General Instructions
for Submitting
Protocols and Supporting Documents for Review

Contents

1.0 Purpose and Use of this Document

The Human Research Protection Program (HRPP) within the Military Health System (MHS) is evolving rapidly, with new technologies and continuous process improvement efforts changing the way we do business. This document will provide investigators a list of services we provide in the Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)) and the Defense Health Agency (DHA), the documents we will need to receive in order to complete our reviews and the manner in which those documents should be submitted to our Office. Detailed, step-by-step descriptions of the submission processes can be found in other documents on the OASD(HA)/DHA Human Research Protection Program website.

NOTE: the OASD(HA)/DHA Human Research Protection Program Office does not have an IRB. Consequently, we do not provide primary reviews of research protocols. Primary IRB reviews for studies that originate in DHA and are not being carried out through contract are, by agreement, reviewed by the Medical Research and Materiel Command IRB at Fort Detrick.

2.0 Submitting Study Documents for Review

In the coming months, the DoD will be "refreshing" the web-based protocol management tool, eIRB, and updated guidance will be provided once this transition is fully implemented. In the meantime, investigators must submit protocol and supporting documents via email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil.

3.0 Requirement for Scientific Review

In accordance with DoD Instruction (DoDI) 3216.02, Enclosure 3 (Procedures), Section 3.a.(2) "The DoD institution shall have policies and procedures to require scientific review of non-exempt research involving human subjects and to ensure this review is considered during the IRB review process."

Additionally, in accordance with DoD Instruction 3216.02, Enclosure 3 (Procedures), Section 4.b.(2) "When a non-DoD institution is conducting non-exempt research involving human subjects, the IRB review must consider the scientific merit of the research, as required by section 219.111 of Reference (c) [32 CFR 219]. The IRB may rely on outside experts to provide an evaluation of the scientific merit."

Accordingly, investigators must submit proof of scientific review along with all other supporting documentation as part of the overall protocol submission package.

4.0 Types of Reviews Provided

We offer five basic review services in the OASD(HA)/DHA HRPP Office:

4.1 Human Subject Research Determination – does the protocol meet the regulatory definitions of a) human subject and b) research in accordance with 32 CFR 219.102?

The typical turn-around time for making this determination once all documentation has been received and all questions and concerns have been addressed is 5 business days. We are often quicker than this; however, it often times depends upon the complexity of the study.

4.2 Exempt Determination – is the research protocol eligible for an exemption from IRB review in accordance with 32 CFR 219.101(b)?

The typical turn-around time for making this determination once all documentation has been received and all questions and concerns have been addressed is 5-7 business days.

4.3 Human Research Protection Official (HRPO) Review – compliance check of protocols that have already been reviewed by a non-DoD IRB for adherence to the ethical standards, particularly those that are unique to the Department of Defense.

The typical turn-around time for completing a HRPO review once all documentation has been received and all questions and concerns have been addressed is 7-10 business days.

4.4 Modification Requests – changes made to approved protocols (*e.g.*, staff changes, study design, *etc.*) must be reported to, and approved by the primary IRB and by this office. Substantive changes to the protocols, including study objectives, design, number of subjects, changes to interventions (especially if they increase the level of risk) must be requested and approved prior to implementation. Other changes, such as staffing (except for PI), extending the length of the study, *etc*. may be reported at continuing review.

The typical turn-around time for completing a modification request review once all documentation has been received and all questions and concerns have been addressed (particularly if an unanticipated problems/adverse events have been reported) is 3-5 business days.

4.5 Continuing Review Requests – if an investigator (or team) wishes or needs to continue work on an approved protocol beyond the expiration date of the approval, then the request must be approved by the primary IRB and this office.

The typical turn-around time for completing a continuing review request once all documentation has been received and all questions and concerns have been addressed (particularly if any unanticipated problems/adverse events have been reported) is 3-5 business days.

4.1 Human Subject Research Determination:

The regulatory definitions for "human subject" and "research" must both be met in order for a study to be classified as human subject research that is subject to the provisions of 32 CFR 219 (Protection of Human Subjects) (also known as The Common Rule).

Additionally, DoDI 3216.02 includes specific examples of common activities within the Department of Defense that do not meet the definition of human subject research. Those examples are in the Definitions section of the Instruction.

The following documents are required to conduct this type of review:
(All templates/forms are available on DHA's HRPP website and fillable Word versions will be sent upon request)

- Request for Research and/or Human Subjects Determination template
- DHA Data Elements Request Summary template
- Primary IRB determination documentation (if applicable)
- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, *etc*.

Submit all documents *via* email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil for review.

4.2 Exempt Determination:

There are provisions in 32 CFR 219.101(b) that describe certain types of research activities involving human subjects that are exempt from IRB review. The exempt Categories are excerpted from 32 CFR 219.101(b) and can be found on the OASD(HA)/DHA HRPP website.

The following documents are required to conduct this type of review:
(All templates/forms are available on DHA's HRPP website and fillable Word versions will be sent upon request)

- DHA Data Elements Request Summary template
- Completed Request for Exempt Determination Review template or Research Protocol that has already been reviewed and approved by an IRB
- Current Curriculum Vitae or biosketch for the PI and associate investigators
- Completed Researcher Responsibilities Form for each investigator and government project manager
- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, etc.

Submit all documents *via* email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil for review.

4.3 Human Research Protection Official (HRPO) Review:

Once a protocol has been reviewed and approved by at least one non-DoD IRB that has a valid Institutional Agreement for IRB Review (IAIR) with DHA, we will conduct a quality check of that review.

For IRBs from other DoD components, we accept the IAIR as its formal attestation of understanding and adhering to 32 CFR 219 as well as the additional protections unique to the DoD given the particularly vulnerable population included in these studies. With the IAIR in place, we will accept the DoD IRB determination and will only conduct an administrative review if necessary.

The following documents are required to conduct this type of review:
(All templates/forms are available on DHA's HRPP website and fillable Word versions will be sent upon request)

- Completed Research Protocol Submission template (that was approved by the primary IRB)

- DHA Data Elements Request Summary template (if applicable)

- Proof of Scientific Review

- Current Curriculum Vitae or biosketch for the PI and associate investigators

- Completed Researcher Responsibilities Form for each investigator and government project manager

- Proof of human subject research protection program (HRPP) training within the past 3 years for all researchers and the government project manager

- Obtain training through CITI (http://www.citiprogram.org/)

  – Register under the "Office of the Under Secretary of Defense (Personnel and Readiness)"

  – If you have completed training provided by your institution, you need only complete the CITI Training Module titled: Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)
  NOTE: OUSD(P&R) is under "O" for "Office"

  – Most will need to take the Social and Behavioral Health Investigators modules

  – Because of the particularly vulnerable nature of the DoD population, we do NOT accept refresher training in lieu of completing the full course

- Copy of IRB approval letter(s) for the study (initial review and continuing reviews if applicable)

- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, etc. (that were reviewed and approved by the primary IRB)

Submit all documents *via* email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil for review

4.4 Modification Requests:

Whenever changes are made to a previously approved protocol (PI/other key personnel, study design, *etc*.), investigators are required to submit a notice of those changes to the primary IRB (when applicable) and to this office. We will review the requests and all supporting documentation ONLY AFTER the primary IRB has reviewed and approved the modifications (when applicable).

The following documents are required to conduct this type of review:
(All templates/forms are available on DHA's HRPP website and fillable Word versions will be sent upon request)

- Protocol Modification Request template

- DHA Data Elements Request Summary template (if applicable)

- Copy of the approval memorandum for the modifications from the primary IRB (when applicable)

- Copies of any new documents (e.g., scripts, consent forms, surveys, etc.) that are the subject of the modification (that were approved by the primary IRB)

- Current Curriculum Vitae or biosketch for the PI and associate investigators who have been added and are the subject of the modification

- Completed Researcher Responsibilities Form for each investigator and government project manager who has been added and are the subject of the modification

- Proof of human subject research protection program (HRPP) training within the past 3 years for all researchers and the government project manager/POC who have been added and are the subject of the modification

  – Obtain training through CITI (http://www.citiprogram.org/)

  – Register under the "Office of the Under Secretary of Defense (Personnel and Readiness)"

  – If you have completed training provided by your institution, then you need only complete the CITI Training Module titled: Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)
  NOTE: OUSD(P&R) is under "O" for "Office"

  – Most will need to take the Social and Behavioral Health Investigators modules

  – Because of the particularly vulnerable nature of the DoD population, we do NOT accept refresher training in lieu of completing the full course

- **NOTE**: an approved protocol modification request does not change the expiration date for the initial or continuing review approval

Submit all documents *via* email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil for review

4.5 Continuing Review Requests:

At least one month before the expiration date of the approval for a protocol, the principal investigator will need to request approval to continue the work beyond that approval date if the team wishes or is required to continue the study. We will review requests for continuation ONLY AFTER the request has been reviewed and approved by the primary IRB when applicable.

The following documents are required to conduct this type of review:
(All templates/forms are available on DHA's HRPP website and fillable Word versions will be sent upon request)

- Protocol Continuing Review template

- DHA Data Elements Request Summary template (if applicable)

- Copy of the approval memorandum for the continuation from the primary IRB (when applicable)

- Copies of any new documents (e.g., scripts, consent forms, surveys, etc.) that have been added to the study (that were approved by the primary IRB)

- Current Curriculum Vitae or biosketch for the PI and associate investigators who have been added since the last approval (not already approved as part of a separate modification request)

- Completed Researcher Responsibilities Form for each investigator and government project manager who has been added since the last approval (not already approved as part of a separate modification request)

- Proof of human subject research protection program (HRPP) training within the past 3 years for all researchers and the government project manager/POC who have been added since the last approval (not already approved as part of a separate modification request)

    - Obtain training through CITI (http://www.citiprogram.org/).
    - Register under the "Office of the Under Secretary of Defense (Personnel and Readiness)"
    - If you have completed training provided by your institution, then you need only complete the CITI Training Module titled: Module for Non-DoD Personnel Conducting Research Involving Human Subjects Supported by the DoD (ID: 16769)
      NOTE: It is under "O" for "Office"
    - Most will need to take the Social and Behavioral Health Investigators modules
    - Because of the particularly vulnerable nature of the DoD population, we do NOT accept refresher training in lieu of completing the full course

Submit all documents *via* email to dha.ncr.dha-cs-mgt.mbx.hrpp@mail.mil for review