

Pepperdine IRB Committee Members

Responsibilities of IRB Members:

⇒ Participate as a reviewer of submitted Pepperdine University research applications assigned by the IRB Chairperson, IRB Manager, or Assistant Provost for Research. Responsibilities of IRB reviewers include reviewing research study protocol/application materials (exempt, expedited, and full review) and evaluating them from the perspective of the regulatory criteria for approval addressed under 45 CFR 46.111, 21 CFR 56.111 (if applicable); and any other relevant ethical, scientific or compliance considerations.

* Pepperdine University anticipates assigning no more than 2 research study protocols/applications per month to each IRB reviewer. This may vary depending on reviewer availability and re-assignment requests.

* All IRB reviewers are expected to adhere to Pepperdine’s IRB review timelines (see below). If a reviewer is unable to review an assigned within the relevant time frame, the reviewer *must* immediately notify the appropriate IRB personnel (IRB Manager or Chairperson) of unavailability so that the study protocol can be re-assigned.

	EXEMPT APPLICATION	EXPEDITED APPLICATION	FULL BOARD APPLICATION
Potential Risk	No more than minimal (see handout)	Minimal to Moderate (see handout)	Moderate to Substantial (determine by IRB)
Submission Process Review Process	e-Protocol: At least 1 reviewer	e-Protocol: At least 2 reviewers	e-Protocol: Full Board Review
Timeline for Receipt of Initial Review	11-15 business days	15-20 business days	30-40 business days; dependent on Board Meeting (see calendar)
Timeline for Receipt of Revisions and Modifications Reviews	6-10 business days	11-14 business days	15-20 business days

Additional responsibilities may include:

⇒ Attend monthly IRB meetings in person, unless exigent circumstances prevent such attendance on an occasional basis, reporting promptly at the designated time that the meeting convenes; and remaining in attendance at the meeting until the full agenda has been addressed;

⇒ Participate in IRB deliberations concerning issues inherent to proposed research studies and related informed consent documents, and making recommendations for reducing risk and improving the informed consent process and otherwise for improving human subject protections;

- ⇒ Recommend improvements to IRB policies and procedures so as to enhance the IRB review process and/or human subject protections;
- ⇒ Inform the IRB Chairperson or the Assistant Provost for Research of human subject research noncompliance problems or ethical issues of which they become aware;
- ⇒ Participate in IRB educational activities, including initial training and ongoing education provided by IRB personnel (e.g. CITI training courses);
- ⇒ Keep abreast of regulations and policies governing IRB review of research and the conduct of human subjects research, including Federal Regulations CFR Title 45 Part 46 Protection of Human Subjects, CFR Title 21 Parts 50 and 56 FDA Protection of Human Subjects and IRBs, the Belmont Report, and the Revised Common Rule;
- ⇒ Review and utilize the Pepperdine University *Protection of Human Subjects in Research: Policies and Procedures Manual*
- ⇒ Request training to learn to use the IRB eProtocol system or refresh your skills, as needed;
- ⇒ Maintain a current CITI certification. In addition to CITI requirements as a researcher, please take the CITI IRB Member Module.

Composition of Pepperdine's IRB Committee

- Minimum of at least 5 members.
- Composed of diverse gender, racial, and ethnic backgrounds.
- At least one member whose primary concerns are in nonscientific areas.
- At least one member who is not affiliated with Pepperdine University.
- Each year, a chairperson is selected for each IRB by the HPA.
- A co-chairperson may be selected on an as needed basis.

IRB Committee Member Recruitment:

The IRB Chairperson(s) will contact school deans/divisional deans of academic departments throughout the institution to seek recommendations for IRB members to replace members rotating off the committee. There is an attempt to achieve broad participation throughout the institution and, in particular, to ensure representation from those specialties that have a high volume of human studies research. The IRB also welcomes requests to join the IRB from members of the academic staff, and these requests are submitted to the individuals' academic chairs for consideration for recommendation to the IRB. Unscheduled vacancies on the committees that occur during the course of the year are filled in a similar fashion. IRB member rosters are confirmed by the Assistant Provost for Research.