

IRB Procedures 7a: IRB Exempt Review

Revision Date: October 6, 2008, revision November 11, 2009, revision July 17, 2010, revised January 27, 2011, revised February 9, 2015, revised October 15, 2015

I. Summary

The IRB policy is to make guidelines and procedures for investigators, IRB staff, and IRB members understandable and available to all involved in the process, including this information about procedures for exempt review.

II. Responsibilities

A. IRB/Institution Responsibilities

1. The IRB Coordinator will receive the proposed project and review for completeness, including attachments of any pertinent documents. If any necessary documents are not present or proposed documents are incomplete, the IRB Coordinator will reject the new protocol submission xform and request missing items or completion of documents. Once the submission is complete, the IRB coordinator completes submission checklist section of the IRB Initial Review stage. The IRB Coordinator makes the initial determination of whether the proposal is routed to the ETSU IRB or the ETSU/VA IRB Chair by evaluating the protocol by the criteria outlined in IRB Policy II. The IRB Coordinator documents this determination on the submission checklist section of the IRB Initial Review Stage. IRB coordinator checks question regarding external sites to identify whether the PI has provided complete information for each external site. For studies that have an associated contract, the IRB coordinator forwards a copy of the contract or, at minimum, a copy of any contract pages referencing provisions for medical care or other care and services for research-related injury and any information regarding the consent process to Sponsored Programs. The IRB Coordinator provides the contract consistency checklist to the IRB Chair when complete. IRB Coordinator contacts PI and/or site if additional information is needed. Appropriate documentation must be received prior to issuance of IRB approval letter.
2. The IRB Coordinator will do appropriate data entry in IRBManager and forwards the new protocol submission xform to the Chair to indicate his/her review of the proposed project.

3. Any changes requested by the IRB Chair will be communicated in writing by the IRB Coordinator to the Principal Investigator (PI).
4. If the study meets the exempt criteria and is approved by the IRB Chair, letter(s) denoting the Chair's decision, including a citation of the applicable category of exemption according to the Code of Federal Regulations, will be drafted using the appropriate template.
5. If the study does not meet the exempt criteria and is not approved by the Chair, the PI will be instructed to submit the protocol for either expedited or full review, as appropriate to the level of risk, by the IRB. The PI will be informed in writing and provided with reasons for denial of exemption.
6. Within 2 weeks of submission of the request for exemption, for non-VA studies, the IRB Coordinator will post the exempt letter on the "New Exempt Submission" event. For VA studies, the IRB Coordinator will post the approval letter as an INTERNAL ONLY attachment on the "New Exempt Submission" event in IRBManager. When the VA R&D approval is verified by the IRB, the IRB Coordinator will remove the "Internal only" status so that the letter is visible to study staff. For both VA and non-VA, the IRB Coordinator changes the status in IRBManager to "approved" and enters the date of the exempt determination as a new approval period, and checks "exempt." The IRB Coordinator enters "exempt" in the fields "last review" and "next review".
7. Proposed projects meeting the criteria of exempt and approved by the Chair will be placed on the next available committee expedited agenda for IRB acknowledgement of approval.

B. Principal Investigator Responsibilities

1. Exemption does not mean "do nothing." If the preliminary evaluation indicates that the study may qualify for exemption under federal guidelines, the PI is responsible for submitting a new protocol submission xform, ICD, if applicable, in addition to any ads or instruments (questionnaires, surveys) intended for participant view or use. For studies that have an associated contract, a copy of the contract or, at minimum, a copy of any contract pages, referencing provisions for medical care or other care and services for research-related injury must be submitted. The PI may make the initial request for exemption, but the final determination is made, as required by 45 CFR 46 and by the FWA of this institution, by the IRB Chair or his/her designee. Proposals may be submitted at any

time during the month. Applications for exempt status must be submitted electronically on the New Protocol Submission xform.

2. The PI is responsible for submitting any modifications prior to implementation. If the modification changes the exempt status of a study, the PI will be asked to submit the study for appropriate review as an expedited or full study and obtain approval prior to initiation. (See Modification policy)
3. Research that is determined to be exempt from IRB review is not exempt from protection of human subjects. The PI is responsible for following all applicable ethical principals as well as institutional and IRB policies and procedures.

C. IRB Committee Responsibilities

1. The IRB Chair determines whether the IRB Coordinator's choice of routing the proposal to the ETSU IRB Chair or ETSU/VA IRB Chair for evaluation is appropriate. The IRB Chair may choose to refer the review to the other IRB Chair as he/she determines. The IRB Chair will evaluate each proposed study and determine whether the proposed study meets exempt status and clearly indicate this decision on the "IRB Chair xform for Exemption Approval". The IRB Chair or his/her designee may review and approve proposed studies that meet the criteria for exemption as detailed in Policy VII.
2. The IRB Chair may request any additional information that may help him/her make the necessary decision for the proposed study.

References:

Policy VII: IRB Exempt Review

Form 103

Modification Policy

Reviewer Form for Exemption Approval