UCLA OHRPP
Office of the Human Research Protection Program

December 22, 2017

Dear UCLA Research Community:

Multisite research studies increasingly involve arrangements for a single IRB to review for multiple sites. Such arrangements reduce redundancy and variation but require additional coordination and communication to account for state law or other local context. See below for upcoming NIH requirements and other important information.

NIH Policy
As discussed at several sessions of the UCLA Research Administrators Forum, NIH released a policy in June 2016 requiring that domestic sites conducting the same research protocol rely on a single IRB. This policy will take effect with grant applications due on or after January 25, 2018 and contract solicitations issued on or after January 25, 2018.

With the recent changes to NIH submission forms, your proposal will need to describe compliance with the policy. One required element is a single IRB plan- a sample is attached.

The NIH policy does allow for certain direct costs related to single IRB arrangements. We expect to have cost information for UCLA in early January.

Please see the NIH FAQ document for additional details about the policy.

If you are preparing a multisite proposal or are part of another institution's multisite proposal for an upcoming NIH deadline, please contact irbreliance@research.ucla.edu so that we can coordinate with you and the Office of Contracts and Grant Administration to best meet the NIH policy.

Other Federal Sponsors
Upcoming regulatory changes include a broader requirement for all federally-funded research. The compliance date is January 2020, so no action is needed on your part at this time.

Non-Federal Sponsors
Industry or other sponsors may ask if you are able to rely on a review provided by another institution or by a commercial IRB. If the proposed arrangement is not already described on our website, please contact us to discuss options.

Single IRB Options
UCLA has a long history of single IRB arrangements dating back to its 2006 MOU with the RAND Corporation. The RAND, University of California, UCLA CTSI and NCI Central IRB arrangements are the most frequently used.

Two recent changes have expanded the available options:

- UCLA is a signatory to the SMART IRB agreement. Under SMART IRB, any combination of the 300+ signatory institutions can enter into a single IRB arrangement for any study regardless of funding source without negotiating a separate agreement. **Use of SMART IRB is UCLA's preferred arrangement**.
- The scope of studies that may be sent to a commercial IRB has been expanded to include device trials and Phase I or II drug trials, as long as the trials are industry-authored and –sponsored. We currently have master agreements with several major commercial IRBs.

Single IRB Tools & Guidance
A page on the OHRPP website is dedicated to single IRB arrangements. We will be updating this site with guidance, tools and training materials as the NIH and other requirements evolve.

Whether a UCLA IRB is reviewing for your collaborators or a non-UCLA IRB is reviewing for you, you will need to enter the study in webIRB. Please reach out to us for instructions before starting your application.

webIRB includes questions that solicit information about the single IRB arrangement. If a non-UCLA IRB is reviewing for you, the registration in webIRB is a shortened version of the usual application and the UCLA IRB does not conduct a second review.

Attached to this message is the latest version of a checklist to use when non-UCLA IRBs ask you to modify the consent template for local use.

For Assistance
OHRPP has a dedicated e-mail address for inquiries about single IRB. Please contact us as soon as possible in your planning process.

Happy Holidays,
UCLA OHRPP

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This message was originally sent via the Human Research News mailing list. If you would like to subscribe to future announcements, please send an e-mail to: investigators-l+subscribe@lists.ucla.edu. The subject line and body of the e-mail can be blank.