

## STUDY RECORDS MANAGEMENT

### Supplement A

This document serves as a supplement to University of Utah SOP# 006: *Study Records Management*. Below is a list of possible study documents that should be filed in either a) study participant charts or b) Regulatory Binder (Trial Master File). This list is not meant to be exhaustive. Individual studies may have additional records felt to be significant to the study, which should also be filed.

- a) **Study Participant Charts** should include the following documentation, when applicable:
- Signed/completed informed consent forms, parental permission forms and/or assent forms
  - Documentation of the informed consent/assent process
  - Medical records (clinic notes, procedure reports, test results, etc.) relevant to study participation or eligibility determination
  - Participant eligibility review and confirmation
  - Study treatment records – physician orders/prescriptions, drug dispensing and compliance records
  - Checklists, flow sheets, or other forms that capture source data
  - Medical history, adverse events, and concomitant medication logs
    - study staff should review concomitant medications with participants at each visit, and update the medication log as appropriate
    - PI or qualified medically trained Sub-Investigator should assess AE's and show timely assessment with signature and date
  - Laboratory reports – documentation of study samples should include date and time of collection, and details of storage and shipment. Laboratory results from all available reports during participation should be assessed and signed/dated by the PI or medically qualified sub-investigator, and should include assessment of clinical significance for abnormal results
  - Radiologic imaging and diagnostic reports such as CT, MRI, PET, DEXA scans, x-rays, and ECGs (all ECGs during participation should be assessed by the PI or a medically qualified sub-investigator for clinical significance, signed and dated)
  - Questionnaires and participant diaries
  - Participant specific report forms submitted to the IRB- including the full report

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form, IRB acknowledgement letter, attachments submitted with the report form and any pertinent communication with the sponsor, CRO, PI, IRB and/or participant

- SAE documentation, including SAE report to sponsor and confirmation of submission and receipt in timely manner, as required by the protocol
- Notes, memoranda and communications

b) **Regulatory Binder/Trial Master File** should include (but is not limited to) the following documents, when applicable:

- IRB approvals: including the initial study application and all subsequent *Amendments, Continuing Reviews, and Report Forms*; documentation should include the IRB correspondence letter and printed application
- Ancillary committee approvals
- Current and previous versions of all documents approved by the IRB, including:
  - Study Protocol
  - Informed Consent Form / Parental Permission / Assent Form
  - Investigator’s Brochure
  - Participant Recruitment Materials
  - Questionnaires
- Form FDA-1572, or Investigator Agreement for device studies – original and all subsequent versions
- Study/Protocol training records for PI and study staff at the beginning of the study as well as for each protocol amendment
- Delegation of Authority log
- Curriculum vitae and medical licenses of PI and sub-investigators
- Financial disclosure
- Laboratory accreditation and reference ranges
- Screening and enrollment logs
- IRB membership and statement of compliance
- Drug or Device shipping and accountability records