NRSP Storage Guidance for Closed 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. The materials listed below must remain within the School of Nursing, either digitally or in locked storage, for seven years after the last date of publication. At UW-Madison, closure occurs when the researcher is no longer accessing identifiable data.

Upon study closure, NRSP will assist PIs in determining the appropriate type of storage or destruction of primary data, signed or audiotaped consent forms, and other records. NRSP will monitor stored files and coordinate destruction of files with PIs for any protocol with materials stored with NRSP. PIs will be consulted before any files are destroyed. In the event of an audit, NRSP staff will work with the PI to facilitate records review. PIs are advised to specify retention plans in IRB protocols that are consistent with the University guidelines of seven-year following publication of findings.

Once the closed study files have been stored in NRSP's secured file room, you can request access to them through NRSP. Any new use of data for a closed study requires a new or reopened IRB protocol.

The following files should be in IRB-approved locations, digitally or physically clearly labelled. Below is a list of materials that must be stored following study closure. A set of file folders can be obtained from IT for the storage of your materials. NRSP will maintain a record of where all research documents are stored. Additional information from campus regarding data storage can be found here.

1. IRB protocol
    a) Initial IRB protocol (download from Arrow site)
    b) Approval notification from IRB
    c) Any subsequent requests for change in protocol and IRB approval
    d) Approval of annual extensions of IRB protocol
    e) Any communication from IRB about noncompliance (keep all communication) or other communication from IRB staff
2. Recruiting (unless specified in IRB protocol that they will be destroyed)
    a) Lists of participant contacts
    b) Participant contact information
    c) Recruiting materials (letters sent, scripts)
    d) Key codes linking identifying information to study data.

3. Consent
    a) Initial consent form approved by IRB
    b) Waiver of consent approval (where appropriate)
    c) Subsequent consent forms adapted after initial approval
    d) Signed consent forms (either digital, electronic or paper: note if kept in different file and current location)
4. Data (either in folder or note in folder to specify location of materials)
    a) Completed surveys
    b) Audio recordings
    c) Video recordings
    d) Transcripts
    e) Other original data
5. Agreements
    a) Subcontracts
    b) Data use agreements
    c) Business associate agreements
6. Protocol closure notification form and acknowledgement from IRB
7. File Storage and Retention form indicating location of all documents (a.-g. above) at protocol closure