

What Makes a Complete Protocol

IRB Form #1 (fully signed)

Application for funding/support (if an application of any kind was submitted, either internally to Brown University or externally, in order to obtain funding/support of the project, attach a copy of the full application.)

Required Protocol Components (if not already adequately addressed in the application for funding)

* *Project aims and methodology* (*what, why, how, and who*) - a description of the project, purpose, procedures, participant population (criteria for inclusion/exclusion including the attempts made to include women and members of minority groups), recruitment procedures, and how confidentiality of data will be maintained (where is data kept, who has access to it, and how is it kept secure).

* *Risks and Benefits*. This section describes the potential risks to participants and how the experimental design will minimize those risks and a description of the anticipated benefits, whether to the individual or to the body of science.

* *Informed Consent*. Explain the methods to be used in securing the informed consent of the participants. Written consent of the research participant is strongly recommended. If the Investigator feels that a verbal consent procedure is more appropriate for the population and circumstances, an explanation for the deviation from the preferred procedure is required along with a written version of the consent monologue. Whether written or verbal, the basic elements of informed consent must be present as outlined on IRB Form #1.

Interview/Survey Instruments. A copy of the final, or draft version, of all interview or survey instruments, must be attached. If no formal instruments will be utilized, provide a list of sample questions/topics that encompass the scope of the activity.

Letters of Support. If it is necessary to secure the approval of any collaborating agencies/institutions/groups prior to the conduct of some or all of the research project, provide documentation of such approvals in writing. (This includes entities such as schools, community organizations, clinics, doctors' offices, and other private organizations. Not included in this requirement are the local hospitals affiliated with Brown University.)

Other IRB Approvals. If it is necessary for other IRB's to review the project, provide copies of those IRB approvals or determinations (if available or applicable.)

Checklist Form for Research Involving the Use of Prisoners as Study Participants (required for all protocols where the participant population includes incarcerated individuals, as defined in 45CFR46, subpart C, sec. 46.303)

Required Protocol Items/Characteristics

1. Pages must be numbered.
2. Identification and description of key personnel - names, ranks, and affiliations.
3. Limited use of jargon. Protocols should be written in lay-person terms, whenever possible.
4. For the re-submission of a previously disapproved protocol, inclusion of a brief description of any subsequent changes to the protocol (including those requested by the IRB or instituted by the PI) in the form of a cover memo on the protocol.