Overview

This guidance document outlines the materials investigators should assemble and include with their applications for IRB review in order to provide sufficient information for the IRB to make specific determinations regarding the risks, potential benefits, informed consent, and safeguards for human subjects. The *IRB submission forms provide additional guidance on what to include in the submission packet.*

Initial Review (* if applicable)

The following materials are **required** for initial review of **all types of research**:

☐ *IRB Request for Initial Review Form* (must be signed by PI)

☐ Description of recruitment and screening procedures and/or materials (e.g., advertisements, email messages, telephone scripts)*

☐ Informed Consent documents(s) and/or description of procedures*

- If consent is not being obtained, submit the *Request for Waiver of Informed Consent Form*
- If using administrative data under Broad Consent procedures, attach a copy of the consent document.

☐ Study protocol/research plan/evaluation plan

☐ Evidence of review by another IRB to include approval notice*

☐ Request for VDSS IRB to defer to another IRB review*

☐ Survey, questionnaires, interview materials and/or other materials related to interactions/interventions with human subjects to include investigator-authored measures*

☐ Principal Investigator(s) curriculum vitae (CV) or NIH biographical sketch

☐ *Research Personnel Form* (NEW; eff. 7/1/2023)

☐ Documentation of completed Human Research Protection Training (e.g., training certification of completion) for PI and research personnel (NEW; eff. 7/1/2023)

☐ Investigator's response to IRB inquiries*

☐ Copy of grant, contract, or data sharing agreement; if administrative data is requested, list of data elements is needed

☐ Any additional pertinent documentation

Sponsored Research

☐ Detailed Sponsor's Protocol/research plan/evaluation plan

☐ Relevant Grant Applications or Contracts

☐ For federally supported Multi-Center trials: Federally approved Consent Forms and Protocol/research plan/evaluation plan

Exemption from IRB Review
Many of the same materials requested for an Initial Review also apply to a Request for Exemption.

☐ *Exemption from IRB Review Request Form*; must be signed by the PI
☐ Study protocol/research plan/evaluation plan
☐ Survey, questionnaires, interview materials and/or other materials related to interactions/interventions with human subjects to include investigator-authored measures*
☐ Consent form and/or description of consent procedures (see notes above)
☐ PI's CV or biosketch
☐ Documentation of completed Human Research Protection training
☐ Copy of funded grant, contract or data sharing agreement
☐ Documentation of exemption determination from another IRB
☐ Any additional pertinent information

Continuing Review

☐ Continuing Review Form
☐ Any relevant multi-center reports*
☐ Currently approved and any proposed recruitment and screening materials*
☐ Currently approved and any proposed informed consent document(s)*
☐ Any additional pertinent documentation

Modifications (Amendments) to Approved Research

☐ *Modification to Approved Study Form*; must be signed by PI
☐ Relevant modified study documents
☐ Modified recruitment & screening materials, consent documents, data collection instruments, etc.; prefer version with edits shown (e.g., use Word Track Changes) or highlighted*
☐ Any additional pertinent documentation

Responses to IRB Correspondence

☐ Investigator's response to IRB inquiries
☐ Revised consent documents, screening and recruitment materials*
☐ All other modified study documents
☐ Any additional pertinent documentation

Study Closure

☐ *Study Close-Out Report*
☐ Summary of research findings in any of the following formats: written report or thesis, Powerpoint presentation, PDF copy of research article (or web link to online publication), report abstract.