

# IRB QUARTERLY NEWSLETTER

## SEPTEMBER 2017



### RECENT CHANGES

- Updated IRB manual
- Human Subjects Research Worksheet (New required form to be submitted with IRB research application)
- New IRB Research Application
- Unit Reviewer Requirement Updated
- Final Common Rule
- IRB Workshops Scheduled

### New (IRB) Investigator's Manual

The Institutional Review Board has established a revised IRB manual. The IRB manual has been updated to be more concise and user friendly. The revised manual and forms can be found on the Human Subjects webpage here: [www.pacific.edu/HumanSubjects](http://www.pacific.edu/HumanSubjects).

### New Human Subject Research Worksheet Form

All principal investigators (researchers) will need to complete and submit the (new form) Human Subjects Research Worksheet to our office prior to completing the IRB research application. This newly required form is designed to help you determine and record whether your research project constitutes research involving human subjects pursuant to federal regulations.

### Updated IRB Research Application (Human Subject Review Form)

The IRB research application has been modified and is now more user friendly for both new and experienced principal investigators. **Note:** Starting November 1<sup>st</sup>, 2017 older versions of the IRB research application will be returned and the newer form will be requested from the principal investigator.

### Unit Reviewer Policy Change

Another change includes a modification to the required departmental approvals. Principal investigators will **no longer be required to obtain unit reviewer approval and signature**. Faculty advisor approval is still required for student research.

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*“Final Rule implements new steps to better protect human subjects”*

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### **Federal Policy Revisions for Human Subject Protection (Final Common Rule)**

“The U.S. Department of Health and Human Services and fifteen other Federal Departments and Agencies have issued final revisions to the Federal Policy for the Protection of Human Subjects (the Common Rule). The “Final Rule” implements new steps to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators” – HHS.Gov



## IRB Review Category Timeline

### Contact Us

All IRB inquiries should be directed to [IRB@pacific.edu](mailto:IRB@pacific.edu)

#### OFFICE OF RESEARCH & SPONSORED PROGRAMS

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**EXEMPT REVIEW:** "Exempt Review" refers to research activities that meet very specific criteria established by DHHS as human subject research exempt from certain regulatory requirements. The research activities may be eligible for Exempt Review if there is minimal risk to research subjects and the only involvement of human subjects falls into one of the specific categories pursuant to [45 CFR § 46.104](#). Exempt Review does not mean that the investigator is exempt from filing the documentation necessary for the IRB to review and document the research.

**Duration of Review: 1-3 weeks**

**EXPEDITED REVIEW:** Research projects not eligible for Exempt Review may be eligible for Expedited Review if the research involves minimal risk. DHHS has established a list of categories of research deemed to involve minimal risk that may be reviewed by the IRB through Expedited Review, unless the review determines the research involves more than minimal risk. The full lists of categories of research that may be expedited are listed in our IRB Manual. Unless determined otherwise by the reviewer, the IRB will use the Expedited Review process: (1) if some or all of the research falls into one or more of the categories below and involves no more than minimal risk to subjects; (2) for minor changes in previously approved research during the period for which IRB approval is authorized; and (3) for Limited Review of exempt research activities.

**Duration of Review: 3-4- weeks**

**Full Review:** Research which involves more than minimal risk to the human subjects is not eligible for Exempt or Expedited Review, and will require Full Review by the IRB. Any research which involves children, prisoners, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons or individuals who may be subject to high risk must be provided Full Review of the IRB at a regular IRB Committee Meeting. Any research involving more than minimal risk to children requires Full Review.

**Duration of Review: 4+ weeks**

**Note: Review categories are ultimately decided by the IRB. Duration of review will be extended if modifications to application are requested.**

## IRB/Human Subjects Research Workshops

Date	Time	Location
Friday, September 29 <sup>th</sup>	12-1PM	DUC 211 A&B (Students)
Thursday, October 26 <sup>th</sup>	2-3PM	DUC 211 A&B
Thursday, November 16 <sup>th</sup>	10-11AM	Dugoni 214-2B
Thursday, December 14 <sup>th</sup>	2-3PM	DUC 211 A&B
Thursday, January 18 <sup>th</sup>	10:30-11:30 AM	McGeorge HR Training Room
Thursday, March 15 <sup>th</sup>	3-4PM	DUC 211 A&B (Students)

To RSVP in an IRB workshop or schedule a one-on-one appointment email [IRB@pacific.edu](mailto:IRB@pacific.edu)

**Faculty & Staff:** You may request a classroom or department workshop by sending request to [IRB@pacific.edu](mailto:IRB@pacific.edu)