UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

November 9, 2023

In This Issue

New Investigator SOPs

Today, OIA is pleased to release to the research community our new set of SOPs for our investigators which are now published on our Guidance page. Thanks to the hard work of our staff and our community of stakeholders, these SOPs are not meant to represent a significant change to research processes. Rather they are intended to codify OIA's expectations of investigators based on the regulations governing human subjects research and best practices.

Note: While these SOPs are not meant to represent a significant process change, research teams and PIs should review the SOPs to ensure their own processes are consistent with these SOPs.

Within this set of SOPs investigators will find SOPs describing:

- Who can serve as a legally authorized representative or guardian for the purposes of providing consent (OIA-013)
- How to conduct the consent process (OIA-090)
- How to document consent when documentation has not been waived by the IRB (OIA-091)
- How to conduct the assent process for adults unable to consent and children (OIA-092)

- How to document assent when documentation is required by the IRB (OIA-093)
- What can be posted on the internet (including social media) for recruitment purposes without seeking specific content approval from the IRB (OIA-094)

In addition to the above SOPs, investigators and research teams will find a new IRB Handbook (OIA-103) which details all the obligations of those conducting human subjects research and provides some helpful insights about the IRB, preparing documents for use in human subjects research, and additional federal criteria that must be met for certain studies.

As always, other offices within the institution including departments and individual research teams may have their own SOPs which mirror or go above and beyond the requirements listed in these SOPs.

Special Note About Consent and Assent SOPs

Based on feedback received during our stakeholder review process, we wanted to say a few words about the consent and assent SOPs (OIA-090, OIA-091, OIA-092, and OIA-093) published today.

These SOPs primarily address the initial process of consenting or assenting an individual and so are written with that in mind. Nonetheless, OIA affirms that consent and assent are ongoing processes and do not simply stop once a form has been signed. Investigators and research teams should use the principles contained within these SOPs (e.g. soliciting questions from participants, making sure they understand what is going to happen, giving them sufficient time to make decisions, etc.) as a part of the ongoing process of consent and assent.

The SOPs on documentation of consent (OIA-091) and assent (OIA-093) only cover the requirements codified in the Common Rule (45 CFR 46.117) and FDA (21 CFR 50.27) regulations. In addition to these requirements, there may be other institutional, departmental, and team-specific requirements which investigators and research teams are obligated to adhere to (e.g. CRF completion, notes in subject binders, EMR/EHR documentation, etc.). These SOPs released today are not designed to address those requirements nor do they override or replace those requirements as they would be outside of OIA's purview. These SOPs are in addition to any other requirements.

Lastly, these SOPs use the regulatory terminology of referring to someone enrolling in human subjects research as a "subject." While "participant" is the preferred term used for these individuals in any subject/participant-facing material, we have opted to use the term "subject" in these SOPs to align with the regulatory text which uses "subject" instead of "participant."

Special Note About the IRB Handbook

While the IRB Handbook is a comprehensive document with many important and informative sections, we want to highlight two of the most important sections for investigators and research teams to be aware of. If you only read two sections of the IRB Handbook today (and we hope you read them all), these are the two not to miss.

First we want to highlight the section on pages 15-17 titled "What are my obligations after IRB approval?" This section contains a listing of all the obligations investigators assume when they seek IRB approval for a study. It covers everything from personally conducting and overseeing the research and not conducting research without IRB approval to ensuring that research is closed out with the IRB once it is completed.

Second we want to highlight Appendix A on pages 26 and 27. This appendix covers all the reportable events and when they are required to be submitted to the IRB. Of note, changes to the protocol done to prevent an apparent immediate hazard, emergency uses of a test article without our IRB review, and premature suspension or termination of a research study by anyone other than the IRB are all reportable within 5 business days. Other reportable events are categorized into events required to be reported within 10 business days and those reportable at the time of continuing review.

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