# 1. PHYSICAL POSSESSION AND STORAGE OF iPHD DATA FILES

1.1. Who will have the main responsibility for organizing, storing, and archiving the data? Please provide name(s) and job title(s).

Click here to enter text.

1.2. Describe how your organization maintains a current inventory of data files.

Click here to enter text.

1.3. Describe how your organization binds all members (i.e., organizations, individual staff) of research teams to specific privacy and security rules in using iPHD data files.

Click here to enter text.

1.4. Provide details about whom and how your organization will notify the iPHD of any project staffing changes.

Click here to enter text.

1.5. Describe your organization's training programs that are used to educate staff on how to protect data files.

Click here to enter text.

1.6. Describe the infrastructure (facilities, hardware, software, other) that will secure the iPHD data files.

Click here to enter text.

1.7. Describe the policies and procedures regarding the physical possession and storage of iPHD data files.

Click here to enter text.

1.8. Describe your organization's system or process to track the status and roles of the research team.

Click here to enter text.

1.9. Describe your organization's physical and technical safeguards used to protect iPHD data files (including physical access and logical access to the files).

Click here to enter text.

## 2. DATA SHARING, ELECTRONIC TRANSMISSION, DISTRIBUTION

2.1. Describe your organization's policies and procedures regarding the sharing, transmission, and distribution of iPHD data files.

Click here to enter text.

2.2. If your organization employs a data tracking system, please describe.

Click here to enter text.

2.3. Describe the policies and procedures your organization has developed for the physical removal, transport and transmission of iPHD data files.

Click here to enter text.

2.4. Describe how your organization will tailor and restrict data access privileges based on an individual's role on the research team.

Click here to enter text.

2.5. Describe the use of technical safeguards for data access (which may include password protocols, log-on/log-off protocols, session time out protocols, and encryption for data in motion and data at rest).

Click here to enter text.

2.6. Are additional organizations involved in analyzing the data files provided by iPHD?

Click here to enter text.

If so, please indicate below how these organizations' analysts will access the data files:

VPN connection
Will travel to physical location of data files at requesting organization
Request that a copy of the data files be housed at second location
Other: Click here to enter text.

2.7. If an additional copy of the data will be housed in a separate location (including cloud-server backups), please describe how the data will be transferred to this location and identification of these additional locations. (Also, please ensure you have included information on this organization's database management under the appropriate subsections of the database management plan.)

Click here to enter text.

### 3. DATA REPORTING AND PUBLICATION

3.1. Who will have the main responsibility for notifying the iPHD of any suspected incidents wherein the security and privacy of iPHD data may have been compromised? Please describe and identify your organization's policies and procedures for responding to potential breaches in the security and privacy of iPHD data.

Click here to enter text.

3.2. Explain how your organization's data management plans are reviewed and approved. Click here to enter text.

3.3. Explain whether and how your organization's data management plans are subjected to periodic updates during the DUA period.

Click here to enter text.

3.4. Please attest to cell suppression principle of not publishing or presenting tables with cell sizes less than ten (10); and if above ten (10), you hereby agree to review the draft publication and based upon the nature and context of the work product, the numerical value is sufficiently large enough to prevent the identification of any individual. 

I agree.

### 4. COMPLETION OF RESEARCH TASKS AND DATA DESTRUCTION

4.1. Describe your organization's policies and procedures to dispose of data files upon completion of its research.

Click here to enter text.

4.2. Describe your organization's policies and procedures used to protect iPHD data files when individual staff members of research teams (as well as collaborating organizations) terminate their participation in research projects (which may include staff exit interviews and immediate access termination).

Click here to enter text.

4.3. Describe policies and procedures your organization uses to inform iPHD of project staffing changes, including when individual staff member's participation in research projects is terminated, voluntarily or involuntarily.

Click here to enter text.

4.4. Describe your organization's policies and procedures to ensure original data files are not used following the completion of the project.

Click here to enter text.

#### Complete only if collaborating organizations will have access to data files

Please note – All questions may not apply but are dependent upon the data sharing arrangement between the organizations involved in the research study.

(\* Information that should be indicated for <u>each</u> collaborating organization that will have access to iPHD data files.)

### A. Access to Files

- 1. What is the name of the collaborating organization?\* Click here to enter text.
- 2. How will the collaborating organization access the iPHD data (secure VPN, a physical copy on site at the collaborating organization, traveling to the DUA holder's site, etc.)?\*

  Click here to enter text.
- 3. Who are the researchers from the collaborating organization? Indicate if each researcher will have access to raw data, analytic files, or output with cell sizes less than 11. (*Please ensure that these individuals and data access rights are listed in the Project Staff list.*)\*

  Click here to enter text.
- 4. What binding agreements are required of the researchers from the collaborating organization?\* Click here to enter text.
- 5. What training is required of researchers from the collaborating organization?\* Click here to enter text.
- 6. How will the collaborating organization notify the DUA holder of changes in staff who are participating on the research team?\*

  Click here to enter text.
- 7. Will the researchers from the collaborating organization abide by the DUA holder's project rules or the policies of their employing organization?\*

  Click here to enter text.

### B. Physical Copies of Files

Please note - if the collaborating organization will maintain a separate copy of the iPHD data, the collaborating organization is required to complete a full Data Management Plan.

- 1. Will a separate copy of the iPHD data be housed at the collaborating organization's location? Click here to enter text.
- 2. How will the collaborating organization receive the iPHD data (shipment from the DUA holder, collaborating organization will request an additional copy directly from iPHD, the collaborating organization will transport the data, etc.)?

Click here to enter text.