HENRY M. JACKSON FOUNDATION
FOR THE ADVANCEMENT OF MILITARY MEDICINE

Advancing Military Medical Research

Office of Regulatory Affairs and Research Compliance

Required Documents Checklist for Human Use Protocols (Protocols conducted outside of the United States)

Please note electronic signatures are acceptable on approval letters and other documents.

- *Provide copies of the study documents in the in-country language AND copies of the translated documents into English*
- *A letter certifying that the document has been accurately translated.*
  Note: The letter should include the signature, name, address, phone number, and email of the translator, and date translated.

❑ **Scientific Committee/Peer Review approval letter**
Protocols supported by DoD funding are required by DoD Component Human Research Protection Offices to have documentation of a review of the protocol for scientific merit and feasibility. This review is to be done by a Scientific Review Committee or subject matter expert.

❑ **Initial Local Institutional Review Board (IRB) approval letter**

❑ **DoD IRB Approval / DoD Human Research Protections Office Approval**
If the protocol is supported with DoD funding, a second-level or even third level review may be required before work on the protocol begins. This DoD review may require completing an International Research Submission Form.

❑ **Protocol application form and Final approved version of protocol**
Application should reflect funding source. In the section of funding, indicate HJF as the foundation managing the funding of the protocol as well as listing the name of the Prime Sponsor.

❑ **Copy of approved stamped informed consent form(s)**
HJF should be listed on the consent form as having access to records.
If the IRB has granted a waiver of informed consent, provide approval letter

❑ **All protocol appendices and supporting documents**
For example- CRADAs, Conflict of Interest forms, questionnaires, instruments, surveys, data collection forms/case report forms, and advertisements

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- ❑ **Current copies of CVs for PI, AIs and all personnel listed on the protocol.**
  Personal identifiers (SSN, spouse's name, DOB, home address, etc.) should be deleted from the CVs. The PHS 398/2590 Biographical Sketch format can be used as a reference.

- ❑ **Human Subjects in Research 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, not the site/workplace.

- ❑ **Copy of signed Financial Conflicts of Interest Disclosure forms**

- ❑ **Current Lab Assurances (if applicable)**
  rDNA, radiation, biosafety committees, environmental safety committee, and/or relevant impact statements (Directorate of Information Management, laboratory and personnel), if required.

- ❑ **Investigation New Drug (IND) or Investigational Device Exemption (IDE) (if applicable)**
  - *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.*
  - *FDA approval or exempt determination letter*

- ❑ **Material Transfer Agreement (MTA) (If applicable)**
  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 signed copy of the Material Transfer Agreement (MTA) may be required between institutions.

- ❑ **Data Use Agreements (DUAs)/Data Sharing Agreements (DSAs) between collaborating parties (if applicable)**

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Documents Required Until Study Closure

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- ❑ **Continuing review/annual progress reporting:**
  - *Copies of continuing review/annual progress report*
  - *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 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)**
  - *Copy of documents submitted to IRB*
  - *IRB approval letter*
- ❑ **Copy of updated Investigator Brochure /Product brochure**
  - *Copy of documents submitted to IRB*
  - *IRB acknowledgment/ approval letter*
- ❑ **Copies of all adverse event reports, protocol deviations and unanticipated problems**

  Note: 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.*

- ❑ **Monitoring and Audit reports**

- ❑ **Study Closure**
  - *Final Report submitted to IRB*
  - *IRB letter*

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