

### Research Documents that Are Subject to Audits by the ORC

1. All original informed consent forms signed by all subjects enrolled in the study.
2. Presence of the following in CPRS:
  - Enrollment note (informed consent note)
  - Scanned signed informed consent form
  - Research Subject Clinical Warning (if applicable)
3. All source documents (e.g. hospital/medical records, clinic/outpatient charts, research/study charts) for all subjects selected for audit.
4. Subject visit log, sign-in record, and/or office appointment book, if applicable.
5. Records of payment to subjects, if applicable.
6. Drug accountability records
  - Shipping and receipt records
  - Dispensing records
  - Final disposition records
  - 10-9012s
  - Documentation of compliance with the Research Methods Accountability Form
7. Device accountability records
  - Shipping and receipt records
  - Maintenance and storage records
  - Dispensing records
  - Final disposition records
  - Documentation of compliance with the ---- Attestation Form
8. Records of staff licensure, credentialing, education and training
9. Regulatory/Study Binder – Essential Documents
  - Protocol and all signed amendments
  - BRAAN protocol and supporting documents
  - Investigator's Brochure and/or package inserts
  - FDA Form 1571/1572 – original and all versions
  - Investigator/sub-investigator curricula vitae
  - Financial disclosure forms
  - Study personnel identification and delegation log
  - Subject screening and enrollment log
  - Subject identification roster
  - Informed consent form – original and all versions
  - CRF completion guidelines, if applicable
  - Study aids (e.g. exclusionary concomitant medications), if applicable
  - Advertisements, if applicable
  - IRB documentation (e.g. submissions, correspondence, approvals for protocols, amendments, informed consent forms, advertisements; SAE notifications; continuing reviews; membership lists)
  - Laboratory licenses
  - Laboratory normal values
  - Monitor sign-in log
  - Correspondence
  - SAE reports
  - Reports of protocol deviations/exceptions
  - DSMP plans and reports