OHRPP Updates

- Single IRB Mandate
- Consent Templates Update
- Subscribe to HRN
- OHRPP Training & what’s on the horizon
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.
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
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 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)
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
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)
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)
Contact Information

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

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