I. IRB Review Process

A. IRB Review Process

1. The Brown IRB reviews a protocol by first assessing the risks and benefits of research participation. After determining that the research benefit outweighs the risks involved, the IRB turns to the consent process to ensure that subjects are fully aware of the risks and the benefits and that they participate in the project voluntarily. The consent form is a key element in this review.

2. After reviewing the application and its supporting materials, the IRB may require revisions in the protocol. When the investigator makes the required revisions, the IRB reviews the project again to see whether its concerns have been adequately addressed. A protocol may undergo several revisions.

3. To fully protect subjects, the IRB must approve a project before investigators start to work on it, prior to recruiting subjects, because recruitment strategies are part of the review. Although there are different types of review, many projects require "full" committee review. The Brown HRPP is committed to conducting an initial review of all protocols/amendments within two weeks of submission if the application is complete. All IRB actions are communicated in writing to the investigator by the HRPP staff.

B. What is the Difference between Full, Expedited, and Exempt Review?

Research projects are reviewed at one of three levels, according to a determination of the project’s potential risk to human subjects and the federal guidelines that define the categories of review. A proposed level of review is requested by the PI at the time of protocol submission and is ultimately determined by HRPP staff, in consultation with the IRB as needed. The potential levels of review are:

1. Exemption from IRB Review

   • If a study fits into an exempt category of research (refer to Exemption policy for specific categories) and is low risk to subjects, it will not need to go through expedited or full-committee review. If the study is not determined to be exempt, it will go through expedited or full-committee review.

   • The Review Process for Protocols that are Exempt from the Regulations

      o Investigators are asked to give their opinion of the category of review that
their protocol will require; however, the regulations specify that you cannot make a final determination of exemption for your own research (see 45 CFR 46.101(b) and (c) & 21 CFR 56.104(c) and (d)). Hence, while research that involves only minimal risk to human subjects is sometimes exempt from full IRB review at a convened meeting, it is still subject to IRB review. Researchers must file an application requesting that the IRB determine exempt status for a project.

In general, the federal guidelines for research on human subjects allow a project to be exempt from review only if the research involves very little risk to the subject and the procedures are limited to the specific criteria detailed in 45 CFR 46. Projects that involve contact with subjects may still qualify as exempt. Copies of the written consent form should be filed with the application or justification for a waiver of written documentation should be provided. See 45 CFR 46.117.

The Exempt Application Form, is available here. The HRPP decides whether the project qualifies as exempt, and the decision is confirmed in writing. If the project does not qualify as exempt, it is referred back to the investigator with the appropriate application forms.

2. Expedited IRB Review

- This type of review is carried out for studies which involve minimal risk to subjects and fit into an expedited review category of research (refer to “Does my Project need IRB Review?” for specific categories). Studies are reviewed by a member of the IRB. This member reviews the appropriate materials and consults with the PI if necessary to come to a decision about the approval of the study.

- Types of Research Qualify for the Expedited Review Process

To qualify for expedited review, a research protocol must be limited to the activities that are federally approved for expedited review and incur no more than minimal risk for participants, or be a minor change in previously approved research that involves no additional risk to research subjects.

The researcher must demonstrate in the application how the proposed project activities fall into one or more of the following categories approved in the federal regulations for expedited review:

1. Clinical studies of drugs and medical devices
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes.
6. Collection of data from voice, video, digital or image recordings made for research purposes

7. Research on individual or group characteristics or behavior

8. Continuing review of research previously approved by the convened IRB

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

The HRPP ensures that all of the elements essential for review, including consent forms and supporting information, have been submitted. The application is then forwarded to a designated committee member for review and decision. Either the research is approved by the committee member (sometimes with stipulations), or it is forwarded for full IRB review.

3. Full Convened IRB Review

- Studies are reviewed at a convened IRB meeting. The Board discusses the study and makes a decision about the approval of the study. This type of review is carried out for studies greater than minimal risk to subjects. Click [here](#) to see the schedule of IRB meetings.

II. What Happens during Full Board Review of my Study?

A. A project that involves greater than minimal risk requires approval by a convened IRB composed of members qualified to review research in that field. Examples of research that normally requires full Board review include:

- Research that involves greater than minimal risk;
- Some non-exempt research that involves children or other vulnerable populations;
- Research that involves experimental drugs or devices;
- Research that involves invasive procedures; and
- Research that involves deception.

B. Other types of research that may require full Board review include:

- Survey research that involves sensitive questions or information about sexual practices or illegal behavior;
- Any survey or interview that is likely to be stressful for the subject

C. The IRB application process starts with your submission of the application form, consent forms and other required appendices/materials. The HRPP staff pre-reviews your protocol to ensure that the required materials are included for the IRB’s review. If the application is incomplete, it is returned to the investigator for completion. We will contact you if we need additional information prior to the convened meeting.

D. On the third Thursday of each month, the convened IRB will meet to discuss and make a decision regarding your protocol via a majority vote of a quorum of Board members. Within
5 business days after the meeting you will receive a letter from the HRPP detailing the outcome of the IRB’s review of your protocol.

E. After review by the IRB, the application will either be:

- Approved as submitted;
- Approved with minor suggestions for changes;
- Approved with stipulations (conditions that must be met before final approval is granted) – *this is the most common outcome*
- Deferred, pending receipt of additional information or major revisions; or
- Not approved

F. All non-exempt research is subject to continuing review at least annually. If research involves significant risk to subjects, the IRB may require more frequent review and may ask to be kept apprised of all research activity.

III. When will I hear from the IRB about my Study?

A. The length of time a study will take to be approved depends on the level of review required (i.e. exempt, expedited, full board), coupled with factors within the investigator’s control, including:

B. Average turnaround times based on review type are as follows:

1. **Exempt Review** (from application submission to granting of exemption): 9 days
2. **Expedited Review** (from application submission to communication of review decision): 22 days
3. **Full-Committee Review** (days after a convened Board meeting): 8 days

   *All correspondence is sent via e-mail. You will have 45 days after the date of the original e-mail from the HRPP to respond or request an extension. If no response is received within 45 days, the submission will be dismissed and you may need to reapply.*

IV. How Long do I have to Respond to the Board’s Request for Additional Information?

You have 45 days to respond or request an extension to Board stipulations and deferrals. You will receive one reminder prior to the deadline to respond and the submission will be dismissed after 45 days if no response is received. You may need to reapply if the submission is dismissed due to no response. An extension to the 45 days may be requested for extenuating circumstances by contacting the HRPP.

V. How Should I answer Questions and Requests from the IRB?

A. Provide a written response to each of the IRB Manager’s or Board’s questions/requests, along with any new or revised documents you are asked to submit. DO NOT submit a revised protocol, as this will delay the review of your response. Be sure to address ALL questions/requests as thoroughly and clearly as possible to avoid additional questions.
B. If changes to the consent documents are required, include revised consent/assent forms with changes highlighted. Include a copy of any documents requested by the Board and highlight any changes made in response to stipulations.

*All correspondence is sent via e-mail. You will have 45 days after the date of the original e-mail from the HRPP to respond or request an extension. After that, the submission will be dismissed and you may need to re-apply.*

VI. **Do Undergraduate Projects need IRB Review?**

A. Learning how to conduct ethical research with human subjects is a vital part of many students’ educational experience. Often undergraduate student projects do not meet the federal definition of human subjects research, and it is important that each student project be evaluated against the following criteria:

- A **human subject** is defined by federal regulations as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.” (45 CFR 46.102(f)(1)(2)).

- Federal Regulations define **research** as “a systematic investigation, including development, testing, and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR 46.102(d)).

B. Importantly, one’s ambition to publish the results of his/her project in a journal does not in and of itself make the project “research.”

C. To facilitate interpretation and application of this definition in the context of undergraduate work involving human subjects and to ensure the ethical and safe treatment of human participants, the IRB in collaboration with the HRPP provides guidance (refer to “Undergraduate Work Involving Human Subjects” guidance) for undergraduates and their faculty advisors in determining if they need to submit a protocol for IRB review.

VII. **What about IAAs (Reliance Agreements) for Collaborative Research?**

A. Reliance agreements, also known as IAAs (IRB Authorization Agreements), are contracts between IRBs for multi-site research studies that seek the use of a single IRB. These agreements vary from institution to institution and cover topics related to IRB oversight, investigator responsibilities and other institutional requirements. The Brown HRPP strives to implement IAAs whenever a research project engages more than one institution in human research activities.

B. If you are interested in pursuing an IAA, please contact the HRPP or make a note in your protocol submission that you would like us to contact another institution’s IRB to negotiate an agreement. The IAA Application (IRB Form #3) can be found [here](#).

VIII. **How do I coordinate with the IRB for Advance-CTR Awards?**

A. It is a shared goal among all Advance-CTR collaborating sites to minimize duplicate review of human subject research protocols. This is currently accomplished via the facilitation of IRB Authorization Agreements (IAAs).
B. IAAs enable an investigator to submit an IRB protocol to the IRB at the institution which will be engaged in human subject research activities (either solely, or where the predominance of such activities will occur) and obtain IRB approval.

C. The Brown University IRB (and as applicable, other collaborating site IRBs) will subsequently accept the review and approval by the partner IRB, cede oversight of the research to the collaborating IRB (affirming that the partner IRB is the "IRB of record"), and formally document this acceptance via an IAA, thereby circumventing time-intensive duplicate review by multiple IRBs.

D. New Advance-CTR awardees may already be conducting human subject research in accordance with an existing IRB-approved protocol at the time when the new funding is awarded. Assuming the new research constitutes human subject research requiring IRB review and approval, the investigator must decide whether the more appropriate approach is to amend an existing protocol or submit a new protocol, to enable the newly funded activities to be approved by the IRB and a grant congruency review conducted by the human research protection office.

E. Investigators may assume that amending an existing protocol is the more logical, expeditious route, but if the new funding from Advance-CTR does not align with the aims of an existing protocol, or the project is intended to be a pilot study, submitting a new IRB protocol may result in faster review and approval. It may be that while the existing IRB approval requires full board or expedited review, a new protocol for a pilot study may qualify for an exempt determination (or even be non-human subject research).