

HPHCI Processes for Data Privacy and Security Agreements and Data Destruction Policy Adherence

Data agreements are coordinated by the OSP GM and the PI/PM. Once the agreement is fully executed, the GM sends a copy to the privacy manager (Garett Kopczynski), and the required elements are entered into the HPHCI tracking database.

When data are being released:

- PI/PM sends agreement to external institution for signature.
- OSP Grants Manager (GM) negotiates with external institution if required.
- GM obtains Institute Admin Director's signature.
- GM distributes copies to PI/PM and Privacy Manager
- Privacy Manager uploads executed agreement into HPHC's Privacy & Security (P&S) database and completes HPHC P&S monitoring form semi-annually. OSP manages BAAs in P&S database.
- Privacy Manager distributes copy to Atrius (if Atrius data involved)

When data are being received:

- PI/PM sends external institution's agreement to GM for review.
- GM negotiates with external institution if required.
- GM obtains Institute Admin Director's signature.
- GM sends to PI/PM to obtain external institution's signature.
- PI/PM sends fully executed agreement to GM.
- GM distributes copy to Privacy Manager.

Data Processes post IRB Closure:

When a project closes in IRBNet, the HSC office will email a form to the PI and the Privacy Manager containing

- Study identification information.
- Data destruction/return requirements.
- Data destruction/return date.
- A notice that all electronic data with PHI must be retained in a restricted access directory by the privacy manager for record retention purposes, unless otherwise specifically approved by the IRB. The PI is responsible for transferring data files to the privacy manager for storage in this directory within 30 days. The privacy manager will maintain a list of projects with stored electronic data, with a schedule for return or destruction, in the data retention database.
- A request for description of all hard copies of study data. The PI is responsible for organizing that these be boxed for storage in Iron Mountain within 30 days. The privacy manager will maintain a list of projects with stored hard copy data, with a schedule for return or destruction, in the data retention database. The Operations Manager will coordinate with Iron Mountain for delivery, destruction, or return of data.

The HSC office will complete the top portion of the form including the study information and the data destruction/return date. The form will contain an attestation statement that no other study data are retained by the study team.

The PI signs and returns the form to the Privacy Manager.

Data Processes at the Close of Record Retention Periods

Each month the Privacy Manager will run reports indicating which data are scheduled for destruction or return in the following 3 month period. In accordance with study requirements, these data, including hard copy and electronic media, will be destroyed or returned. The Privacy Manager will coordinate with the Operations Manager as needed. The Privacy Manager will update the database to indicate the date and disposition of data for each study.