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 (Health Affairs) (OASD[HA]) and the TRICARE Management Activity (TMA), 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)/TMA Human Research Protection Program website.

NOTE: the OASD(HA)/TMA 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 TMA 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 Online Submission Site

Beginning in early 2012, the Research Regulatory Oversight Office transitioned to using IRBNet for submitting protocols and supporting documentation for HRPP review. You can access the submission portal through Army Knowledge Online at the Defense Medical Research Network link. This site should be used for submitting documents to be reviewed by the OASD(HA)/TMA HRPP Office. If you have submitted protocols *via* email previously, then you will not need to resubmit them to us in IRBNet. However, if you intend to modify a current, approved protocol or wish to continue beyond the current approval expiration date, then those requests must be submitted to us using IRBNet.

3.0 Requirement for Scientific Review

In accordance with DoD Instruction 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, proof of scientific review must be submitted along with 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)/TMA 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 competent IRB for adherence to the ethical standards, particularly those that are unique to the Department of Defense (this was formerly referred to as a "secondary review")

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

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/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 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 can be found in the Definitions section of the Instruction.

The following documents are required to conduct this type of review: (all templates/forms are available on TMA's HRPP website and in the Forms and Templates library in IRBNet)

- Research Protocol Contact Sheet
- Completed protocol (either using the TMA protocol template or format submitted to your primary IRB)
- Completed Researcher Responsibilities Form for each investigator and government project manager
- Primary IRB determination documentation (if applicable)
- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, *etc*.
- If the protocol involves a survey, then notification must be provided to TMA Communication and Customer Service Office. The *Heads Up and Frequently Asked Questions* template must be completed

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)/TMA HRPP website.

The following documents are required to conduct this type of review: (all templates/forms are available on TMA's HRPP website and in the Forms and Templates library in IRBNet)

- Research Protocol Contact Sheet
- Approval from HA/TMA Gatekeeper Review for Duplication for all TMA-sponsored studies
- 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
- Proof of human subject research protection program (HRPP) training within the past 3 years for all researchers and the government project manager/POC. 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: Non-DoD Researcher Training Requirements

  Notes-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
- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, *etc*.
- If the protocol involves a survey, then notification must be provided to TMA Communication and Customer Service Office. The *Heads Up and Frequently Asked Questions* template must be completed

4.3 **Human Research Protection Official (HRPO) Review**:
Once a protocol has been reviewed and approved by at least one competent IRB that has either a valid Institutional Agreement for IRB Review (IAIR) with TMA, or a valid DoD Addendum to their HHS Federal-wide Assurance, 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. For institutions outside the DoD, we accept the DoD Addendum for this purpose. Each of these forms can be found at the OASD(HA)/TMA website.

The following documents are required to conduct this type of review: (all templates/forms are available on TMA's HRPP website and in the Forms and Templates library in IRBNet)

- Research Protocol Contact Sheet
- Approval from HA/TMA Gatekeeper Review for Duplication for all TMA-sponsored studies
- Completed Research Protocol Submission template[1] (that was approved by the primary IRB)
- 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: Non-DoD Researcher Training Requirements **Notes**-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 the project requires negotiation of Data Use Agreements (DUAs), please attach the DUA(s) or include the DUA # provided by the TMA Privacy Office.
- If applicable, attach copies of consent forms, interview scripts, questionnaires, marketing materials, *etc*. (that were reviewed and approved by the primary IRB)
- If the protocol involves a survey, then notification must be provided to TMA Communication and Customer Service Office. The *Heads Up and Frequently Asked Questions* template must be completed

[1]We prefer investigators from within the Military Health System (MHS) use our Research Protocol Submission Template; however, if you have completed a different template for the primary IRB review, then we will accept that in place of our template. Any additional information contained within our template that is not included on the primary IRB template will be required from you during our review. You will be asked to provide that information.

4.4 **Modification Requests**:

Whenever changes are made to a previously approved protocol (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 TMA's HRPP website and in the Forms and Templates library in IRBNet)

- Protocol Modification Request template
- 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 have 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: Non-DoD Researcher Training Requirements
  Notes-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.

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 TMA's HRPP website)

- Continuing Review Status Update template
- 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 have 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: Non-DoD Researcher Training Requirements

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