Exempt Submissions

January 2017

Background:

HHS Regulations (§ 46.101(b)) define categories of human subjects research that are exempt from IRB review. See Section entitled “Human Subjects Research Exempt from IRB Review.” All nonexempt research will be reviewed in accordance with 45 CFR 46.

Q: How do I know if my research meets the Exempt criteria?

Research investigators who intend to involve human subjects in research will not make the final determination of exemption from applicable Federal regulations; rather IRB Executive Reviewers (IRB Chair, Vice Chair or designated IRB Administrative Staff) are responsible for reviewing the preliminary determinations of exemption made by investigators and their supervisors. Only the IRB may make the final determination that proposed research meets the regulatory criteria for exemption. For VA research, the IRB will defer to the requirements for Exempt research as outlined in the current VHA Handbook.

Q: How do I submit an Exempt Study?

All studies are submitted through our electronic myIRB system. The system allows an investigator to select the requested review type, in this case, Exempt. The investigator will continue to complete the remainder of the smartform applications.

Q: What kind of IRB review is required for Exempt studies?

There are no deadlines for submission of exempt protocols. Exempt submissions are reviewed and approved by an IRB Administrative Exempt Reviewer. If there is any question as to whether proposed research meets the criteria for exemption or if the proposed research poses ethical questions or concerns relating to human subjects protection, the IRB Administrative Exempt Reviewer will refer the submission for evaluation by the Chair/Vice-Chair. Chairs/Vice-Chairs may not only request changes or determine the research meets exempt criteria, but also disapprove the study if the study does not meet exempt criteria or refer the study for more stringent review (within Expedited or Full Board categories/requirements.

Q: Do I have to obtain consent from subjects on Exempt studies?

If there are interactions with participants, the IRB Administrative Exempt Reviewer can decide if an informed consent process is required, disclosing such information as: that the activity involves research, a description of the procedures, that participation is voluntary, name and contact information for researcher, adequate provisions for maintaining privacy and confidentiality, and/or possibly other elements of consent as deemed necessary.

Q: Do I have to submit a Continuing Review or Revisions?

Projects approved as exempt research are not assigned an expiration date and do not require continuing review by the IRB. Changes in research activities must be submitted to the IRB as a Revision and
approved prior to initiation. The IRB may, depending upon information submitted, change protocol status depending upon the proposed changes in the research activities. VA approved exempt protocols require continuing review by the VA R&DC as outlined in the VHA Handbook.

Q: Do I submit a closure for Exempt Studies?

Yes, it is strongly encouraged that you let the IRB know you are done with your Exempt study. The activity for submitting a closure is on the study workspace within myIRB and is a very simple one page smartform.