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| 1. Name of Relying Site: | | | | |
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| 2. Study Title: | | | | |
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| 3. Name of Relying Site Investigator and credentials: | | | | |
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| 4. Relying Site Investigator phone number and email address: | | | | |
| Phone |  | | | |
| Email |  | | | |
| 5. Who is primary contact for this site: | | | | |
|  | | | | |
| 6. Primary Contact phone number and email address: | | | | |
| Name | |  | | |
| Phone | |  | | |
| Email | |  | | |
| 7. UM eProst Submission Number | | | | |
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| 8. Please list all research personnel involved in this study at this site: | | | | |
| First Name | | | Last Name | Email address |
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| 9. Select the procedures this site will conduct for this research (check answer that applies): | |
|  | This site is the grant recipient |
|  | This site is the data coordinating center |
|  | Faculty and staff at this site will be interacting or intervening with subjects to obtain data or specimens (this response includes administrating a test article) |
|  | Faculty and staff at this site will be collecting information from subjects through surveys or interviews |
|  | Faculty and staff at this site will obtain private, identifiable data about subjects through review of records or other information that were collected for another purpose (e.g. EMR, student records, records from another study.)  Note: Do not check this box if the data received are coded and linked to the subjects’ identity and the researchers will not have access to the subjects’ identities. |
|  | Faculty and staff at this site will obtain anonymous or de-identified data about subjects that were collected for other purposes (e. g. a different research study, or a di-identified data base)  Note: Check the box if the data you are receiving are in a Limited Data Set with a Data Use Agreement or when the data are coded and linked to the subjects’ identity and the researchers will not have access to that link. |
|  | Faculty and staff at this site will obtain identifiable human biospecimens that were collected for another purpose.  Note: Do not check the box if the biospecimens are coded and linked to the subjects’ identity when the researchers receive them and when the researchers will not have access to that link. |
|  | None of the above (additional information required)  Please provide a description of the procedures you will be conducting for this research: |

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| 10. Sites relying on the University of Miami IRB are responsible for ensuring required ancillary reviews are completed prior to commencing the research.  Please indicate below that you will fulfill this responsibility by checking box: | |
|  | I agree to ensure all required ancillary reviews are completed prior to starting this research. |
| **Interest Disclosure and Conflict of Interest Management**  Disclosure of interests related to the study not only ensures an investigator’s compliance with federal regulations and institutional policies, but also allows an administrative body to identify and manage conflicts of interest. The University of Miami requires that relying sites confirm that each individual engaged in the research have disclosed any interest(s) related to the study, and that conflicts of interests are managed in order to reduce the introduction of bias into the results of a project.  Check one: | |
|  | This site does not have an administrative body to identify and manage conflicts of interest.   * Please ensure each investigator completes the UM Interest Disclosure Form (IDF) and submit all forms into UM’s eProst System using the public comment function.   I agree to ensure all conflict of interest concerns will be addressed prior to starting this research. |
|  | This site has an administrative body to identify and manage conflicts of interest. (Check one below)  The administrative body has not identified any conflicts of interest related to this study.  The administrative body has identified conflict of interests related to this study. Please find attached  the approved Conflict of Interest Management Plan(s). |

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| **11. Please confirm that all the individuals involved in the research are in compliance with local training and qualification requirements (e.g. CITI courses):.** | |
|  | I confirm the above statement. |
|  | This site does not have access to local human subject research training. |

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| 12. Please confirm that all the individual at your site who conduct the consent process will have sufficient knowledge about human subject protections and the protocol to obtain legally effective consent from participants (check answer that applies):. | |
|  | I confirm the above statement. |
|  | Not applicable – consent is either waived or not being conducted at this site |

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| 13. Please confirm that your informed consent process will comply with the following  (check box that applies): | |
| * Discussions with subjects will take place in a private area: * Potential subjects will be allowed as long as needed to review the consent form and will be allowed an opportunity to discuss research with family or friends: * The PI or other knowledgeable person will be available to answer subjects questions during the informed consent process; * A copy of the signed informed consent document will be provided to the subjects; * Participants will be informed of alternative treatments or procedures prior to participation in the research study; * No information will be presented that waives or appears to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the * Coercion and undue influence will be minimized thoroughly explaining the research and answering all of the participants’ questions prior to obtaining consent. | |
|  | I confirm that the informed consent process will comply with the above |
|  | Not applicable – consent is either waived or not being conducted at this site |

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| 14. Are you enrolling subjects who do not speak/read English (check box that applies): | |
|  | No |
|  | Yes, please explain how you will communicate with participants during the consent process, study visits and emergencies: |

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| 15. How will you verify who may act as a legally authorized representative (LAR) for the participant?  (check box that applies): | |
|  | Not applicable, this study will enroll only subjects who can personally consent |
|  | This study will enroll cognitively impaired adults and the process we follow to verify the authority of the LAR is as follows: |

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| 16. How will you protect participant’s privacy? (check all that apply) | |
|  | Use of drapes and other barriers to vision to protect subjects are required to disrobe |
|  | Collect sensitive information only after measures are in place to prevent disclosure to or access by others |
|  | Obtain consent before obtaining photographs of participants or audio/video recording participants |
|  | During screening, the site will delay obtaining information that will identify a subject until after sufficient data are collected to demonstrate meets eligibility criteria to consent |
|  | Other, please specify: |

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| 17. How will you protect the confidentiality and security of participants’ data? (Check all that apply) | |
|  | Paper records will be kept in a secure location, accessible only to authorized personnel involved in the study. |
|  | Electronic records will be maintained on an encrypted, password-protected device |
|  | Data will be collected in a de-identified coded manner and a link to the participants’ identity will be maintained in a location separate from the data |
|  | Identifiable electronic health information obtained in this study will be stored in a manner compliant with the HIPAA Security Rule |
|  | Site team members sign agreements to protect the security and confidentiality of the information collected in this study |
|  | Electronic records will be maintained in a secure website (e.g. RedCap) that is compliant with either 21 CFR Part 11 and/or HIPAA Security Rule |

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| 18. Are there any laws in your jurisdiction or requirements of your institution that are in addition to those established by federal regulations? (check box that applies) | |
|  | Yes |
|  | No |

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| 19 Do you have a document that provides information about local law and other information about local context? | |
|  | Yes, please provide a copy of document describing local law and local context. |
|  | No, please provide any additional information that you believe will help us ensure that this research is approved according to your local requirements: |

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| 20. Please describe the local attitudes (e.g. religious, ethical, ethnic or economic) that could affect the conduct of this research at this site (check box that applies): | |
|  | Positive |
|  | Negative – Please explain: |

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| 21. Will your institution accept a Waiver of the Requirement for a HIPAA Authorization from the University of Miami IRB? (checking box that applies) | |
|  | Yes, my institution will accept waiver |
|  | No, Waiver of Requirement for a HIPAA Authorization must be approved by an IRB/Privacy Board at my institution |
|  | N/A, this research does not require access or disclosure to protected health information (PHI) |

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| 22. How does your site handle medical emergencies? (Check all that apply) | |
|  | N/A, this research involves no more than minimal risk |
|  | Call 911 |
|  | Emergency Room is very close by |
|  | This site has medications and equipment for emergencies |
|  | This site has ACLS trained personnel readily available |
|  | Other, please specify: |