sIRB Review & Proposal Submission

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Background

- sIRB requirement established to mitigate perceived inefficiencies in multiple IRB reviews of multisite studies (i.e. streamline reviews)
- NIH implemented sIRB requirement effective 1/25/2018
- Revised Common Rule (45 CFR 46) went into effect in January 2019 with a similar, but different sIRB requirement for most federally funded HSR overseen by OHRP. The sIRB compliance date under 45 CFR 46.114(b) was 1/20/20.

sIRB per NIH Requirements

- Applies to applications and/or contract solicitations for **multi-site, domestic, non-exempt** HSR
- Same protocol is used at all sites
- Applies to career development (K) and fellowship (F) awards also
- For clinical trials there are 4 key questions:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Your study is considered to meet the NIH definition of a clinical trial even if:

- Your study uses healthy participants, or does not include a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study utilizes a behavioral intervention
- Your study uses an intervention for the purposes of understanding fundamental aspects of a phenomenon

Under the Common Rule …. sIRB

- Applies to most federally- funded, domestic HSR conducted at more than one institution (i.e. any agency that has signed on to the Revised Common Rule)
- Some exceptions when OHRP policy overlaps with NIH
- ***Each site could be engaged in different procedures with subjects, which differs from NIH's sIRB policy***

So why the fuss over sIRBs?

- Submission of plan with the proposal describing the sIRB arrangement!

- Often the Lead Institution is the IRB of Record, but does not have to be. Must consider:
  - Capacity and Expertise of IRB at Lead Institution
  - Policies about serving as IRB of Record
  - How many other institutions are involved
  - Resources of the IRB's institution and processes needed for multi-institutional project
  - Is it an NIH Clinical Trial or a federally funded multi-institutional project?
  - What will it cost other institutions in project to rely on the Lead's IRB?
  - Build into the budget money for both sides

At proposal submission time…

- Make sure the PI communicates with OPHS in advance to ensure:
  - 1. If UCB is the Lead Institution, that we (CPHS/OPHS) can handle serving as the IRB of record for all Institutions. ***This is a critical step!***
  - 2. If we cannot not serve as the Reviewing IRB, that there is an alternate plan for IRB review which can be proposed (e.g. commercial IRB, a different academic institution, etc.); OR,
  - 3. A request is submitted to the federal agency requesting a waiver of the sIRB requirement.

OPHS must be notified prior to submission if a proposal includes conducting HSR at more than one institution. And, the budget for UCB and all subcontracts to engaged institutions must include money to cover the cost of IRB review by an sIRB!

Resources

- **NIH** https://grants.nih.gov/policy/humansubjects/single-irb-policy-multi-site-research.htm
- **NIH Single IRB & Exceptions Process Webinar** https://grants.nih.gov/node/1272
- **NIH Costing FAQs**
  - https://osp.od.nih.gov/clinical-research/nih-policy-on-the-use-of-a-single-irb-for-multi-site-research-faqs-on-costs/
- **45 CFR 46.114(b) sIRB** guidance:
  - https://www.hhs.gov/ohrp/regulations-and-policy/single-irb-requirement/index.html

Thanks for listening today!

Questions?