

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 and copies of any associated minutes.
- Second-level review approval with signature [A second-level review may be required depending on the funding source and where the primary investigators (PIs) or associate investigators (AIs) are billeted.]
- Scientific committee review approval letter and copy of associated minutes (if applicable for studies that involve greater than minimal risk to participants).
- Protocol application form and final approved version of protocol **with signatures where indicated**.
- Copy of approved stamped informed consent form(s) and HIPAA authorization form (as applicable).
- All protocol appendices: Questionnaires, instruments, surveys and data collection forms (as applicable).
- Current copies of CVs for PI, AIs and all personnel listed on the protocol.
- 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: Select HJF as your affiliation.**
- Copies of advertisements for recruiting human subjects and associated IRB approvals for such advertisements.
- Assurances from rDNA, radiation, biosafety committees and/or relevant impact statements (Directorate of Information Management, laboratory and personnel).

- For studies conducted at non-military sites, copies of state licenses for physicians, nurses, nurse practitioners, physician's assistants and any other licensed health care provider(s) listed on the protocol.
- For non-military sites, copy of IRB roster (if available) and documentation of Federalwide Assurance number.
- Copy of form FDA-1572 (if applicable), a copy of the investigator's brochure and good clinical practice (cGCP) training certification for personnel listed on form FDA-1572 [required for vaccine studies or studies conducted under an investigational new drug (IND) application].

Documents Required Until Study Closure

- Continuing review/annual progress reporting:
 - Copies of continuing review/annual progress report (APR) **with signatures** submitted to the IRB.
 - IRB approval letter for continuing review/APR **with signatures**.
 - Stamped informed consent form(s) from continuing review (if applicable).
- Amendment documents:
 - Copies of protocol amendment requests **with signatures** 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 advertisements (not previously submitted) for recruiting human subjects and associated signed IRB approvals for such advertisements.
- Copies of all adverse event reporting submitted to the IRB. (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 public affairs department **with signatures** must be received **prior** to submission of data for publication or presentation.
- Copies of program progress reports if your grant is required to submit these on a quarterly or annual basis. These reports should be submitted to the HJF Office of Sponsored Programs, which will forward a copy to the Office of Regulatory Affairs and Research Compliance.

- Copy of updated Investigator Brochure (for studies conducted under an IND 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.**
- IRB approval letter of study closure with signatures.**