|  |  |
| --- | --- |
| Study Number | Click or tap here to enter text. |
| Study Title | Click or tap here to enter text. |
| Principal Investigator | Click or tap here to enter text. |
| Primary Data Custodian[[1]](#footnote-1)*\*if other than Principal Investigator* | Click or tap here to enter text. |

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| 1. Will data be collected and/or stored in a manner that is ***directly identifiable[[2]](#footnote-2)***?
 |
|  | [ ]  Yes *Please complete section A1-A3* | [ ]  No*Please skip to Section B* |
| 1. If Yes where will ***directly identifiable*** data be stored?
 |
| [ ]  UM Velos[ ]  UM REDCap[ ]  UM Box[ ]  UM OneDrive [ ]  UM Secure Workbench[ ]  UM-owned and maintained computers/laptops/servers | [ ]  UMIT or UHealth IT-maintained portable or other devices. [ ]  UM Institute for Data Science and Computing systems.[ ]  JHS Cerner and/or SharePoint *(for JHS data only)*[ ]  UM Qualtrics *(not recommended for Biomedical Research)*[ ]  Physical records with appropriate security |
| [ ]  System provided and maintained by study sponsor\*[ ]  System provided and maintained by collaborating institution\* [ ]  Other\**\* If an item with a red asterisk is selected, please explain below:*Click or tap here to enter text. |
| 1. If selection in A(1) above has a red asterisk, please identify the system and security measures in place for the locations specified above:
 |
| [ ]  Data encryption[ ]  Data destroyed or deleted when no longer needed[ ]  Access logs or other documentation of users accessing data[ ]  User permissions set to minimum necessary to perform tasks[ ]  User accounts disabled after leaving project/University[ ]  Other, please describe:Click or tap here to enter text. |
| 1. If selection in A(1) above has a red asterisk, please identify data backup and recovery method to be utilized and where data backups will be stored:
 |
| Click or tap here to enter text. |

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| 1. Is any data being shared of a particularly ***sensitive nature***?*See question (1) below for examples*
 |
|  | [ ]  Yes *Please complete section B1* | [ ]  No*Please skip to Section C* |
| 1. If Yes, please select all that apply:
 |
| [ ]  Mental Health[ ]  HIV, Hepatitis or Sexually Transmitted Diseases[ ]  Criminal History[ ]  Substance Abuse |
| [ ]  Other, please explain below:Click or tap here to enter text. |
| 1. ***Study-Required*** Data Sharing that *does not require* DSAC approval

*Contact HSRO for template language to be included in the Informed Consent Form* |
|  | [ ]  A third-party vendor has been contracted to manage payments or reimbursements to participants, schedule home healthcare visits, or otherwise provide transportation, lodging or other services that require sharing of contact information, financial information or other identifiable data for these purposes. Specify:Click or tap here to enter text. |
| [ ]  This study involves payment to participants and may require reporting to the IRS. |
| [ ]  This study involves HIV, Hepatitis, STD or other testing which may require reporting to state authorities. |
| [ ]  Study involves questions where participants may be likely to disclose intent to harm themselves or others, child or elder abuse or other information which must be reported to appropriate authorities. |
| 1. Will all data sent to, and maintained by, the sponsor or other parties be identified using ***study codes only*** and the recipients of such data will not receive linking information?
 |
|  | [ ]  Yes *Please complete section D1* | [ ]  No*Please skip to Section E* |
| 1. If Yes, where will ***linking data[[3]](#footnote-3)*** be stored?
 |
| [ ]  UM Box[ ]  UM-owned computers/laptops[ ]  UM-owned portable or other devices [ ]  UM REDCap | [ ]  UM OneDrive[ ]  JHS Cerner and/or SharePoint*(for JHS data only)*[ ]  Physical records with appropriate security |
| [ ]  Other, please explain below:Click or tap here to enter text. |

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| 1. Recipient(s) of ***Directly Identifiable*** Data & Method of Data Transfer*(For recipients not previously listed in section C above)*
 |
|  | Identify recipient(s): Click or tap here to enter text. |
| Select applicable methods.[ ]  Encrypted Data Capture or Transfer System (including eCRF and Secure FTP systems)[ ]  UM Box (or other UM Cloud Storage Solution)[ ]  UM REDCap [ ]  Other |
| *If other software is used or some recipients use different methods, please explain:*Click or tap here to enter text or attach separate document to study application. |
| 1. ***Type(s) of data*** shared and agreement status
 |
|  | [ ]  [Protected Health Information (PHI)](http://privacy.med.miami.edu/faq/privacy-faqs/which-specific-data-elements-are-considered-protected-health-information) | ☐ Disclosure in Informed Consent☐ HIPAA Waiver of Authorization☐ provisions incorporated into Business Associate Agreement, Clinical Trial Agreement (CTA), or other agreement governing the use of identifiable data. Status of agreement:[ ]  Agreement has been executed[ ]  Agreement in process |
| [ ]  [Limited Data Set (LDS)](https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/limited-data-set/index.html) | Status of Data Use Agreement (DUA) or other agreement governing the use of data:[ ]  Agreement has been executed[ ]  Agreement in process |
| [ ]  [Personally Identifiable Information (PII)](http://privacyoffice.med.miami.edu/faq/privacy-faqs/what-is-personally-identifiable-information-pii) |
| [ ]  [De-identified Data](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#standard)  | Status of Data Transfer Agreement (DTA) or other agreement governing the use of de-identified data:[ ]  Agreement has been executed[ ]  Agreement in process |
| [ ]  Aggregate Data Only | [ ]  Coded Data (Link maintained at UM)[[4]](#footnote-4) |
| *Please explain any variation from the above:*Click or tap here to enter text. |
| 1. Will data be shared outside of the United States?
 |
|  | [ ]  Yes | [ ]  No |
| *If Yes, please specify the country(ies) and purpose* Click or tap here to enter text. |

1. The ***Primary Data Custodian*** is accountable for research data; is in control of the complete research data flow; protects the privacy and safety of study subjects; protects research quality and reproducibility; uses available expertise and recommended infrastructure; thinks ahead about intellectual property rights; shares data responsibly. Please see [Research Data Stewardship for Healthcare Professionals](https://www.ncbi.nlm.nih.gov/books/NBK543528/) for additional guidance. [↑](#footnote-ref-1)
2. ***Directly Identifiable Data*** includes Protected Health Information (PHI) as defined by HIPAA ([click here for guidance](https://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#safeharborguidance)) and Personally Identifiable Information (PII) as defined in [NIST ITL BULLETIN FOR APRIL 2010: GUIDE TO PROTECTING PERSONALLY IDENTIFIABLE INFORMATION](https://tsapps.nist.gov/publication/get_pdf.cfm?pub_id=905656), but are not limited to:

• Name, such as full name, maiden name, mother’s maiden name, or alias;

• Personal identification number, such as social security number (SSN), passport number, driver’s license number, taxpayer identification number, or financial account or credit card number;

• Address information, such as street address or email address;

• Personal characteristics, including photographic image, especially a face image or other identifying characteristic; fingerprints; handwriting; or other biometric data, such as retina scan, voice signature, and facial geometry; and

• Information about an individual that is linked or linkable to one of the above categories, such as date of birth, place of birth, race, religion, weight, activities, geographical indicators, employment information, medical information, education information, and financial information [↑](#footnote-ref-2)
3. See UM Investigator Manual, Chapter 10: Privacy and Confidentiality for definition [↑](#footnote-ref-3)
4. See UM Investigator Manual, Chapter 10: Privacy and Confidentiality for definition [↑](#footnote-ref-4)