

SUBJECT FILES AND SOURCE DOCUMENTS LOG

- Ineligible subject(s) records. **
- Study subject records including: **
 1. Signed consent document(s).
 2. Copies of completed case report forms (CRF).
 3. Source documents and correspondence related to specific study subject.
 4. Copies of data edits.

**** NOTE:** *Subject's files will consist of individualized CRFs (hardcopy and/or electronic) and the medical record/chart of each subject.*

Alternate locations(s) if not filed in this binder

Item	Location
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____