UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: Meet the OIA Leadership Team

The Office of IRB Administration (OIA) has undergone a number of staffing changes in the last year with the majority of our current staff having been hired since January 2022. While OIA continues to be run by our two directors Ben Mooso (OIA Director) and Dr. Anthony Magit (OIA Medical Director), recent changes have also brought us three new members of the OIA leadership team:

Kacey Pratt, Assistant Director

Kacey Pratt has been with the UCSD IRB office for 10 years, previously serving as the analyst for the oncology committee and more recently, the neuroscience committee. She has been working in the field of IRB administration for nearly 15 years on both the east and west coasts. In her spare time, she enjoys the performing arts and spoiling her dogs.

Kacey began her role as OIA Assistant Director in April 2022. In her new role, Kacey oversees the team of analysts supporting the 6 IRB committees and the Stem Cell Research Oversight Committee (SCRO). As Assistant Director, Kacey's role also includes general oversight of the OIA along with the Directors.

Dan Gonzalez, Non-Committee Supervisor

Dan has been part of the University of California system for over 16 years and has extensive experience overseeing human subjects research. After completing 10 years at the UC Los Angeles IRB, Dan joined the Office of IRB Administration at UC San Diego in 2018.

Formerly serving as the Reliance Manager, Dan has now taken the role of Supervisor for the non-committee group, overseeing minimal risk research reviewed at the Exempt and Expedited levels, as well as reviewing administrative determinations of Non-Engagement and Not Human Subjects Research (NHSR). Dan is passionate about protecting the rights and welfare of humans participating in research and is proud to be part of a community that sparks discoveries that advance society. During his free time Dan enjoys playing soccer and golf, but most importantly spending time with his wife and two children.

Carmen Thompson, Reliance Supervisor

Carmen Thompson joined the UCSD OIA in August as IRB Reliance Supervisor. Prior to joining UCSD, she worked at WCG IRB for 8 years as our IRB liaison. There she worked with all levels of the organization to improve relationships with institutional clients. In that role, she began working directly with researchers and research teams with the implementation of the New Common Rule. Her interest in the field of IRB led her to obtaining her CIP certification in 2018. Prior to her working in the field of IRB, she worked in marketing and communications in the pharmaceutical industry.

Carmen currently lives in Puyallup, WA (pew-al-lup) with her husband, children and the cutest Malshi ever named Luna. She enjoys cooking, walking Luna, and Zumba.

Carmen is the newest addition to our office and recently started with OIA on August 8, 2022 in the role of Reliance Supervisor. As Reliance Supervisor, Carmen oversees and works alongside the team of analysts conducting administrative and local context reviews of studies submitted for reliance on external IRBs and executing reliance agreements.

To contact any members of OIA, please visit our Contact Us page.

NEW: Part 11 Compliance Training and Guidance from OCP

As the research community is aware, the FDA has provided guidance on the use of electronic records, in the conduct of research, in regards to the Code of Federal Regulations Title 21, Part 11. The University of California San Diego has produced a Position Statement on the issue, specifically in regards to the EPIC system. As well, a number of departments have provided guidance and attestations regarding compliance with the regulations.

The Office of Compliance and Privacy has posted a brief informational presentation to their intranet site at https://suite.ucsd.edu/departments/compliance/research-compliance/Pages/21-CFR-Part-11-Compliance.aspx which provides not only guidance to our research community, but can be shared with our research sponsors and partners, as an affirmation of our institution's compliance.

For questions, please contact OCP at hscomply@health.ucsd.edu.

NEW: sIRB/Reliance Webpage

Have you heard about single IRB (sIRB) or reliances and wanted to learn more? Do you want to learn more about how OIA reviews requests to serve as the sIRB for a study or to rely on an external IRB? Has a sponsor ever asked you if the UCSD IRB is signed on to SMART IRB or has an agreement with WCG, Advarra, or Sterling?

To answer these questions and more the OIA Reliance Team has developed our IRB Reliance webpage now available here.

Have a question that isn't addressed on this page? Write us an email at irbrely@ucsd.edu.

EVENT: OHRP Research Community Forum October 25th & 26th

On behalf of our sister campus, UC Davis, we want to make you aware of the OHRP Research Community Forum being hosted by the University of Nevada, Reno, UC Davis, and the University of Nevada, Las Vegas in Reno, NV on October 25th and 26th, 2022. The theme of the event is "Trust, Technology, and Consent" and is geared towards human subjects researchers in both biomedical and social/behavioral disciplines. For more information about the event, please see their webpage here.

Reminder: Deadline to Begin Using New ICF, Assent, and Protocol Templates

Back in December 2021, OIA quietly rolled out three new protocol templates and made them available on our forms webpage here. These templates were designed to complement the Kuali application and not require duplicative information.

With the new rollout of the updated ICF and assent templates, we're ready to make both sets of templates official. As such, starting September 1st, all new studies (except for secondary use studies which only require the Kuali application) will be required to use the master protocol if one exists (e.g. from an industry sponsor, cooperative group, etc.). Otherwise, you must use one of the three new protocol templates.

Additionally, all new UCSD studies requiring an informed consent or assent document will be required to use the new ICF and assent templates starting September 1st.

Reminder: Renewal of Business Systems Accounts

As we approach the end of 2022 we are now past the one year anniversary of the beginning of the Kuali transition. Since access to Kuali is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kuali. Those accounts are generally good for only a year and need to be renewed. As such, we want to remind everyone about this.

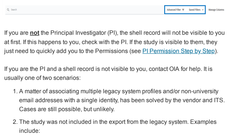
If you are a **user** who has a business systems account that you use to access Kuali, check in with the department who sponsored your account to see if there is anything they need you to do to ensure your account is renewed.

If you have **sponsored** someone for a business systems account, please be sure to follow your departmental policies on renewing (or not) accounts in a timely fashion so that requested do not lose access to Kuali. Furthermore, please be on the lookout for automated emails asking you to renew access for these individuals throughout the course of the year.

Reminder: Troubleshooting Missing Studies

OIA exported limited information from the legacy e-IRB Services system to create shell records for studies in Kuali. Although the export went smoothly, some users don't see all the studies they expect. Here's why (and what to do if it happens to you):

The first step for any user is to make sure no Advanced Filter or Saved Filters are limiting views (buttons near the right of the Manage Protocols screen; see blue box in screenshot).



If you are not the Principal Investigator (PI), the shell record will not be visible to you at first. If this happens to you, check with the PI. If the study is visible to them, they just need to quickly add you to the Permissions (see PI Permission Step by Step).

If you are the PI and a shell record is not visible to you, contact OIA for help. It is usually one of two scenarios:

1. A matter of associating multiple legacy system profiles and/or non-university email addresses with a single identity, has been solved by the vendor and ITS. Cases are still possible, but unlikely.
2. The study was not included in the export from the legacy system. Examples include:
   - some older reliances on external IRBs,
   - new studies that were submitted in the legacy system after mid-June, or
   - new studies that were on hold pending approval from an ancillary review body.

Reminder: Getting Help

Kuali iRB Knowledge Base Articles (KBAs) are part of the growing Research Knowledge Base. We generate new articles and update older articles in response to trends in questions or problems submitted by the research community.

Install and enable the WalkMe extension in your browser to get contextual help as you navigate Kuali iRB. This includes tips about using the system as well as key regulatory background. The extension is approved for Campus and Health Sciences computers.

Contact OIA by email at irb@ucsd.edu or by voicemail at 858.246.4777 with questions or to report errors/issues. For questions about Kuali in relation to single IRB/reliance arrangements, contact irbrely@ucsd.edu.

Please be sure to include the protocol number, if available. This will help the OIA team triage and troubleshoot.

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