# Non-Exempt IRB Protocol

**For Non-Exempt (Expedited or Full Board review) research**

**Please complete this application thoroughly. Give as much detail as possible. If a question is not applicable to your study, please indicate this by responding “N/A”.**

Additional information and templates are available at [Office of Research Integrity and Compliance](http://www.cmu.edu/research-compliance/human-subjects-research/)

\*Note that incomplete applications will result in delays.

**Protocol Number: (must match the study number provided by SPARCS - e.g., STUDY2023-00000999)**

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**Study Title: (must match title in SPARCS form)**

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**Principal Investigator (PI) Name:**

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| 1. Study Scope |

1. **What is the purpose of the study (what is your research question/hypothesis) and how will the data collected be used to provide evidence for your hypothesis?**

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1. **For each activity and subject population, clearly and completely describe the research procedures that will be conducted. In the SPARCS system, upload any questionnaires, surveys, tools, device manuals, pictures, links to videos, Manual of Procedures, test protocols, etc. that will be used to collect data or to direct the conduct of the study. Anything that will be seen by the subjects of the research or used to conduct the research must be submitted to the IRB for approval.**

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1. **For each activity and subject population, indicate the location(s) where the research will be conducted. Specify whether the subject will be engaged in person, remotely via the internet, etc.:**

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1. **For each activity and subject population, describe the time required of the subject (time for each study visit AND overall time commitment for the study):**

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1. **Will questionnaires or surveys be used?**

**If yes, please upload all surveys or questionnaires to the Local Site Documents section of the SPARCS application.**

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| 2. Participation Information |

1. **What is the age range of subjects in the proposed study?**

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1. **How many subjects/records/specimens are needed for the study? Cannot be “unlimited”.**

**Please note that you are not permitted to enroll more subjects or use more specimens/records without prior IRB approval of a modification to increase enrollment. Each subject, record, or specimen used is considered an “enrollment”. If it is anticipated that any subjects will be enrolled, but will not complete the study for any reason, please include this estimation in your requested enrollment number. These subjects are considered to be enrolled, but withdrawn. For example, if you require 100 subjects to complete the study, but anticipate that approximately 20 subjects will not complete for any reason, you should request enrollment of 120 subjects total.** **Enrollment or use of specimens/records above and beyond this number approved by the IRB is a protocol violation that constitutes Non-compliance.**

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1. **How was the requested enrollment number determined? Provide power analysis or other justification for the number requested.**

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1. **Please list all inclusion and exclusion criteria for your selection of eligible subjects** **(include any age ranges, locations, abilities, experiences, or other qualifications that either include or exclude subjects from participating):**

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| Inclusion Criteria:*

Exclusion Criteria:*
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1. **What do you estimate the ratio of males to females to be?**

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1. **Will any of the following vulnerable populations of subjects be involved in the proposed study? Select an answer for each population below. Please note that additional protections for any vulnerable populations will be required.**

**Pregnant women or human fetuses**

**Neonates**

**Prisoners**

**Children**

**Cognitively Impaired Adults**

**Students or Employees**

1. **Will the subjects be capable of understanding the nature of the study and the consent process?**

**If not, please explain:**

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1. **Will you target your research to enroll any specific demographics of the population, (e.g., race, ethnicity, sexual orientation, gender identity, religious group, etc.)?**

**Please explain:**

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1. **Do you anticipate that your subjects will demonstrate an accurate representation of the population in the region where the study is being conducted?**

**If yes, please describe and estimate the percentage that will be from minority groups:**

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**If no, please describe your study population and address why minority representation is not considered:**

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1. **Will subjects located outside of the United States be enrolled?**
2. **If yes, will specific countries be targeted for enrollment?**

**Please note that targeting subjects in other countries or cultures may require IRB/ethics committee/local government review within each country. Please see the** [**OHRP Compilation of International Research Standards**](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) **to determine whether local IRB/ethics/governmental approval is required for each country targeted. If no review is required according to local laws, a Local Cultural Context Review completed by an impartial third party may be required by CMU IRB for each country/ethnic group targeted. Additional local laws and regulations may also need to be followed (e.g. GDPR Privacy laws for subjects in European Union countries and the United Kingdom).**

**If specific countries will be targeted for enrollment, please describe how you will ensure that the research will not violate the laws, cultural norms and values of the subjects or put the subjects at risk not normally encountered by US subjects.**

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**If enrollment in specific countries is targeted, please provide information below:**

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| **Name of Non-US Country(ies) in which subjects will be enrolled** | **Number of subjects to be enrolled in this Non-US Country** |
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| 3. Recruitment |

1. **Describe how subject recruitment will be performed:**

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1. **Indicate how and by whom potential subjects are introduced to the study. Include any processes for screening for eligibility and conducting the informed consent discussion:**

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1. **Check all forms of recruitment that will be used for this study and upload all documents or language to be used in the Recruitment section of SPARCS:**

[ ] **Flyers - State where will they be posted below.**

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[ ] **Radio or TV**

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[ ] **E-Mail - Indicate how the email addresses are obtained below:**

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[ ] **Web-based - NOTE: If you are recruiting on mTurk, Qualtrics, Prolific or another similar online system, the title**

**of the HIT/advertisement must include the SPARCS study number for identification of the study.**

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[ ] **Subject Pool - State which one below.**

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[ ] **Other - Describe below:**

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1. **Will subjects undergo screening for eligibility prior to their participation? If yes, please note that you must request a Waiver of Documentation of Consent for screening purposes by completing the appropriate section within this form.**

**If yes, please describe:**

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**Please upload all recruiting and screening materials in the Local Site Documents Section of the SPARCS application.**

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| 4. Consent |

1. **Do you plan to use consent forms? This includes any consenting language (written or verbal) provided to subjects prior to participation.**

[**Link to CMU Consent Form Templates**](https://www.cmu.edu/research-compliance/human-subjects-research/guidance-forms.html)

**If yes, describe the process of how consent will be obtained, and by whom. Please include that consent will be obtained prior to any research procedures or data use/collection.**

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**If yes, please upload your consent form(s) in SPARCS.**

1. **Will the consent form be presented on paper?**

1. **Will the consent form be presented online?**

1. **Will the consent be presented verbally to subjects via a script? If yes, please complete the Waiver of Documentation of Consent section below.**
2. **Are you requesting to use a consent form that is different from the CMU template consent?**

**If yes, please explain:**

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**Please upload into SPARCS any Informed Consent Forms or language, introductory scripts, or other documents that you will use to inform subjects (or parents, if subjects are minors) about the research.**

**Waiver or Alteration of Informed Consent/Assent**

**A Waiver of Informed Consent means that the requirement to obtain informed consent is waived in its entirety for an entire study or for a component of the research. If the waiver is granted, Informed Consent for all or part of the research will not be required.**

**Alteration of Informed Consent means that the subjects are purposefully consented with inaccurate or incomplete information (for studies involving deception or incomplete disclosure). This waiver alters the required elements of consent temporarily, but subjects must be provided complete and accurate information at the earliest possible time and be given the opportunity to withdraw their data after being given the complete information. Please upload this debriefing information that will be provided to subjects in the Informed Consent section of SPARCS.**

**Please note that certain requirements must be met and appropriate justification for the Waiver or Alteration must be provided. If requesting a Waiver or Alteration of Informed Consent, please complete the following:**

1. **Are you requesting a Waiver of Informed Consent or an Alteration of Informed Consent?**

* **If yes, please explain how each of the following apply to your request for a waiver or alteration:**
1. The research involves no more than minimal risk to the subjects:

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1. The waiver or alteration will not adversely affect the rights and welfare of the subjects:

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1. The research could not practicably be carried out without the waiver or alteration:

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1. If the research involves using identifiable private information or identifiable biospecimens, indicate how the research could not practicably be carried out without using such information:

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1. The subjects should be provided with additional pertinent information after participation and be given the opportunity to withdraw their data from the study. Describe how this debriefing will be accomplished. Please upload any debriefing information sheets, scripts, or other methods of notifying subjects in the Informed Consent section of SPARCS.

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* **Is the waiver or alteration intended for all study subjects?**

**If no, to whom does the waiver apply?**

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* **Is the waiver or alteration intended for all study procedures?**

**If no, to what procedures does the waiver apply?**

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**Waiver of Documentation of Consent/Assent**

**A Waiver of Documentation of Consent is used in certain cases when the study team provides a subject with the required consent information, but will not obtain the subject's signature (either written or electronic) on the informed consent document. This is often used when subjects will be completing eligibility screening procedures prior to signing consent or if procedures will occur remotely with no possibility of obtaining signed consent.**

**Please note that certain requirements must be met and appropriate justification for the Waiver must be provided. If requesting a Waiver of Documentation of Consent, please complete the following:**

1. **Are you requesting a Waiver of Documentation of Informed Consent?**

* **If yes, please indicate which one of the following applies:**

[ ]  The only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern.

[ ]  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 ***(Most common – used for eligibility screening prior to signing consent or online research procedures where signed consent cannot be obtained)***

[ ]  If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

* **Explain how the research activity meets the criteria you selected above:**

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* **Is the Waiver intended for all study subjects?**

**If no, to whom does the waiver apply?**

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* **Is the Waiver intended for all study procedures?**

**If no, to what procedures does the waiver apply?**

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**Minor Participation**

1. **Will this study involve minors (children) as subjects?**

**If yes, please provide the ages and describe how assent from the minors will be obtained:**

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**If yes, are minors at a developmentally appropriate age to assent? Generally, minors are considered able to provide assent using age-appropriate language at the age of 7 and older. Assent should be obtained in addition to parental/guardian consent. Please describe how you will determine that the minors are able to understand the assenting process and provide assent.**

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1. **Are you requesting a Waiver of Assent or a Waiver of Written Assent (similar to the rules for such Waivers of Informed Consent above)? If yes, please complete the appropriate Waiver section above.**

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| 5. Risks and Benefits |

**There must be sufficient benefit to conducting the research to outweigh any potential risks to participating subjects. Please be sure to list any potential direct or indirect benefits to subjects OR to the scientific community from the knowledge that will be gained by conducting the research and any potential risks to the subjects or others.**

1. **Will subjects receive a DIRECT BENEFIT from the study?** **Compensation for participation and experience with research-related technology or topics are not considered to be benefits. In many cases, subjects do not experience a direct benefit, but if they may, please list it here.**

**If yes, describe the expected direct benefits to subjects:**

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1. **Indicate the expected INDIRECT BENEFITS to subjects, future individuals or groups, OR to the scientific community from the knowledge that will be gained. Please note that the research MUST have sufficient benefits to outweigh any risks.**

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1. **Indicate all of the POTENTIAL RISKS to subjects. If any identifiable information from subjects will be accessed, used, recorded, or collected, please include a risk of Breach of Confidentiality:**

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1. **Indicate how each potential risk listed above will be managed and/or minimized:**

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1. **Indicate the level of possible risk you believe the research will pose to human subjects (e.g., physical, psychological, legal, social, reputational, financial, etc.). Please see the Risk Definitions in yellow below:**

[ ] **Minimal Risk** OR [ ] **Greater than minimal risk**

**Describe how the study fits in the selected risk level.**

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**Risk Level Definitions:**

**Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Greater than Minimal Risk:** A risk is greater than minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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| 6. Deception or Incomplete Disclosure |

* **Deception occurs when an investigator gives false information to subjects or intentionally**

**misleads them about some aspect of the research.**

* **Incomplete disclosure occurs when an investigator withholds information about the purpose, procedures, nature, or another aspect of the research.**
* **Deception or Incomplete Disclosure is only permissible in minimal risk studies.**
* **Researchers must be granted an Alteration of Consent to use Deception or Incomplete Disclosure in the study.**

**Investigators must explain why the deception or incomplete disclosure is necessary to achieve the study goals and how the degree of deception or incomplete disclosure is kept to a minimum. Subjects should be debriefed as early as is feasible and be given the opportunity to withdraw their data from the study once they learn the complete information.**

1. **Will deception or incomplete disclosure be used?**

**If no, proceed to the next section.**

**If yes, please explain the deception or incomplete disclosure:**

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**If yes, please include a justification as to why deception or incomplete disclosure is necessary to conduct the research:**

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1. **Describe how subjects will be debriefed (provided the accurate, complete information and given the opportunity to withdraw):**

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**Please upload the de-briefing material and/or script in the Local Site Documents section in the SPARCS application. Debriefing must include the option for the subject to withdraw their data after learning the true, complete information about the research.**

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| 7. Compensation |

1. **Are subjects to be compensated for their study participation in any way? Compensation includes cash, checks, gift cards, course credit, parking, food/snacks, physical gifts, or chances in random drawings.**

**If no, proceed to the next section.**

**If yes, what is the value of compensation:**

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**If yes, what is the type of compensation (e.g., gift card, cash):**If using a gift card, specify the retailer/type (e.g., Amazon, Visa, Target, etc.).

* **Please also indicate how the subjects will receive their compensation (e.g., email, mail, in person, online platform such as Prolific)**

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1. **Will subjects receive any non-monetary compensation (e.g., parking validation, snacks, chances in a random drawing)?**

**If yes, please describe:**

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1. **Are there any costs to subjects?** **Please include all potential costs related directly to their participation such as data charges for use of their phones, software licenses, membership fees, etc. These are costs that subjects only incur due to their participation in the research.**

**If yes, please describe:**

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1. **Will you compensate subjects for injury resulting from participation?**

**If yes, please describe:**

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1. **Will subjects who are students be offered class credit?**

**If yes, please describe:**

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| 8. Data Security and Confidentiality  |

1. **INITIAL identifiability state of research information – Select the type of information to be accessed/collected/obtained/used for this research.** **Please note that if you will ever have access to any information about subjects that can identify them (even if this information isn’t being analyzed as “data”), your research is identifiable.**

[ ]  **Anonymous** - no identifiable information will be available, accessed, collected, or obtained. No

 identifiable information will ever be available to the researchers.

[ ]  **Identifiable** - research involves access to ANY elements that allow for the identification of a subject (directly or indirectly), including name or email address used only for contact or payment purposes or coded data to which the researchers have access to the code enabling them to re-identify subjects (whether or not it is the intention to do so).

* Please note that if the research never involves any interaction with subjects, intervention with subjects, or access to any information that could be used to identify subjects (directly or indirectly), the research does not involve Human Subjects and does not require IRB approval.

**If identifiable, check each identifier accessed/collected/obtained/used:**

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| [ ]  **Name (including initials)** | [ ]  **Email address**  | [ ]  **Driver’s License number or any other government ID**  | [ ]  **Any other unique identifying number, code or characteristic (such as student identification numbers)**  |
| [ ]  **Street Address**  | [ ]  **URL address**  | [ ]  **Device identifiers and serial numbers**  | [ ]  **Medical Record numbers**  |
| [ ]  **Dates (Anything more than the year)**  | [ ]  **IP address**  | [ ]  **Vehicle identifiers and serial numbers**  | [ ]  **Health plan beneficiary numbers**  |
| [ ]  **Telephone/Fax number**  | [ ]  **Social Security Number**  | [ ]  **Biometric identifiers (e.g., fingerprints and voiceprints)**  | [ ]  **User ID (e.g., mTurk user ID)** |
| [ ]  **Social Media Handles** | [ ]  **Account number, credit or debit card number, in combination with any passcode that would give access to an individual’s financial account**  | [ ]  **Full face photo/video and other comparable images**  | [ ]  **Other** Click or tap here to enter text. |

1. **Describe the information being collected and/or used for the research. Provide a list of all data elements to be included in the research. You may provide a list here OR upload a spreadsheet or list of all data points into the SPARCS application in the Local Site Documents page.**

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1. **Will the research use existing data sets/recordings/specimens?**

**If yes, describe: 1) where the data/recordings/specimens originated, 2) whether they were collected with consent from the subjects, and 3) if they were collected under a different IRB protocol.**

* **Provide any related IRB protocol numbers below and upload any related informed consents in the Local Site Documents page in the SPARCS application.**
* **If data is being obtained from a non-CMU source, provide documentation that the data is permitted to be used for this research purpose (e.g., copy of consent used for the original research indicating permission to share data for future research use, permission letter from organization providing data, HIPAA Waiver from the Privacy Board of the HIPAA Covered Entity, etc.)**

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1. **Describe your procedure for coding your data (encoding), if applicable:**

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1. **Will AUDIO OR VIDEO RECORDINGS be made?**
* **Please note that recordings should not be made or stored on personal devices or software accounts. All recordings should be made on devices designated for research use only. Use of personal devices or non-CMU accounts increases the risk to subjects of a breach of confidentiality.**
* **When recording and whenever possible, ensure that you are in a private space to avoid capturing non-consenting bystanders.**
* **Because Pennsylvania and many other US states require the express consent of both parties to record audio, please describe below how you will document subjects’ consent to be audio recorded prior to starting the recording. This may be done via a signed informed consent form describing the recording.**

**If yes, please describe the recordings that will be made, the process, and who will have access to the recordings:**

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1. **Did you obtain a Certificate of Confidentiality (CoC) from NIH? Note that research funded by NIH is automatically provided a CoC by NIH. Principal Investigators of non-NIH funded research may request a CoC from NIH, if desired.**

1. **In addition to the individuals listed on the study personnel page, who will have access to research data (e.g. surveys, questionnaires, recordings, interview records, etc.)? Include a comprehensive list and indicate if information may be shared outside the research team and/or CMU (including with collaborators, vendors, sponsors, etc.). Include what data each party will have access to and how the data will be transmitted/shared with them.**

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1. **Describe how you will protect subject confidentiality and secure research records (e.g. password protected, encrypted, etc.). Include location of where the data will be stored. If the PI should leave the university indicate your plan for the storage of research information and who will be responsible for oversight.**

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1. **Describe your process for overseeing your study.   Include a description regarding monitoring of data (to ensure that study goals are met and adherence to the IRB-approved protocol is maintained). Examples: Review of lab notebooks, frequency of meetings to review data, who will be present at the meetings, how recruitment and retention will be monitored, etc.:**

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1. **Describe your process for ensuring that adverse events, unanticipated problems, and subject complaints are reported to the IRB Office in a timely manner. Please note, all reportable events are required to be reported to the IRB via a Reportable New Information (RNI) form in SPARCS within 3 days.**

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1. **Please describe the intended FINAL IDENTIFIABILITY STATE of all information collected/obtained/used/generated for this study (e.g., Will you initially be collecting identifiable information for this research, but during the course of the study you will de-identify it?). The FINAL state of data at the end of the study will be:**

[ ]  **De-identified** - ALL identifiable information will be completely and permanently removed with NO

 code or link to the original identifiers. Data and subjects will never be able to be re-identified.

[ ]  **Coded data** - all identifiable information will be completely removed from the data set, BUT a code or link will exist enabling the possibility of re-identification of subjects

[ ]  **Anonymous data** - ONLY select this option if the INITIAL state of the data listed above is anonymous. No

 identifiable information was collected or obtained. No identifiable data ever existed.

[ ]  **Identifiable** – the research will retain access to ANY element in the chart above that allows for the identification of a subject, including name or email address used only for contact or payment purposes

1. **Please check this box to confirm that all research data will be retained at CMU for a minimum of three (3) years past study completion as required by the Federal Regulations for Human Subject Research:** [ ]

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| 9. External Collaborators (not CMU-Affiliated) |

1. **Is this research to be done in collaboration with any institutions, individuals, or organizations that are not affiliated with CMU?**

**If no, STOP here.**

1. **List the collaborators involved in the study:**

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| **Names of collaborating individuals and their affiliated Institutions or Organizations (e.g., Jane Smith from Duke University)** | **Will the collaborator participate in any interaction or intervention with subjects?** | **Will the collaborator receive or have any access to identifiable data?** | **Will the collaborator consent subjects?** | **Is the Collaborator’s Institution the Prime awardee on a Federal grant funding this research?** |
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| **Click or tap here to enter text.** | Enter Yes or No | Enter Yes or No | Enter Yes or No | Enter Yes or No |
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1. **If any answer in the chart above is “Yes” for an external collaborator, that collaborator must either obtain their own, separate IRB approval from another IRB to cover their work for this research OR a Reliance Agreement must be signed between their affiliated IRB and the CMU IRB. To request a Reliance Agreement, email** **sIRB@andrew.cmu.edu****. Please note that Reliance Agreements must be approved and agreed to by both IRBs.**

**A Reliance Agreement with CMU serving as the IRB of Record for external collaborators will ONLY be used for non-Exempt, Federally-Funded research where a single IRB (sIRB) process is required by the Federal Regulations.**

1. **Is there or will there be IRB approval from another IRB for this study?**

**If yes, attach the IRB approval documents on the Local Site Documents page in the SPARCS application.**