Section 1: About the Databases and Repositories Form

If the human subjects study involves creating or sending data and/or samples to a repository or database to be saved for future research uses, this form is required.

Section 2: When to Use This Form

If you answered yes to 12.1.4) Creating or sending data and/or samples to a repository or database to be saved for future research uses) in the New Study Application, you need to complete this form.

If you will be creating or sending data and/or samples to a repository or database to be saved for future research uses for this study, and if you did not yet select yes in Section 12.1.4 of the New Study Application, please update the appropriate New Study Application section and then complete this form.

Section 3: Protocol Information:

Please complete the information below.

1) Principal Investigator:

Please enter the names of the PI’s.

2) Protocol Number:

Please enter the Protocol number. (If this is a new study application, the protocol number will be assigned and completed by OPRS once the application is submitted.)

3) Project Title:

Please enter the Project Title.

Section 4: Databases and Repositories - Questions

1) Select the items that will be banked:

Choose all that apply.

[ ]  Data

[ ]  Audio/Video recordings or Images

[ ]  Biological Samples

2) What type(s) of future research will be allowed on the data/samples?

Detail below:

Click or tap here to enter text.

3) Who manages the repository and where will the data/samples be stored?

Detail below:

Click or tap here to enter text.

4) Indicate whether the data/samples in the repository will be identifiable directly or through a code/link.

Answer these questions from the perspective of those who manage the repository.

- Identifiable means that the participant can be identified by the repository using information kept with or linked to the data/sample.

- The local PI and study team may not be managing the repository associated with this study; for example, the PI may send data/samples to the sponsor and the sponsor manages the repository.

4.1) Identifiable data/sample option used for study:

Select one option below.

[ ]  **Option 1: All data/samples will be identifiable to one or more individuals who have responsibilities to manage or oversee the repository.**

*Examples:* Data/samples are received into repository with identifiable information; those managing the repository will have access to participant identifiers for all of the data/samples while the repository is active.

[ ]  **Option 2: Some data/samples will be identifiable and some data/samples will be de-identified to one or more individuals who have responsibilities to manage or oversee the repository.**

*Examples:* Participants can choose in the consent form to have their data/samples identifiable or de-identified; data/samples are received from many sources and may be identifiable or de-identified; data/samples received with identifiers will not be de-identified before entering the repository; those managing the repository will have access to participant identifiers for some of the data/samples while the repository is active.

[ ]  **Option 3: All data/samples will de-identified to all individuals who have responsibilities to manage or oversee the repository. No link or code will be accessible to or maintained by the repository.**

Examples: Data/samples are received into the repository without identifiable information. If the repostiory is managed outside of the local institution, the local PI may maintain the code or link to identifiable information; however, the repository will never have access to the code or identifiers; data is recorded without identifiers. Only non-identifiable information is recorded; identifiable clinical data/samples are used for study purposes and are then completely de-identifier BEFORE being sent to the repository.

Identifiable data/sample questions, continued:

4.2.1) If you selected Option 2 or 3 above (in question 4.1), describe the process for de-identifying the data/samples.

Click or tap here to enter text.

4.2.2) Who will de-identify the data/samples?

Click or tap here to enter text.

4.2.3) When will the data/samples be de-identified?

Click or tap here to enter text.

5) Describe the procedures for participants to withdraw their data/samples from the repository. If participants will not be able to withdraw their samples, please provide an explanation.

Detail below:

Click or tap here to enter text.

6) Will future results or findings be communicated to the participants?

Select Yes or No.

[ ]  Yes [ ]  No

If yes, please describe the process for providing these results to participants:

Click or tap here to enter text.

7) Describe the procedures for other researchers to obtain data/samples from the repository for use in future research.

Note: Future research projects using repositories may require IRB approval before data/samples are used.

Detail below:

Click or tap here to enter text.