

IRB NEWSLETTER – JUNE 2018



RECENT CHANGES

- Thesis/Dissertation CITI Requirement - Updated
- New Resource Available – FAQ Section
- New Resource Available – IRB Research Application Examples
- IRB Forms (2018) - Updated
- Full Board Review Schedule - Updated
- Final Rule Implementation Delayed
- IRB Workshops

Thesis/Dissertation CITI Requirement Updated

The Institutional Review Board has established a policy indicating that Thesis/Dissertation committee members are no longer required to have CITI training unless they are listed as **research personnel** (research team members) by the Principal Investigator.

New Resource Available – Frequently Asked Questions (FAQ) Section

Our Human Subjects webpage has been updated to now include an FAQ section for both new and active researchers.

New Resource Available – IRB Research Application Examples

Our office has developed examples of completed IRB research applications for the Exempt, Expedited, and Full Review risk level categories. For each example of an “approved protocol version” there will be an example of a “delayed protocol version”. The reason for this is, so that the Principal Investigators are able to contrast both “approved” and “delayed” versions of the protocols while they craft their own research proposal. The “Approved” protocol example will demonstrate strengths of a protocol which are “**Clarity, Consistency, and Conciseness**”. On the other hand, the “Delayed” protocol example will highlight common errors made by principal investigators that delay the review/approval process of that perspective research proposal.

IRB Forms Updated

Our office has updated the **Human Subjects Worksheet, IRB Research Application, and Existing Information/Biospecimen Research Application Forms**. The forms have been amended to provide clearer content and formatting to assist the research community with the IRB application process. The updated IRB forms are currently available and will be required for submission **starting June 15th, 2018 and forward**.

Full Board Review/IRB Meeting Schedule

The Institutional Review Board has voted to uphold scheduled meetings to evaluate full review research proposals in the following months: January, April, July and October. Specific dates/times will be updated on our webpage as soon as they become available. At this time it is important for faculty to inform potential student researchers to submit full review projects 30 days before a scheduled full board meeting (E.g. Submit a full review protocol in **December** for the January meeting, **March** for the April meeting, **June** for the July meeting, and **September** for October meeting).

Full Review research proposals submitted in the month below will be evaluated on the prospective IRB meeting listed on the right column	Institutional Review Board Meeting Schedule (Months)
October, November, December	January
January, February, March	April
April, May, June	July
July, August, September	October

“Revisions to the Federal Policy for the Protection of Human Subjects delayed”

Final Rule Implementation Date Delayed (Again)

Proposed Revisions to the Common Rule Delayed (Again): On April 19, 2018, the Department of Health and Human Services (HHS) and 16 other federal agencies announced a notice of Proposed Rulemaking (NPRM) proposing to delay the **implementation** (general compliance) date of the “**Final Rule**” (revisions to the Federal Policy for the Protection of Human Subjects – known as The “Common Rule”) for an additional 6 months (therefore the implementation of the “Final Rule” is now scheduled for **January 21, 2019**). The revised Common Rule implementation date was initially scheduled for January 19, 2018. Pacific's IRB will continue to function and remain in compliance with all pre-2018 Requirements during the period in which the implementation date for the “**Final Rule**” is delayed.



Contact Us

All IRB inquiries should be directed to IRB@pacific.edu

OFFICE OF RESEARCH & SPONSORED PROGRAMS

IRB & IACUC Administrator

Valerie Andeola | 209-946-7716

vandeola@pacific.edu

IRB Program Specialist

Gilbert Ojeda | 209-946-3903

gojeda1@pacific.edu

IRB/Human Subjects Research Workshops

Date	Time	Location
Thursday, September 13, 2018	1-2pm	DeRosa Center – 211A & B
October (Date-TBD)	TBD	Dugoni School of Dentistry
Thursday, November 8, 2018	3-4pm	DeRosa Center – 211A & B
Tuesday, December 4, 2018	1-2pm	DeRosa Center – 211A & B
Wednesday, January 23, 2019	3-4pm	(McGeorge School of Law) Muddox – Human Resources Training Room
Monday, February 11, 2019	1-2pm	DeRosa Center – 211A & B
Wednesday, March 20, 2019	3-4pm	DeRosa Center – 211A & B

All IRB related forms and schedules mentioned above can be found on the Human Subjects webpage here:

www.pacific.edu/HumanSubjects