

Office of Clinical Research

Central Study File Contents

- Protocol and Amendments
- Investigator Brochure
- Informed consent
- FDA 1572 (if applicable) or applicable FDA forms for investigational devices
- Financial Disclosure (if applicable)
- C.V.s and licenses (if applicable)
- Laboratory and Pharmacy's licenses and certificates (if applicable)
- Laboratory normal value or ranges
- Delegation of authority statement or log
- Site signature log
- Master subject list (if applicable)
- Master subject randomization log (if applicable)
- Sample of case report forms or source documents
- IRB approval documents
- Confidential disclosure agreement
- Clinical trial agreement
- Drug/device accountability logs
- Drug / device packing or shipping list
- Correspondences to/from sponsor

- Correspondences to/from IRB
- Confirmation of training log
- Monitoring reports and logs
- IRB membership list
- IRB Statement of compliance
- Site Data protection form (if applicable)
- Ethics and compliance acknowledgement and certification form (if applicable)