*INSTRUCTIONS: All research data and biospecimen banks/repositories managed by the University of Utah must have a management plan to receive IRB approval for the collection and use of the data and biospecimens for future research. Using the template below, attach your management plan to your IRB application. Attach the document under “Other Documents” on the Documents and Attachments page.*

**Plan for the Management and Oversight of Data/Biospecimen Repositories for Future Research**

1. **Describe the consent process for collecting the data and/or specimens, which may include:**

* Waiver of consent (authorization)
* Informed consent document
  + Ensure that the informed consent document includes all elements of informed consent for future use of private information or biospecimens (see the [Consent Document Checklist](https://irb.utah.edu/informed-consent/consent-document-checklist.php) on the IRB website).

1. **Describe the procedures for protecting privacy and confidentiality during collection, during storage, and after release of the data and/or specimens, which may include:**

* De-identification procedures
* Data and/or sample coding procedures
* Encryption of data
* Limited access to the data
* Confidentiality agreements between investigators and research staff

1. **Describe the process future investigators will used to gain access to the data and/or specimens for use in new research projects, including**

* Agreements between investigators
  + Data use agreements for limited data sets
  + Material transfer agreements
  + Agreements should address the following points
    - Acceptable uses of data/specimens and any restrictions on use
    - How human subject protection will be ensured (e.g. IRB approval for individual future use)
    - Sharing of specimens with third parties
    - Return of samples, data, results
    - Commercial use of specimens
* Specify what will be involved in the process for gaining access to the data/specimens.
  + What information must be provided in a request to access data/specimens?
  + How are requests submitted?
  + Who will receive the requests?
  + How will data/specimens be prepared before sharing (e.g., de-identification, coding, physical preparation/storage, etc.)? Who will make the preparations?
* Specify who must give approval to access the data/specimens (e.g., Repository/Bank Manager, IRB, data/specimen use committee, etc.).
* Specify how requests for access will be prioritized.
* Specify how data/specimen sharing will be tracked.
  + Consent form options
  + Release andreturn of data/samples
  + Running out of samples

1. **Describe the procedures for returning research results to participants.**
2. **Describe and governance and oversight over the data and/or specimen collection, which may include**

* IRB
* Steering and/or oversight committees
* Sponsors
* Government entities

1. **Describe the process for custodianship of the data and/or specimens, including**

* Note: the custodian is the bank manager
* Process for transfer or destruction of the data/specimens if the repository closes or is discontinued
* Process for maintaining the data/specimens if the custodian/investigator leaves the institution