

## Office of Regulatory Affairs and Research Compliance Required Documents Checklist for Human Subjects

The following documents must be on file at HJF before funding is released for any research involving human subjects:

- Initial local Institutional Review Board (IRB) approval letter with signature(s) (electronically signed is acceptable).
- Second-level/Third-level approval letter with signature(s) (electronically signed is acceptable) [A second-level review may be required depending on the funding source and where Principal Investigator (PI) /Associate Investigator (AI) is located/billeted. If second-level/third-level approval is required, all documentation must be submitted through the Office of Regulatory Affairs and Research Compliance, who in turn will forward to the appropriate agency/department for review/and approval.
- Scientific committee review approval letter with signature(s) (electronically signed is acceptable)
- Protocol application form and final approved version of protocol **with signature(s) where indicated** (electronically signed is acceptable).
- Copy of approved stamped informed consent form(s) and HIPAA authorization form (as applicable). If the IRB has granted a waiver of informed consent, provide approval letter with signatures (electronically signed is acceptable).
- All protocol appendices: Questionnaires, instruments, surveys and data collection forms (as applicable), etc.
- For protocols and associated documents that are conducted internationally and are not in the English language, the following additional documentation is required:
  - A translation letter certifying that the foreign version of the protocol and informed consent is an accurate and true translation of the English version. The letter should include the signature, name, address, phone number, fax number, and email of the translator, and the date translated.
  - Copies of all documents in the foreign language

- Current copies of HIPAA compliant CVs for PI, AIs and all personnel listed on the protocol. All personal identifiers should be deleted from the CVs. The PHS 398/2590 Biographical Sketch format can be used as a reference.
- Human subjects protection training certificates for all personnel listed on a protocol and for all other personnel involved in the research. **Course must have been completed within the past three years.** Human subjects training can be completed online at <http://www.citiprogram.org>. **For HJF employees/HJF contractors: Select HJF as your affiliation.**
- Copies of advertisements for recruiting human subjects and associated IRB approvals for such advertisements.
- Current assurances from rDNA, radiation, biosafety committees, environmental safety committee, and/or relevant impact statements (Directorate of Information Management, laboratory and personnel), if required.
- Copies of current state licenses and Basic Life Support (BLS) certification for physicians, nurses, nurse practitioners, physician's assistants and any other licensed health care provider(s) listed on the protocol.
- For studies that involve an Investigation New Drug (IND) or Investigational Device Exemption (IDE), the following additional documents are required:
  - a copy of the signed form FDA-1572
  - a copy of the investigator's brochure (for drug studies)/product brochure (for device studies)
  - Good Clinical Practice (GCP) training certification for personnel listed on protocol and the FDA 1572.
- For studies with material transfers (biological materials, such as select agents, cell lines, plasmids, and vectors, chemical compounds, data, and even some types of software and machinery), a copy of the Material Transfer Agreement (MTA).
- Copy of any Data Use Agreements (DUAs) between collaborating parties.

## Documents Required Until Study Closure

- Continuing review/annual progress reporting:
  - Copies of continuing review/annual progress report (APR) **with signature(s)** (electronically signed is acceptable) submitted to the IRB.
  - IRB approval letter for continuing review
  - Stamped informed consent form(s) and HIPAA form from continuing review (if applicable).
- Amendment documents:
  - Copies of protocol amendment request(s) **with signature(s)** (electronically signed is acceptable) with all supporting documents submitted to the IRB.
  - IRB approval letter and any approved forms for amended protocols (informed consent forms, HIPAA, etc.).
- Copies of advertisement(s) (not previously submitted) for recruiting human subjects and IRB approvals with signature(s) (electronically signed is acceptable) for such advertisements.
- Copies of all adverse event reports and protocol deviations submitted to the IRB(s) and corresponding approval/acknowledgement by the IRB(s). All adverse events must be reported as indicated in the protocol and according to the institutions' policies where the research is conducted, Department of Defense requirements, and federal regulations.
- Copies of approved presentations and publications resulting from the study. This includes all submissions, whether or not they are accepted for publication. Approval from the relevant IRB(s) and other departments as required by the institution where study is conducted. **Approval** must be received **prior** to submission of data for publication or presentation.
- Copy of updated Investigator Brochure /Product brochure (as required for studies conducted under an IND or IDE application).
- Copies of any audit reports received from the IRBs, clinical investigations departments, Food and Drug Administration or other regulatory agencies. If you are notified that you will be audited, please contact HJF Regulatory Affairs as soon as possible, so that we are aware of the audit and can help you prepare.
- Final report submitted to IRB and IRB approval letter of study closure with signature(s) (electronically signed is acceptable) and second and third level approvals as required.**