

NRSP Research Storage Guidance for Active Protocols

This guidance applies to all UW IRB-approved protocols, including student studies (for which faculty are the PI of record). It is necessary to ensure the protection of human subjects and data integrity requirements are upheld and aligns with both UW-Madison's Human Research Protection Program (HRPP), HIPAA and related governing bodies. Where appropriate, this guidance ensures studies have appropriate local infrastructure to monitor, store and inventory the location of paper and digital files. While your study is active, PIs will complete a NRSP Data Storage for Active Projects form annually for any protocols with materials stored with NRSP space. Moreover, it is the PI's responsibility to notify NRSP of changes to information relevant to your study within 30 days of a change. In the event of an audit, NRSP staff will work with the PI to facilitate records review. This guidance also facilitates study closure and archival activities. Accurate records rely on PIs completing the annual Data Storage and Security form.

- a. The following files should be in IRB-approved locations, digitally or physically clearly labeled. Below is the list of materials that must be stored while a project is active. A set of file folders can be obtained from IT for the storage of your materials. IRB protocol
 - i. Initial IRB protocol (download from ARROW site), including scientific protocol (if applicable)
 - ii. Approval notification from IRB
 - iii. Any subsequent requests for change in protocol and IRB approval
 - iv. Approval of annual extensions of IRB protocol, if applicable
- b. Any communication from IRB about noncompliance (keep all communication) or related communication from IRB staff
- c. Recruiting (unless specified in IRB protocol that they will be destroyed)
 - i. Lists of participant contacts
 - ii. Participant contact information
 - iii. Recruiting materials (letters sent, scripts)
 - iv. Key codes linking identifying information to study data.
- d. Consent
 - i. Initial consent form approved by IRB
 - ii. Waiver of consent approval (where appropriate)
 - iii. Subsequent consent forms adapted after initial approval
 - iv. Signed consent forms (either digital, electronic or paper: note if kept in different file and current location)
- e. Data (either in folder or note in folder to specify location of materials)
 - i. Completed surveys
 - ii. Audio recordings
 - iii. Video recordings

- iv. Transcripts
- v. Other original data
- f. Agreements
 - i. Subcontracts
 - ii. Data use agreements
 - iii. Business associate agreements