine if further information is required.

Attach supporting information, if applicable
[]

Is this device generally considered to be a medical device? (e.g. MRI, pulse oximeter, wheelchair)
Yes

Please select if each item below applies to the device, algorithm, mobile application as it is used in this study:
Intended for use in diagnosing a disease or condition

What is the initial risk determination of the device study according to the investigator and/or sponsor?
As used in this study, the device is a non-significant riskdevice.

Confirm each of the following criteria to verify the definition of a non-significant risk (NSR) device:
The medical device is NOT intended as an implant that presents a potential for serious risk to the health safety, or welfare of a subject, The medical device is NOT purported or represented to be for use in supporting or sustaining human life that presents a potential for serious risk to the health, safety, or welfare of a subject, The medical device is NOT for a use of substantial important in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health that presents a potential for serious risk to the health, safety, or welfare of a subject., The medical device does NOT otherwise present a potential for serious risk to the health, safety, or welfare of a subject., The medical device is not banned.

Provide justification of why the medical device being investigated in this study meets the definition of an NSR device.
Justify why this product is a non-significant risk device.

Describe the plan to control, store, and dispense the investigational device. This plan should ensure that the device is only used by qualified investigator(s) for the participants enrolled in this research project.
How will you make sure that only the researchers have access to the device, algorithm, or mobile application.

Section 22: HIPAA

22.1) What UIUC department is conducting the research?
This question is blank.

22.2) Is that department part of the Covered Entity?

To check if your department is within the Covered Entity, check for “covered components” here: https://www.uillinois.edu/hipaa.

○ Yes

○ No

22.3) Where will the data be stored?

This question is blank.

22.4) Select the method(s) of authorization that will be used.

☐ (Consent and) Authorization Document

☐ Waiver of Authorization

☐ Limited Data Set

☐ De-identified

22.10) Will PHI (identifiable or de-identified) be disclosed outside the Covered Entity?

○ Yes

○ No

Section 23: Documents

23.1) Consent Documents

This question has no entries.

23.2) Recruitment Materials & Advertisements

This question has no entries.

23.3) Surveys, Questionnaires, etc.

This question has no entries.

23.4) Grant Application/Documents

This question has no entries.

23.5) Investigator’s Brochure, Package Insert, Instructions for Use

This question has no entries.

23.6) Literature Review/Cited References

This question has no entries.

23.7) Other Documents

This question has no entries.