

What to submit for review

The requirements for what needs to be submitted for protocol review relate directly to the **criteria** according to which the project will be assessed.

All project materials that relate to the human subjects involved in the project should be included in the packet for review. That includes the grant application or research protocol document, copies of recruitment materials, consent documents, questionnaires or other items as applicable, and material pertinent to the IRB review of the protocol (the IRB approval/exemption letter, the IRB application, and all correspondence with the IRB).

We have developed a **checklist of materials** to help you know what to include in your packet for review. To see that checklist, please click on the link on the “Human Subjects Review” page.

In addition, every submission must be accompanied by a **cover memo** that details the pertinent features of the project related to human subjects review. The template for that cover memo can be found by clicking on the link on the “Human Subjects Review” page.

Complete Protocol Package Checklist

All protocols requesting review from the HSRRO should contain the following elements, in the following order:

- Memo requesting review (please use template)
- HSRRO Conditional Approval Memo (for final approval requests)
- Fact Sheet (NHEERL only)
- IRB Materials*: in reverse chronological order - most recent first (for final approval requests)
 - Approval letter(s)
 - IRB-Approved Research Protocol
 - IRB-Approved Consent Forms
 - Copies of questionnaires, interview scripts, and advertising stamped approved by the IRB
 - Ethics training reports required by the IRB
- Complete protocol/grant application
- Copies of extramural scientific reviews and responses (when applicable)
- Copies of medical, statistical, or other required reviews and responses (when applicable)