

FREQUENTLY ASKED QUESTIONS (click on the question below to jump to answer)

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ANSWERS:

1. What's an IRB?

Answer: The IRB stands for Institutional Review Board for the Use of Human Subjects in Research. Any Institution that receives federal funding to conduct research with human participants, such as Brown, is required to establish an IRB to review all research that directly or indirectly involves human subjects, and to set forth institutional policy governing such research. Their major responsibility is to assess the risks and benefits of proposed research.

2. How do I know if I'm conducting research with human subjects?

Answer: The Federal Regulations define research as:

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Activities which meet this definition constitute research for this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. For additional guidance on what types of projects are likely, or not likely, to be considered research for IRB purposes, please refer to the following web page: http://research.brown.edu/rschadmin/hrpo_question1.php.

And Human subjects as:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) data through intervention or interaction with the individual, or

(2) identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

In order for your project to be considered human subjects research, **both** definitions must be met. If you are unsure if your project involves research with human subjects, please consult with RPO staff who can provide guidance in making this determination.

3. How long will it take for me to obtain approval to do my study?

Answer: That depends on the nature of your study and the characteristics of the people you intend to recruit. You should allow at least 4-6 weeks for review and approval of your study.

4. When may I begin data collection for my study?

Answer: You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis. A memo will be sent to you via e-mail when your project has IRB approval.

5. Do projects conducted by Brown students need IRB approval?

Answer:

Graduate/medical students: Yes. Projects conducted by Brown graduate or medical students need IRB approval, **if** the project fits the definitions of “research” and “human subjects” as described above. Graduate and medical students are urged to discuss these definitions with their advisors in order to make the determination of whether IRB review is necessary. For further guidance in determining whether a project needs IRB review, go to <http://research.brown.edu/rschadmin/hrpo_does_my_project.php> or contact RPO at x36838.

Undergraduate students: Yes. Projects conducted by Brown undergraduate students need IRB approval, **if** the project truly fits the definitions of “research” and “human subjects” as described above. Undergraduate students should discuss these definitions with their advisors so that the faculty advisor can make the determination of whether IRB review is necessary. For further guidance in determining whether a project needs IRB review, go to <http://research.brown.edu/rschadmin/hrpo_does_my_project.php> or contact RPO at x36838.

****Important Undergraduate Note****

Please note that undergraduate students may not be the principal investigator (PI) on research protocols submitted to the IRB. Please refer to the RPO website for more information about who may serve as a PI on a human research protocol:

http://research.brown.edu/pdf/WhoMayServeAsPIonHumanResearchProtocol_6_19_06.pdf.

6. I've heard that the Federal Regulations make certain categories of research exempt. If my research fits into one of these categories, does this mean that I don't have to have it reviewed by the IRB?

Answer: No. Federal Regulations are clear that it is not up to the investigator alone to determine if a project is exempt. Brown University policy requires all research, if determined to meet the definition of human subjects, receive IRB review. "Exempt" in this case does not mean exempt from review, nor does it mean exempt from ethical responsibility. The process is the same for all types of research involving human subjects.

7. Do I always have to obtain the informed consent of the research participants?

Answer: In general, yes, you do, but there are some limited exceptions. The IRB has the authority to waive some or all of the Federal requirements for informed consent in certain extenuating circumstances. The Brown IRB is responsible for ensuring that basic ethical principles are abided by in all research. The expectation that the informed consent of research participants be obtained is based upon the Belmont principle of respect for persons, and regarded as extremely important in conducting ethical research.

8. Do research participants always have to sign the consent document?

Answer: Not always. In certain situations, all involving no more than minimal risk, the IRB can waive the requirement that you obtain the participant's signature on the consent form.

9. What do the terms "consent" and "assent" mean? Aren't they the same thing?

Answer: Sometimes the word "consent" is used to include consent and assent. In research involving adults, "consent" is obtained from the participant to participate in the study. In research involving minors, a parent must give permission to allow the child to participate in the research, and children who are able to understand information about participation are asked to "assent" or agree to participate as well.

10. My research will be done in another country. Do I have to obtain IRB review and approval from Brown?

Answer: Yes. If you are a member of the Brown University faculty or staff, or a Brown University student, and you are the person responsible for the conduct of the study (PI), you must get Brown IRB approval to conduct your research regardless of where the research takes place. You should also be aware that your project may need IRB approvals in addition to Brown if being conducted in another location.

11. Is it true that I need IRB review even if I am not doing an “experiment”, but am only conducting interviews or surveys, using secondary data, or simply observing people?

Answer: Yes, as long as your research involves collecting data or information from or about living individuals, you need to have it reviewed by the IRB.

12. I want to conduct a study that involves the use of deception. Is this allowed? What do I need to consider?

Answer: The use of deception in research is not prohibited by either the Federal Regulations or Brown. However, because the use of deception in research violates the trust that the participant puts in the researcher, this method should be considered carefully. Deliberate deception of subjects may occur only in situations where withholding information about the nature of the study is necessary to ensure valid results, and never to get the subject to do something that they would not do if the information was fully disclosed to them.

13. Do I need IRB approval if my research isn't externally funded?

Answer: Yes, all research involving human subjects conducted under the auspices of Brown University must be approved by the IRB regardless of funding source.

14. If I have approval to conduct research involving human subjects from another IRB, do I still need to get approval from Brown?

Answer: Yes. All research involving human subjects conducted under the auspices of Brown University must have Brown IRB approval.

15. After I download the IRB form from the internet and complete it, can I send it back to you by e-mail?

Answer: Sorry, Brown is not set up to process protocols in this way. “Hard” copies must be signed and received in the Research Protections Office in order to be processed.

16. What is the difference between the terms “confidentiality” and “anonymity?”

Answer: Something that is truly anonymous has no known name or identity or known source. For research to be considered anonymous, no identifiers of any kind (e.g. name, code number, etc.) are used that can link the data or information to the individual who provided it. In contrast, research data that do have identifiers present that link individual participants with their information need to have appropriate provisions made to protect confidentiality. The researcher has been entrusted with private information and is responsible for addressing how sensitive information will be protected.

17. Can the IRB approve a project “retro-actively”?

Answer: No. There is no provision in the Federal Regulations that allow for IRB approval of research that has already been done. If data was collected for purposes that the IRB determines to be non-research (e.g. classroom projects) IRB approval can be sought for the data analysis going forward.

18. Do I have to promise confidentiality? What if my participants want to be identified?

Answer: The research should be designed in such a way that you protect the information that needs to be protected. The issue needing to be addressed is not one of requiring confidentiality or anonymity on participants in research where none is needed, but rather making sure that participants are fully informed. Some consent procedures allow for a participant the option of having their identity disclosed.

19. When do I need to complete the CITI education course?

Answer: The Brown University Education Program in the Protection of Human Research Participants (CITI) is required for all research personnel involved in

human research projects. This includes the Investigator, and in cases of student research, the advisor. Although completion of the program is not required before you submit your protocol, IRB approval is contingent on the Investigator (and the Advisor, if applicable) successfully completing the program.

For more information about the CITI program at Brown, follow this link: http://research.brown.edu/rschadmin/hrpo_citi.php. To register and complete the CITI training, go to the following web page: <http://www.citiprogram.org>

20. I don't know where to start to write a protocol. What needs to be included?

Answer: Every new protocol submitted to the IRB must include a completed and signed Form 1 (available at: http://research.brown.edu/pdf/IRBForm1_rev_6-30-06.pdf) and protocol checklist (http://research.brown.edu/policies/hrpo_protocolchecklist.pdf). More information about putting together a complete protocol can be found at the following web page: http://research.brown.edu/policies/hrpo_completeprotocol.pdf and <http://research.brown.edu/policies/hrpo.php>.

21. Are there "sample" protocol submissions available for research projects in specific disciplines?

Answer: No, not at this time. The IRB encourages Investigators to consult with their colleagues who have done research at Brown in guiding them in preparing their protocol. IRB staff will develop new tools to aid Investigators as time and resources permit, and will make them available on the RPO website. The IRB staff is available to answer questions about the IRB review process and to assist researchers and staff in the preparation of protocols at two open sessions, Tuesdays from 12-1 and Fridays from 2-3, and by appointment.

More information about putting together a complete protocol can be found at the following web page: http://research.brown.edu/policies/hrpo_completeprotocol.pdf.

22. Are there "samples" or templates for consent forms?

Answer: No, the Brown IRB does not require consent documents to be in any specific format. There are, however, required elements that all consent processes must contain, including a description of the procedures and any risks involved in participation. A complete list of required elements of consent can be found at

http://research.brown.edu/pdf/IRBForm1_rev_6-30-06.pdf.

23. What Brown-specific information needs to be included in the consent form?

Answer: All consent forms must state clearly at the beginning of the document that the project is Brown University research. Contact information should also be provided for participants to contact the Brown University Research Protections Office if they have any questions about their rights as a participant in research. The contact person is Susan Toppin, Assistant Director, 401-863-3050. For projects that will involve out-of-area participants, our toll-free number may be included (1-866-309-2095 – within the United States and Canada).

24. When is the next deadline for submission/IRB meeting date?

Answer: The deadline for receipt of protocols for full board review is usually the last business day of the month. When the last day of the month falls on a weekend, the submission date is usually the following Monday. Generally, meetings are held the 3rd Thursday of every month. A complete list of submission and meeting dates can be found at http://research.brown.edu/rschadmin/hrpo_meetingdates.php.

When a full board protocol is complete and all necessary signatures have been obtained on the cover sheet, the original and 11 copies can be delivered to the RPO by the end of the day on the deadline day.

For protocols that do not require review at a convened meeting (i.e., exempt and expedited protocols), there is no specific deadline for submission. These protocols are reviewed on a continuous basis as they are received in RPO.

For more information about submitting a protocol, please refer to the RPO Policies & Procedures web page: <http://research.brown.edu/policies/hrpo.php>.

25. How do I modify my protocol?

Answer: Any changes to the protocol, including consent forms and questionnaires, must be submitted to the IRB for review and approval before implementation. The process for modifying a protocol is as simple as submitting a memo. The request memo should include the following:

- A brief project summary

- A complete description of the changes to be made; the reasons for the changes; and your assessment of how the changes will affect the overall risk to participants in the study.
- If the modification requires any changes to documents, such as the consent form or advertisements, attach revised documents with the changes highlighted.
- Principal Investigator's signature

The review of modifications for full board protocols will be completed at a scheduled meeting. Therefore, the regular submission deadlines must be met. Please submit the original modification request and 11 copies. For modifications to exempt or expedited protocols, only the original is necessary.

More information about submitting modification requests can be found on the RPO policies and procedures web page: <http://research.brown.edu/policies/hrpo.php>

26. Which changes to the consent form need to be submitted to the IRB?

Answer: The IRB needs to have the most recent versions of consent forms on files, so all changes to consent documents must be submitted to the IRB for review. Not all revisions to the consent form will need to be reviewed by the full board. If a change is very minor (like correcting typos, re-formatting or changing phone numbers), RPO staff will most likely be able to review it administratively. Other minor changes may be reviewed with the expedited procedure.

27. Does the Research Protections Office (RPO) provide any training for investigators about the IRB?

Answer: Yes. RPO staff strives to provide information and assistance to investigators and research staff in several ways. Several times throughout the year RPO may hold formal seminars to help educate the research community about different IRB and human research topics. Arrangements can be made to have RPO staff present informational sessions for small groups which can be tailored for the needs of a specific group. And, as always, open hours are held every Tuesday from 12 – 1 and Friday from 2-3pm. If you can't make that time, feel free to call the office for an appointment.

The RPO staff is available during Brown University business hours to answer your questions about the IRB process and provide assistance with any human subjects

protection issues. Contact information can be found at the following page:
http://research.brown.edu/rschadmin/hrpo_staff.php.