Clinical Research Study Files

Study Number:	
Study Title:	

- These study files contain the final, not draft documentation that is required and may be inspected by regulatory agencies (e.g., FDA) and sponsors, CROs, and/or IRBs.

- These study files retain most, but not all, final documentation (e.g., patient data) that are an integral part of the clinical research study. Documentation that is not included in these study files needs to be clearly cross-referenced by location.

Instructions:

- File promptly all final documentation (and updates) in chronological order (most recent to oldest) upon receipt and completion.

- Retain all final documentation for the longest time period specified by the regulatory agency, sponsor, CRO, and/or the Washington University HRPO.

- Do not destroy or discard any final documentation without prior written permission (signed and dated) by the appropriate party (sponsor, CRO, and/or the Washington University HRPO.