**HRP-503-NON-EXEMPT STUDY PROTOCOL**

**Expedited and Convened Board Research Protocol Template Instructions**:

This template is designed for investigator-initiated research studies written and designed by a Purdue University investigator.

All sections must be addressed. Respond to all applicable instruction prompts. For those that do not apply, type “N/A.” Once complete, upload the documents on the protocol page of the application SmartForm.

Text in **BLACK** font and the gold instruction boxes must remain on the page and unchanged.

Delete instructions/examples in **RED** font and replace with applicable study-specific language using black font.

Complete the template and any appendices\*\* (located in the PERA library after October 27th) relevant to your research design (e.g., waivers, special populations including children, devices, drugs).

|  |  |
| --- | --- |
| **Research includes:** | **Complete Document:** |
| Adults with Impaired Decision-Making Capability | Appendix A |
| Children | Appendix B |
| Deception | Appendix C |
| Devices | Appendix D |
| Drugs, Biologics, Dietary Supplements, Foods | Appendix E |
| Genetic Testing | Appendix F |
| Multiple Research Sites | Appendix G |
| Non-English Speaking Individuals | Appendix H |
| Pregnant Women and Fetuses | Appendix I |
| Prisoners | Appendix J |
| Radiation | Appendix K |
| Repositories | Appendix L |
| Waiver of Documentation of Consent/Parental Permission | Appendix M |
| Waiver of Parental Permission Process | Appendix N |
| Waiver or Alteration of Informed Consent Process | Appendix O |

\*\*Appendices are currently still under development and will be released as they are completed. Please check the [PERA Go-Live Page](https://pera.research.purdue.edu/pera-irb-go-live-information/) for updates and to download these documents. Consent templates and all other guidance may still be found on the [Purdue IRB website](https://www.irb.purdue.edu/)

**Study Title** (Insert title here)

|  |  |
| --- | --- |
| **Principal Investigator/Faculty Advisor** | Name: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Telephone Number: Click or tap here to enter text. |
| Email Address: Click or tap here to enter text. |
| **Student Investigator (if applicable)** | Name: Click or tap here to enter text. |
| Current Academic Status: Click or tap here to enter text. |
| Department: Click or tap here to enter text. |
| Telephone Number: Click or tap here to enter text. |
| Institutional Email Address: Click or tap here to enter text. |

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# **Abbreviations and Definitions** (enter N/A if not needed)

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# **Background and Rationale**

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| --- |
| **2.1** Summarize and synthesize the available research, including published data, to provide justification for the study. |

Click or tap here to enter text.

**Consider the following:**

* Evaluate prior research for relevance to the research question under study.
* When the proposed research is the first of its type to involve human participants, the results of relevant animal studies may be included.
* Discuss the anticipated results and potential pitfalls.
* Describe the significance of the research including potential benefits for individual participants or society at large.
* Discuss how public health and social welfare might be enhanced when applicable.
* If the research involves drugs or medical devices, describe the proposed rationale for choice of the agent(s) in the research (compared to other drugs that could have been used).

# **Objectives**

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| **3.1** Describe the purpose of the study.  |

Click or tap here to enter text.

* Clearly and succinctly state the purpose of the study (e.g., research questions and/or study objectives).
* In experimental designs, objectives may be stated as hypotheses to be tested.

**Primary Objectives and Outcome Measures**

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| **3.2** Describe the study objectives and outcomes.  |

Click or tap here to enter text.

**Examples:**

* Objectives: To determine the efficacy of [cognitive therapy X] when administered in participants with [condition Z].
* Outcomes: percent change from baseline to Week 12 in response to commonly used scales to measure depression and anxiety, etc.

**Secondary Objectives and Outcome Measures**

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| **3.3** Describe any secondary objectives and outcomes if applicable.  |

Click or tap here to enter text.

**Examples:**

* Measurable increase in test scores
* Increase in GPA from previous year
* Decrease in misbehavior as reported by the teacher
* Decrease in missing assignments
* Safety
* Pharmacokinetics
* Pharmacodynamics
* Preliminary clinical responses

# **Study Design & Procedures**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Y | N | Comments |
| * 1. Is this a multi-site study?
 |[ ] [ ]  If yes, complete the Multi-Site Research appendix.  |
| * 1. Does the research involve the use of an approved drug or biologic, use of an unapproved drug or biologic, or use a food or dietary supplement intended to diagnose, cure, treat, or mitigate a disease or condition?
 | ​​​ [ ]  | ​​​ [ ]  | If yes, complete the Drugs Appendix |
| * 1. Does the research involve the use of a device to evaluate its safety or effectiveness?
 |[ ] [ ]  If yes, complete the Device Appendix |

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| **4.4** Provide information about all research interventions and activities that are to be performed. |

Click or tap here to enter text.

**Research Design**

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| **4.5** Identify the research design appropriate to answer the question(s) under study.* Describe the type of research proposed (e.g. experimental, correlational, survey, qualitative).
* Describe the specific study design that will be used (e.g. pre-test /post-test control group design, cross-sectional design; prospective longitudinal cohort design, phase III double-blind randomized control group design).
* Describe the study intervention (e.g., procedure, therapy, curriculum) and/or investigational agent (e.g., drug, device, procedure, therapy) that is being evaluated
 |

Click or tap here to enter text.

 **Detailed Study Procedures**

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| **4.6** Describe the selected procedures sufficiently to justify their use in answering the defined research question(s). |

Click or tap here to enter text.

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| * 1. Describe procedures for data collection. Be sure to specify the source records that will be used to collect data about participants.

Upload all surveys, scripts, and data collection forms/spreadsheets to the Other Attachments section of the SmartForm. |

Click or tap here to enter text.

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| * 1. Describe the timeline for participant evaluations and the duration of project participation, for both individual study activities and total study participation, when applicable. List or provide a visual schedule (table, flowchart) of study activities (e.g., visits, contacts/touchpoints with participants, screening procedures, randomization/stratification procedures, etc.).

 **Include:** * Only those procedures that contribute to participant eligibility, study objectives and endpoints.
* The expected window of time for each activity (e.g., day 4 +/- 2 days, weeks 2-5, Month 1, 1st trimester, post-activity 1 month), as applicable to the study.
 |

Click or tap here to enter text.

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| **4.9** Describe plans for long-term follow-up once all research-related procedures are complete, if any, and specify what data will be collected during this period.  |

Click or tap here to enter text.

**Alternatives to Participation**

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| **4.10** Indicate any alternatives to participating in the research, if applicable, including available procedures outside the research that may be advantageous to the participant. |

Click or tap here to enter text.

# **Participant Population**

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| * 1. Specify the participant population(s). Check all participant groups that apply. For any population other than adults, complete the applicable appendix referenced on Page 1.
 |
| [ ]  Adults[ ]  Adults with impaired decision-making capacity[ ]  Children[ ]  Economically or educationally disadvantaged[ ]  Immigrants[ ]  Non-English-speaking individuals[ ]  Pregnant women/fetuses (only if pregnant women will be intentionally recruited and/or studied)[ ]  Prisoners[ ]  University Students[ ]  Employees |

|  |
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| **5.2** Describe the sample population from which the study team plans to either recruit or access private, identifiable information for the research. If student subject pools are involved, please specify the applicable pool. |

Click or tap here to enter text.

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| **5.3** Create a numbered list of the inclusion/eligibility criteria that define who will be included in the final study sample (e.g., age, gender, condition). These are the characteristics that every potential participant must satisfy to qualify for the study.  |

Click or tap here to enter text.

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| **5.4** Describe why certain populations may be excluded/ineligible for study participation. These are factors that would cause harm or increased risk to the participant, or that preclude the participant’s full adherence with or completion of the study. Exclusion criteria should be appropriate for the study design and level of risk to participants. * Provide a statement that all individuals meeting any of the exclusion criteria will be excluded from study participation and then list each criterion.
* Provide a justification if specific populations will be excluded from the study to establish that inclusion is inappropriate with respect to the health/safety of the participants or for the purpose of the research.
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Click or tap here to enter text.

**Number of Participants**

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| 5.5 The number of participants is defined as the number of individuals who agree to participate (i.e., those who provide consent or whose records are accessed) even if all do not prove eligible or complete the study. The total number of research participants may be increased only with prior IRB approval. |
| Indicate the number of participants to be enrolled locally by Purdue researchers. | Click or tap here to enter text. |
| For multi-site studies, indicate the total number of participants to be enrolled across all sites. | Click or tap here to enter text. |

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| **5.6** Explain how this number was derived (e.g., meets statistical power, limited population). If applicable, explain how many individuals are expected to agree to participate and how many evaluable participants are needed to conduct the study (excluding screen failures). |

Click or tap here to enter text.

**Participant Identification**

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| **5.7** Describe how potential participants will be identified (e.g., advertising, individuals known to the investigators, record review).  |

Click or tap here to enter text.

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| **5.8** Explain how the investigator(s) will gain access to this population, as applicable, and provide evidence that you will be able to recruit the necessary number of participants to complete the study. |

Click or tap here to enter text.

**Participant Recruitment and Selection**

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| **5.9** Describe how potential participants will be screened or otherwise determined to be eligible. |

Click or tap here to enter text.

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| **5.10** Describe how, when, and who will recruit participants for the study. Identify general strategies for participant recruitment and retention (e.g. use of research participant pools, patient advocacy groups, online recruitment services, community advisors, newspaper, local flyers) and indicate where recruitment will occur. Include rationale for why the strategy will be appropriate for reaching the targeted study population |

Click or tap here to enter text.

**NOTE:** The final versions of recruitment materials require IRB approval prior to use. Upload the materials to the documents page of the application SmartForm.

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| **5.11** Explain how the recruitment process respects potential participants' privacy. * Using a query to identify potentially eligible individuals prior to accessing identifiable information directly.
* Accessing educational records in a private setting.
* Limiting the number of study team members accessing identifiable information.
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Click or tap here to enter text.

# **Cost to Participants and Incentives to Participate**

**Potential Costs/Reimbursements**

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| **6.1** Describe any potential costs participants will incur as a result of study participation (e.g., parking). Indicate here which costs, if any, will be reimbursed or covered by the study.  |

Click or tap here to enter text.

**Incentives**

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| **6.2** Describe any compensation or other incentives (e.g., cash payments, gift cards, classroom extra credit) that will be offered to potential participants. Include the amount and timing of all incentives or compensation, the form of compensation (e.g., cash, check, gift card), and how the compensation will be received (e.g., mailed, in person, online). This information must also be included in the consent form. |

Click or tap here to enter text.

**NOTE:** Reimbursements are not considered incentives.

**Compensation for Research-Related Injury**

**6.3** If the research involves **greater than minimal risk to participants**, describe the available compensation in the event of research related injury or explain why no compensation is available.

​​Click or tap here to enter text.​

# **7. Informed Consent/Assent Process**

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| 7.1 Specify the consent process(es) to be used for the study. Check all processes that apply. For any waivers or alterations, complete the applicable appendix.  |
| [ ]  Informed Consent with Written Signature (e.g., on paper)[ ]  Informed Consent with Electronic Signature Note: If the method used to obtain electronic signatures does not qualify as a legally valid signature, also check “Waiver of Consent Documentation.” [ ]  Waiver of Consent/Parental Permission Documentation [ ] Deception (i.e., procedure in which investigators deliberately mislead participants during research by withholding information or providing false information).Note: If this is selected, also check “Waiver or Alteration of the Consent Process.”[ ]  Waiver or Alteration of the Consent Process [ ]  Waiver of the Parental Permission Process |

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| **7.2** Describe the consent process. Explain when and where consent will be obtained and how participants or their legally authorized representatives will be provided sufficient opportunity to consider participation. Indicate who on the study team will conduct the consent process.  |

Click or tap here to enter text.

**NOTE:**

* If any additional tools (e.g., quizzes, visual aids, information sheets) be used during the consent process to assist participant comprehension, upload the materials to the Local Site Documents page of the application SmartForm.
* If any other consent forms will be used (i.e., consent forms from other institutions), upload the materials to the Local Site Documents page of the application SmartForm.

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| **7.3** Specify who will provide consent or permission (i.e., participant, legally authorized representative, parent and/or guardian) and how consent will be documented. If you are not collecting signatures, provide justification for a waiver of documenting consent.  |

Click or tap here to enter text.

**NOTE:** If legally authorized representatives will provide consent for adults with impaired decision-making capacity, mark the appropriate box in section 5.1 above.

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| **7.4** Explain how the possibility of coercion or undue influence will be minimized in the consent process. |

Click or tap here to enter text.

# **8. Privacy of Participants**

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| **8.1** Describe the steps that will be taken to protect participants’ privacy and make them feel at ease with the research situation in terms of the questions being asked and the procedures being performed. |

Click or tap here to enter text.

**NOTE:** Privacy refers to a person’s desire to place limits on with whom they interact or whom they provide personal information. Privacy is about the person and protection of their information leading up to and during the act of data collection, as opposed to confidentiality which is about the management/protection of data after it is collected.

**Consider:**

* Conducting an interview in a private place where others cannot hear what is said.
* Limiting the number of study personnel who access private information about a participant.

# **9. Confidentiality and Management of Data**

|  |  |  |  |
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|  | Y | N | Comments |
| 9.1 Does the research involve obtaining and storing participants’ data for future, unspecified, research? |[ ] [ ]   |

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| **9.2** Describe the steps that will be taken to secure study data. If research data/samples will be coded, describing how access to the “key” for the code will be limited. Include description of security measures (password-protected database, locked drawer, other) applied to protect the code key. List the positions of persons with access to the code key. |

Click or tap here to enter text.

**Consider:**

* Training
* Authorization of access
* Password protection, encryption
* Certificates of confidentiality
* Separation of identifiers and data during storage, use, and/or transmission.

**NOTE:** Methods for handling and storing data (including the use of personal computers and portable storage devices) must comply with university policies. Restricted data, including protected health information and Sensitive data, including research health information, must be encrypted if stored or used on portable devices, if removed from a secure university location, or if electronically transmitted. For more information, see the [**Secure Purdue Data Classification and Handling Procedures**.](https://www.purdue.edu/securepurdue/data-handling/index.php)

|  |
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| **9.3** Describe any procedures that will be used for quality control of collected data. |

Click or tap here to enter text.

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| **9.4** Describe how data will be handled study wide. |

Click or tap here to enter text.

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| **9.5** Specify the identifiable information that will be included in the data. |

Click or tap here to enter text.

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| **9.6** Specify where and how data will be stored and for how long. |

Click or tap here to enter text.

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| **9.7** Specify who will have access to the data. |

Click or tap here to enter text.

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| **9.8** Specify who will be responsible for receipt or transmission/transport of the data and how transmission/transport will occur. |

Click or tap here to enter text.

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| **9.9** Indicate what will happen to identifiable data at the end of the study (e.g., kept identifiable, coded, deidentified). If identifiers will be maintained, provide the rationale supporting this request. If the data will be deidentified, describe the process. |

Click or tap here to enter text.

**NOTE:** In general, research data should be deidentified at the end of a project unless there is a compelling reason to maintain linked identifiers.

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| **9.10** If data will be shared broadly with outside groups, specify what will be shared, with whom, in what form (e.g., identifiable, coded, deidentified/anonymized). |

Click or tap here to enter text.

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| **9.11** If data will be shared broadly with outside groups or databases, specify whether participants will have the ability to opt-in or remove the data from these outside groups later if they choose. Generally, if the data are identifiable, a participant should be able to withdraw them unless retention is required under federal regulation. |

Click or tap here to enter text.

**NOTE:** Research-related records should be retained for a period of at least three years after the research has been discontinued and study closed (i.e., no further data collection, long term follow-up, re-contact, or analysis of identifiable/coded data.). HIPAA research authorization forms must be retained for six years after study closure.

**9.12** Certificate of Confidentiality ( *type n/a if not applicable)*

Click or tap here to enter text.

**NOTE:** NIH automatically provides [Certificates of Confidentiality (CoC)](https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc) to NIH-funded research studies involving identifiable, sensitive information. Remember to insert the ***standard CoC language*** into the study’s consent document.

If your study is not NIH-funded, indicate whether you will be requesting a CoC from the NIH or other authorized federal agency. If so, include a copy on the documents page of the SmartForm.

# **10. HIPAA Research Authorization**

PHI is health information that is individually identifiable and created or held by a covered entity. Health information is considered individually identifiable when it contains one or **more** [***HIPAA Identifiers***](https://www.purdue.edu/legalcounsel/HIPAA/)or when there is a reasonable basis to believe the information can be used to identify an individual.

For more information, see [***The HIPAA Privacy Rule***](https://go.osu.edu/hipaa45cfr160and164)***.***

|  |
| --- |
| 10.1 Is individually identifiable Protected Health Information (PHI) subject to the HIPAA Privacy Rule requirements to be accessed, used, or disclosed in the study?  |
| [ ]  No[ ]  Yes |
| NOTE: The PHI obtained as part of this research must not be reused or disclosed to any other person or entity other than those with IRB approval, except as required by law or for authorized oversight of the research project, without additional approval. IRB approval must be obtained for other research involving the use or disclosure of this PHI. |

|  |
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| **10.2** If PHI is accessed, used, or disclosed, specify how authorization requirements will be met (**check all that apply**). For any waivers or alterations, complete the applicable appendix. |
| [ ]  Written Authorization[ ]  Partial Waiver (for identification and recruitment purposes only)[ ]  Full Waiver (authorization will not be obtained)[ ]  Alteration (written authorization will not be obtained or all required elements will not be included) |
| **NOTE:** Purdue University will not waive HIPAA Authorization for third parties. If you are receiving PHI from another covered entity (not Purdue), then you will need to obtain a full or partial waiver of authorization from them. |

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| **10.3** Explain how the requested PHI (i.e., HIPAA identifiers and associated health information) are the minimum necessary information to accomplish the research objectives. |

Click or tap here to enter text.

# **11. Reasonably Anticipated Benefits**

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| **11.1** List the potential benefits that participants may expect as a result of this research study. If there are no direct benefits to individual participants, indicate so. |

Click or tap here to enter text.

**NOTE:** Compensation, reimbursements, or other research related incentives provided by the study team are not to be considered research benefits.

**Potential Societal Benefits:**

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| **11.2** List the potential benefits that society and/or others may expect as a result of this study. |

Click or tap here to enter text.

# **12. Risks, Harms, & Discomforts**

**Potential Risks, Harms, and/or Discomforts**

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| **12.1** Describe all reasonably expected risks, harms, and/or discomforts that may apply to the research. At a minimum, include the risk of breach of data confidentiality. **Discuss severity and likelihood of occurrence.** As applicable, include potential risks to an embryo or fetus if a woman is or may become pregnant. Consider the range of risks, including physical, psychological, social, legal, economic, and any other potential risk to the study population. Address both immediate and long-term risks.  |

Click or tap here to enter text.

**NOTE:** Risks related to clinical or other activities that may coincide with the study procedures but would be borne by the participants regardless of joining the study, do not have to be addressed in this section.

**Risk Mitigation**

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| **12.2** Describe how risks, harms, and/or discomforts will be minimized. Address all risks described in the section above.  |

Click or tap here to enter text.

**Risk/Benefit Ratio Assessment**

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| **12.3** Include an assessment of known risks and potential benefits, addressing each of the following:* Rationale for the necessity of exposing participants to risks
* A summary of the ways that risks to participants are minimized in the study design
* Justification as to why the value of the information to be gained outweighs the risks of participation in the study
 |

Click or tap here to enter text.

# **13. Data Analysis**

**Internal/External Validity**

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| **13.1** Describe measures that have been taken to avoid study bias (consider the threats to internal/external validity). |

Click or tap here to enter text.

**Data Analysis Techniques**

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| **13.2** Specify the analytic techniques the researcher will use to answer the study questions. Indicate the statistical procedures (e.g. specific descriptive or inferential tests) that will be used and why the procedures are appropriate. **NOTE:** The IRB does not need the actual formulas to be used, just a description of them. If applicable, specify the proposed analytic approaches for qualitative data. |

Click or tap here to enter text.

# **14. Data Safety and Monitoring**

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| --- | --- | --- | --- |
| **14.1** Does the research involve greater than minimal risk (i.e., the harms or discomforts described are beyond those ordinarily encountered in daily life or during the performance of routine physical or psychological tests)? | **Y** | **N** | **Comments** |
| ​​☐​  | ​​☐​  | If yes, describe a data and safety monitoring plan below.  |

|  |
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| **14.2** Describe the plan to oversee and monitor data collected to ensure participant safety and data integrity. If the plan is outlined in a separate document, upload it to the documents page of the application SmartForm. If not, describe it below and include the following: * The information that will be evaluated (e.g., incidence and severity of actual harm compared to that expected)
* Who will perform the monitoring (e.g., investigator, sponsor, or independent monitoring committee/board)
* Timing of monitoring (e.g., at specific points in time, after a specific number of participants have been enrolled/treated) and
* Decisions to be made as a result of the monitoring process (e.g., provisions to stop the study early for unanticipated problems)
 |

​​Click or tap here to enter text.​

# **15. Bibliography**

Click or tap here to enter text.