

Protocol Checklist and Submission Procedures

Protocol Checklist

All protocols for IRB review (full board, expedited, or exempt) must be submitted in the following format. Protocols that do not follow this required format will be returned to the investigator without IRB review.

- #1 _____ IRB Form #1 (fully signed)
- #2 _____ Application for funding/support (pages must be numbered)
- #3 _____ Required protocol components - not already provided in the application for funding/support (pages must be numbered) (see 'What Makes a Complete Protocol' for a more detailed description)
- #4 _____ Consent forms, including assent forms (if applicable) (pages must be numbered)
- #5 _____ Interview instruments/questionnaires (if applicable) (pages must be numbered)
- #6 _____ Recruitment documents (such as advertisements, flyers, cards)(if applicable)
- #7 _____ Letters of commitment/approval from collaborating organizations (see 'What Makes a Complete Protocol' for a more detailed description)(if applicable)
- #8 _____ Copies of other IRB approvals (if applicable)
- #9 _____ Checklist Form for Research Involving the Use of Prisoners as Study Participants (if applicable)

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Protocol Submission Procedures

Full Board Protocols - submit the original and 10 copies of the complete protocol (as identified above) to the Human Research Protections Office, Box 1986 , in sufficient time to meet the agenda deadline (see http://www.brown.edu/Administration/Research_Administration/nwww/human/IRB_deadlines.html for upcoming IRB meeting dates and protocol deadlines).

Exempt or Expedited Protocols – There is no specified deadline for submissions of Exempt or Expedited Protocols. Review time varies depending upon the project. The average review time is approximately 4 weeks. Please submit the complete (as identified above) original protocol to the Human Research Protections Office (HRPO), Box 1986, with sufficient time to allow for review and revisions, if necessary.

[Note that the IRB (not the investigator) makes the final determination of whether a protocol is full board, expedited, or exempt. Thus, full board review may be necessary even if you suggest expedited or exempt review in your protocol.]