UCLA Research Administration

OHRPP Updates

October 10, 2019

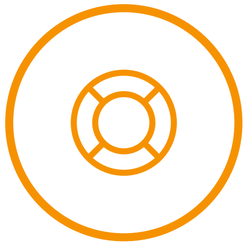
OHRPP Updates

- Single IRB Mandate
- Consent Templates Update
- Subscribe to HRN
- OHRPP Training & what's on the horizon

sIRB Mandate

NIH grants (with grant application due dates from January 25, 2018 onward) for multi-site human subject research require that a *single IRB ("sIRB")* review for all participating sites. The NIH has prepared a FAQ on the NIH sIRB requirement.

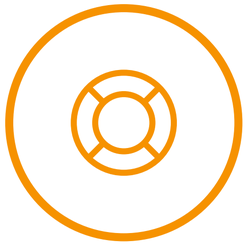
sIRB Mandate



The revised common rule *expands this mandate* to require sIRB review for IRB review of cooperative research funded or conducted by *any* Federal agency/department in the US.

- **This part of the revised common rule *goes into effect on January 21, 2020***

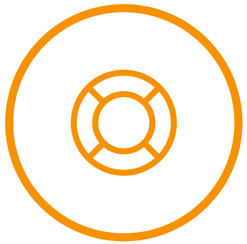
sIRB Mandate



Exceptions to the sIRB mandate:

- When more than single IRB review is required by law (such as tribal law passed by the governing body of an American Indian or Alaskan Native tribe)
- When the federal department/agency conducting or supporting the research determines that sIRB is not appropriate (this is expected to be RARE)

sIRB Mandate



sIRB recommendations:

- **If an investigator wants a UCLA IRB to be the sIRB, *contact OHRPP early* *reliance@research.ucla.edu***
- **The UCLA IRB *may or may not* be able to act as the sIRB for your cooperative project**
- ***If* the UCLA IRB cannot act as the sIRB for your cooperative project, we can direct you to alternative IRBs (including commercial IRBs)**

Consent Template Updates

The OHRPP updates consent templates when:

- There are *changes in the regulations* (such as the revised common rule)
- *OHRP and/or FDA issue guidance* that impact the consent template verbiage or instructions
- There are *changes in UC or UCLA policy* that impact the consent template verbiage or instructions

Consent Template Updates

With the *revised common rule*, a number of changes were made to required elements of the consent form:

- **"Key information" summary at the beginning of the form**
- **Whole document must be written to "facilitate understanding"**
- **Statement about possible secondary use of data/specimens**
- **Statement about potential commercial profit and whether the participant will or will not share in that profit**
- **Statement about return of clinically-relevant individual test results**
- **Statement about whether or not the research will include whole genome/whole exome sequencing (as applicable)**

Consent Template Updates

History:

- **The last update of the consent templates was in 2011**
- **The revised common rule relevant to consents went into effect on January 21, 2019**
- **Since then (in the absence of a revised template), the IRB has been sending investigators study-specific consent change requests, based on our revised common rule implementation page, to meet the requirements of the new regulations**

Consent Template Updates

We have been waiting for OHRP guidance/tools for "key information" before issuing the updated consent templates.

- *We are no longer waiting, as guidance does not appear to be forthcoming*
- We anticipate rolling out the new templates ***within the month***
- If OHRP issues guidance at a future date that is not aligned with our template, we will modify the template again

Consent Template Updates

Roll-out of revised consent templates:

- New templates will be uploaded to the ORHPP website
- Informational/training session(s) on this new consent content will be provided by OHRPP to the research community
- A notice will be sent out through the OHRPP listserv (a.k.a. "Human Research News") to announce the availability of the new templates and time/location of training session(s)

OHRPP “Human Research News” - Reminder

To be the first to know when OHRPP releases guidance and other updates, please subscribe to our listserv

- ***To subscribe, send an email (blank subject and body) to: investigators-l+subscribe@lists.ucla.edu***

OHRPP Training Opportunities

- ✓ **OHRPP Quality Improvement Unit *will come to your division/department for IRB-related training*, customized to your needs.**
- ✓ **"*Learn at Lunch*" training series will re-launch in early 2020. Please send in your suggestions for topics.**

➢ *To request a custom training or suggest a Learn at Lunch topic, please contact: OHRPP Assistant Director, Education & Quality Improvement Moore Rhys (310) 794-6339*

OHRPP "on the horizon"

- The *annual PI* (and faculty sponsor) *assurance* function in webIRB is coming for certain types of studies
- The PAR application is being revised in webIRB

OHRPP "on the horizon"

OHRPP is hiring!

- **One position to support the Quality Improvement Unit of OHRPP (education, post-approval monitoring, and quality improvement)**
- **One position to support the Director including for special projects (such as AAHRPP accreditation)**

Any Questions?

Contact Information

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http://ora.research.ucla.edu/ohrpp

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