

Ancillary Committee Data Assessment

Study Number: _____

Study Title: _____

Version: 2

Primary Data Custodian:

(Provide name and role/title as identified in the study protocol)

Backup to Primary Data Custodian:

(Provide name and role/title as identified in the study protocol, (a backup data custodian is recommended but not required))

I. Data Sharing

Please answer the following questions if you will be sharing data outside of the University of Miami. If you will not be sharing data outside of the University of Miami, please move on to Question II.

A. Will data be shared outside of the United States?

- No
 Yes

Please specify the country and the purpose:

B. Will data be shared with any individual/entity other than the CRO, Sponsor, or study team identified in the HIPAA Authorization Form B?

- No
 Yes

Please identify the individual and specify the purpose:

C. Is the data being shared of a particularly sensitive population (e.g., minors or cognitively impaired) or of a sensitive nature (e.g., HIV or mental health)?

- No
 Yes (check all that apply)
- | | |
|----------------------------------|--|
| <input type="checkbox"/> Elderly | <input type="checkbox"/> Prisoners |
| <input type="checkbox"/> Minors | <input type="checkbox"/> Sexually transmitted diseases |

- Pregnant women
- Mental health
- Substance abuse
- Criminal history
- Cognitively impaired
- Other (provide explanation below)

Please identify the population and specify the nature:

- D. In most instances, a Business Associate Agreement must be in place for the sharing of [protected health information](#), a Data Use Agreement must be in place for the sharing of a [Limited Data Set](#) and/or [Personally Identifiable Information](#), and a Data Transfer Agreement must be in place for the sharing of [De-identified Data](#).

Is the data being shared in accordance with the above?

- No
- Yes

Please identify the data set being shared and the agreement currently in place for such sharing (please state if no agreement is currently in place):

- E. Please identify the method of data transfer (e.g., email, fax, FTP):

II. Data Collection and Storage

- A. Will identifiable data be collected and stored?

- No
- Yes

If no, please stop here and submit.

Please specify the type of identifiable data collected and stored (i.e., protected health information, limited data set, and personally identifiable information) and give data points as examples (e.g., name, age, gender):

- B. Please indicate the media type(s) that will be used to store the data.
- Paper (e.g., case report forms and paper surveys)
 - Electronic
 - Both

If paper only, please stop here and submit.

- C. Is the data storage system provided and maintained by the University of Miami, the Sponsor, or both?
- University of Miami (hint: most UM systems require single-sign on)
 - Study Sponsor
 - Government Contractor
 - Institutional Consortium
 - Other

If University of Miami only, please stop here and submit.

If Other, please identify who will be providing and maintaining the data storage:

Please identify the system and security measures in place:

Examples include: Encryption (at rest/in transit), Secure data destruction when no longer needed, Controlled access to data, such as: 1) Documentation of authorized users accessing data; 2) User permissions set to least privilege to perform tasks; and 3) User account disabled within 24 hours after leaving project; etc.

- D. Will a data backup and recovery method be utilized?
- No
 - Yes

Please identify where study data backups will be stored:
