PEPPERDINE
UNIVERSITY

IRB FREQUENTLY ASKED QUESTIONS

1. If I checked the "expedited" option on my application, does this mean that my application will be reviewed faster than other applications?

No, expedited only refers to the type of research based on the potential risks to the participants. Expedited applications actually take longer to review than the other type of typical research study called exempt. On a rare occasion, a very complex/very high risk study may be flagged for full review by the IRB, after submission.

2. If I need my study to be approved in four weeks from the day my application is submitted, can the IRB office help me in reviewing my application in a timely manner?

The IRB does not offer review priority based on the applicants' timetable. We highly encourage all applicants to submit their application as soon as they can. To get an estimate of response and approval time, you can consult the information on the IRB website homepage.

3. Instead of answering a question within the application, can't I just include an attachment or ask the IRB to review my attachment instead?

No. If a question within the IRB application asks for an explanation, or a description of a concept or a procedure, that question needs to be answered accordingly and in full within the specific e-protocol prompt.

4. Does the IRB have a copy of my chair's CITI certificate?

No, the IRB does not keep copies of these certificates and each study must be associated with specific CITI certificates to be considered complete. You must attach a copy of your CITI certificate and the chair's certificate to **each** application.

5. *Can I contact the IRB for guidance about the methodology development of my research study?*

No, the IRB's duty is to ensure the protection of the human subjects. Any questions regarding research study methodology or research study guidance needs to be discussed with the applicant's chair prior to IRB submission.

6. *My IRB application was returned to me for modifications; can I just type my responses in the comments boxes?*

You must respond to the recommendations and make all edits and revisions to the actual IRB e-protocol application and also respond in the comments section to overview what changes have been made to the e-protocol application.

7. *Am I required to specify the amount of funding being conducted in my research?*

Yes, you are required to specify the amount of funding in order to maintain credibility of the research being conducted by the researcher and to protect subjects from unethical research practices.

8. *Am I still required to apply for IRB if I am dealing with non-human subjects?*

Yes, you are required to complete a non-human subjects form found on the IRB website: https://community.pepperdine.edu/irb/content/revisednhsform09-03-2020.pdf along with the submission of your research abstract and possibly full proposal draft to gpsirb@pepperdine.edu, cc'ing both the current IRB chair and IRB Manager, whose emails can be found on the IRB website.

9. *How long will it take for me to complete the Protocol?*

The completion process typically takes approximately two-three hours.

10. *How can I ensure a fast and successful experience when submitting my study for approval?*

The IRB asks all of its applicants to plan with ample time their IRB application process and to work closely with their chair to ensure a speedy and successful approval. You may contact the IRB (gpsirb@pepperdine.edu) in regard to technical difficulties or queries about the e-protocol submittal process.

11. *Is there a sample application available?*

Yes, you can find a sample on the IRB website:
https://community.pepperdine.edu/irb/investigator-resources/

12. *What are the guidelines for conducting Continuing Review for both Expedited and Exempt studies?*

A continuing review application is submitted within EProtocol for a study that was previously approved. The request for Continuing Review is submitted at least a month (30 days) prior to the expiration of the approved study – ***no exceptions***.
The IRB will then assess whether there is new information that would necessitate revision, including consent forms. If the research study, or the request for Continuing Review does not satisfy all of the above criteria, the IRB must require changes that would result in research satisfying these criteria, defer taking action, or disapprove the request for continuing review.

13. *I am an external researcher that would like to work with Pepperdine, including recruiting subjects for my study. What do I do? Who do I contact?*

You would contact the IRB office at gpsirb@pepperdine.edu for specific instructions.

14. I am working with a researcher whose primary affiliation is another institution. Do I need to submit an application to both institutional IRBs?

You can elect to have one of the two institutional IRBs be the primary IRB for your study, and have the second institution sign an IRB Cooperative Authorization Agreement to rely on the primary IRB:
https://community.pepperdine.edu/irb/content/cooperativeauthorizationagreementnewcommonrule.pdf.

Please consult with Pepperdine's IRB to determine which IRB should be primary (Pepperdine or the other institution) and to discuss next steps.

15. What are the guidelines for conducting Amendments for both Expedited and Exempt studies?

All amendments, or modifications made to any section of a previously approved research study must be submitted and approved by the IRB prior to implementation, or execution of the planned changes.
The following table provides examples of minor changes (generally can be reviewed via Expedited Review) and major changes (generally reviewed by Full Committee pending upon the overall risk level) to previously approved protocols:

Minor Changes	Major Changes
• Administrative changes • Minor consent form changes • Minor changes to recruitment procedures, recruitment materials or submission of new recruitment materials to be used in accordance with approved recruitment methods • Minor changes to study documents such as surveys, questionnaires or brochures • New study documents to be distributed to or seen by subjects that are similar in substance to those previously approved • Changes in payment to subjects or the amount subjects are paid or compensated that are not significant enough to affect the risk/benefit ratio of the study • Decrease in the number and volume of sample collections as long as they do not negatively alter the risk/benefit ratio of the study • Editorial changes that clarify but do not alter the existing meaning of a document • Addition of or changes in study personnel • Addition of a new study site (in many but not all cases) • Translations of materials already reviewed and approved by an IRB	• Changes that adversely affect the risk/benefit ratio of the study or specifically increase the risk to subjects • Changes in inclusion/exclusion criteria that impact the risk/benefit ratio of the study • Significant changes in study design, such as the addition of a new subject population or the elimination of a study arm • New risk information that is substantial or adversely affects the risk/benefit ratio of the study • Significant changes to the study documents to be distributed to or seen by subjects • New study documents to be distributed to or seen by subjects that include information or questions that are substantively different from materials already approved by the IRB. • New or revised financial conflict of interest management plans (e.g., change in PI or change to study design).

16. What if my study has a Conflict of Interest (COI) component?

In case of a COI scenario, you can find the COI form here, under *Special Circumstances*: https://community.pepperdine.edu/irb/irb-forms/
This form will need to be completed and attached to your IRB application.