SINGLE IRB & EXCEPTIONS PROCESS WEBINAR

Q&A SCRIPT

I'm going to go to questions from the audience. The first being:

1. **Does the IRB that's being determined to be the single IRB of record have to be accredited?**

   I assume this person means AAHRPP accredited? And the answer is no, not for the NIH policy.

2. **The next question: How will you address an issue where one or more of the other IRBs, some of the local IRBs from the other sites, so participating sites, post-award insist on reviewing the protocol themselves as a local IRB rather than relying on the single IRB of record?**

   This is really an issue with the investigators. The NIH policy has the expectation that all participating sites, unless there is an exception, should rely on the single IRB of record. NIH does not prevent or stop local IRBs from reviewing the protocol, however unless there is an exception granted, NIH will not pay for this separate to the other costs of the award. So we cannot prevent a local IRB from doing its own review, however it cannot be paid for by the NIH funding. Unless there's an exception.

3. **The next question is have you heard what the VA, veteran affairs, policy, is going to be? Presently they do not allow IAA's or authorization agreements.**

   Currently the VA and the D.O.D. have very stringent or strict requirements if they are relying on an IRB that is not their own. And when those policies are in existence that would be a policy-based exception. So if a site is the VA, you can identify that site in your single IRB plan as requiring an exception to the single IRB review because of the VA's policy. So it just needs to be noted in the single IRB plan.

4. **Next question, what SACHRP is doing to work on this? That is the advisory committee for the office of human protection so we don't know what it is working on at that time, but we get the information when most others do. Are you going to explain what justifications are acceptable and which are not?**

   We cannot do that at this time because we don't know. So NIH is creating an exceptions review committee that will decide which justifications are acceptable. We are working on a plan to make sure that -- first what we do know is that the Program Officer or Contracting Officer who submits your request to the Review

Committee- will communicate with the applicant or investigator what the decision was. So you will have information about what the Review Committee decided on your particular exception request. We're also working on a plan to publicize acceptable justifications and those that are not considered acceptable on a kind of case study basis. So that's in works and you will get more information about that as it's developed.

5. **The next question is are you asking for actual rosters and IRB requirements to be submitted?**

   No, we're not. The IRB rosters go to OHRP. They do not come to NIH. And we are not asking that the reliance agreement or the communication plan be shared in your application. Now, a Program Officer or Contracting Officer may request that documentation specifically for your application or proposal that's going to be on a case-by-case basis and that's at the discretion of the Program staff.

6. **The question is about the exceptions review committee. Who will be on the review committee?**

   That would be NIH staff members.

7. **And will organizations have an ability to make the case directly and/or appeal?**

   So a request for a single IRB exception will be directed to the Review Committee by the Program Officer of the grant application, or the Contracting Officer of the proposal, and so all interaction with the Committee will be done by NIH staff who would then communicate the decision back to our investigators. There's no formal appeals process. If there is additional information, then we would recommend that the investigators work with the Program Officer or the Contracting Officer to make sure that the Review Committee has all pertinent information to make their decision.

8. **Any advice for handling study personnel across all sites?**

   We recommend you work with them early and communicate openly as early as possible. NIH cannot intervene in those matters for the most part, but we recommend that once you have identified your sites, you work with the other investigators to determine the best IRB that everyone is comfortable with, communication is probably your biggest asset in that relationship.

9. **What if nine out of ten sites agree to a single IRB? This is that one site that no longer is part of the multi-center award?**

   So again, if there's one holdout site, we strongly recommend -- and there is no policy-based exception for that site, we strongly recommend that you work with

the investigators. That site is not automatically removed from the award, and it's at the NIH's discretion to not provide funding to that site if the site cannot or does not agree to rely on the single IRB, but again that's a case by case decision. And it's up to the Program staff of that award. There's no easy answer for that. We really hope that all 10 sites, all 50 sites can agree to the selected single IRB of record and that's why we really stress communicating, and communicating early. If you have an application that you are currently writing and you know the sites that you would like to work with, this is the opportunity now to discuss with them the single IRB policy.

10. **Someone asked about the position, so what is the NIH's positions of the Exceptions Review Committee?**

    They are all senior level staff within their own offices.

11. **Here's a question for budget and costs. Does the institutional F&A rate have to be budgeted for IRB review?**

    The direct cost for single IRBs should be activities that are above and beyond what's included in your F&A rate, however, if you do have any questions about how your F&A rate is calculated and whether any adjustments need to be made to that, we recommend consulting with your rate negotiator at your cognizant agency.

12. **Next question is: it seems that more detail was given for the single IRB plan for contracts. Do single IRB plans for grants also require composition of IRB, etcetera?**

    So the single IRB plan is the same for grants and contracts. I'm not sure that we are requesting the composition of the IRB, and I don't believe that's the case for contracts. That is not the case for contracts. So the plan itself is the same for grants and contracts. If you found different information, please contact us offline and we can correct that.

13. **Do statistical and/or operational center for research networks need to abide by the single IRB policy and accede IRB approval to a single IRB? For example, we support a network under a cooperative under several research sites. One of our statistical centers does not have any contact with participants, specimen or identifiers. But does conduct analysis of coded human subjects data. The relevant statisticians are members of the research protocol investigative teams, therefore, they also have IRB review approval.**

    This is a couple of layers. So the easy answer is if a site is engaged in non-exempt human subjects research and it's a shared protocol among over all research sites -- several different sites, so the same protocol would be submitted

to several IRBs. Currently, if you're applying for a grant or contract after January 25th, 2018, all of the sites that are using the shared protocol will fall under the single IRB policy. So the question here had several different layers and I'm not sure if I have enough information to answer specifically to this particular network, but if the statisticians or the statistical center is not conducting the non-exempt human subjects research, and does not have a shared protocol with other sites, then that center does not have to rely on the single IRB of record.

14. **If grant applications are already submitted and under review, but then don't get funded and need to be resubmitted after January 25th, 2018, must the single IRB now be included in the plan and budget when it was not there on the first application?**

    So the answer is yes. A resubmission that is applying for a due date on or after January 25th will now fall under the single IRB policy.

15. **So the next question is: what are some examples of compelling justifications?**

    At this time the committee has not met and decided, so we're unable to provide any, but again, as we move forward we hope to provide more information to the public as to what this means and what's acceptable and what is not.

16. **Are there any special considerations for studies that require waiver of consent for emergency requirements for community innovation and input?**

    There are none at this time. If that particular study feels like that a site should have an exception because of a compelling justification, we would recommend that that information is provided in the application or proposal and be given to the Review Committee. Again, we haven't made any decisions on the compelling justifications.

17. **Are costs of single IRB inclusive of the direct costs cap of a grant?**

    If you're applying to a grants funding opportunity that has a direct cost cap, any direct costs that you're asking for a single IRB must fit within that cap. Single IRB costs are not excluded from direct cost caps.

18. **Does a single IRB require co-PIs, institutions, to have a reliance agreement, or only sites collecting data?**

    This is what the assumption that the co-PI's institutions are not conducting the nonexempt human subjects research, so if that's the case, again, the only sites that are required -- that are expected to rely on the single IRB of record are those that are sharing or conducting the same protocol. So if there are co-PIs or different PIs at different institutions that are not doing -- or conducting the same

protocol, they're not expected to sign the reliance agreement or rely on the single IRB of record. However, they can. The single IRB of record can be the IRB for the entire network if that's what the investigators choose, but there's no expectation that they do.

19. **If the NIH exceptions review committee will review and reject compelling justifications based on past precedent, where can one look to find past precedent?**

    So I think this is probably going to be the last question I ask about the Review Committee because there's just not much information. We will provide information for the research community when those past precedents, probably on a case study basis on some of the things that the Review Committee has adjudicated on. At this time the Review Committee has not seen any exception requests so there's very little information to provide.

20. **Can you please define what is meant by the same protocol at each site? This makes sense for clinical trials, but when you say that this policy applies to all human subjects research, not just clinical trials, it seems more vague. For example, we can see a protocol that is not a clinical trial where multiple sites will be working on different parts of the protocol. Would this type of work require a single IRB?**

    Okay. So I agree, we can make the definition vague, however, I'm not sure if I can make it any more straightforward with the exception because there's not much to work on. But again, if multiple sites have a protocol that they would submit to their own IRB, and it's the same protocol at multiple sites, then those sites should rely on the single IRB of record.

    So we have in our FAQs, there's a question that says: what is meant by the same research protocol? What if two sites are conducting very similar protocols, the study populations are the only differences?

    So protocols that address the same research questions, involve the same methodologies and have the same outcomes are considered to be the same research protocol. Investigators who have questions should discuss them with the Program Official listed on the Funding Opportunity Announcement or the Contracting Officer in the solicitation. Hopefully that helps. Again, that's going to be gray depending on the study. And ICs may need to use their own discretion in determining what the same protocol is.

21. **Next question: What should sub-contractors performance sites do at this time in terms of the single IRB change implementation? Presumably wait to find out which IRB is selected as the single IRB?**

That's a good question. Again, I think -- I like to stress communication. This is an opportunity for the performance sites to talk with the PIs and figure out which way the PI -- which direction the PIs are going for the single IRB of record. If the performance sites know that they have a compelling justification for an exception, they need to communicate that to the Principal Investigator so it can be noted and identified in the single IRB plan at the time of application. So again, communication is the key here.

22. **Next question: Our current institutional policy has restrictions on the type of studies that can rely on an external IRB. Would these policies qualify for automatic exception?**

    I don't think so unless those policies are based in some local, state or maybe Federal regulation, then at this time that probably would not qualify, but we cannot tell you not to request an exception if you feel that it's necessary.

23. **Our site participates in clinical trials as a member of Alliance, so is it up to Alliance to designate the single IRB?**

    Again, I believe that the investigators and the members of Alliance would decide that if you have -- I assume Alliance is a collection of sites that have already signed a reliance agreement or already designated to work together, so those decisions are up to the investigator.

24. **If a government provided single IRB is used, what is the expected turnaround time for the review?**

    I'm not sure which Government provided single IRB you may be referring to. NCI, the National Cancer Institute, has a Central IRB that many of our studies use. And I don't know the turnaround time. I assume this is going to be dependent on the IRB itself.

25. **What does membership to adequately review the study mean for NIH purposes? i.e., meet FDA roster requirements or something more?**

    So membership to adequately review the study is a phrase from the Common Rule, 45 CFR 46, for the protection of human subjects. It requires -- it describes a quorum to the IRB. So there should be expertise relevant to the study that's been reviewed. Again, NIH doesn't make that determination, it going to be internal and at the institutional level.

26. **Next question. Are there examples of policies that would be accepted for an exception.**

Not at this time. So other than the single IRB based policy based exceptions and the time limited exception for ancillary studies, we cannot identify any of the compelling justification exceptions at this time.

27. **For studies with IRB approval before January 25th, 2018 that are facing IRB continuing review, does this mean that single IRB review will be required or at the time the grant needs reviewed by NIH?**

    So it's only related to the NIH review or granting process. So this is not related to the IRB approval or the revised Common Rule. So NIH's policy is for NIH grants with a due date on or after January 25th, 2018 or NIH contracts, R&D contracts that are responding to a solicitation that was published on or after January 25th, 2018. So if your IRB approval is before or after that date, it's irrelevant to our policy.

28. **So you mentioned that VA sites would be considered an exception. Would this also apply to a situation where the non-profit corporation for VA-based studies is the prime grantee but has several non-VA institutions as sub-awardees?**

    So if the non-VA institutions are not subject to the VA policy, then those sites would not be accepted.

29. **Next question: If you have a combination of foreign, such as Canada, and domestic sites. So the domestic sites would be expected to rely on a single IRB of record whereas the foreign sites would not be expected to?**

    They can if they choose to. They can coordinate their own single IRB for their own sites if they would like to, but they're not expected to rely on the domestic US-based single IRB.

30. **Do institutions have to have the single IRB agreements in place before the contract or grant is submitted to NIH for consideration?**

    No. We hope that you have as much as possible, you've identified perhaps a single IRB of record, but you really have to indicate that the sites will sign the reliance agreement, they will rely on the single IRB.

31. **Next question: What happens if you underestimate the single IRB budget and the entire budget has been depleted halfway through the study?**

    So in that case I would recommend contacting the NIH Grants Management Specialist for your award. You may have to discuss options such as an Administrative Supplement in order to cover costs that were unforeseen at the time of the original grant application, but you will have to consult with the NIH IC

in your Grants Management Specialist to see what options are available at that time.

32. **Next question: If there is an established single IRB for 10 sites for an approved study and another institution wants to take over the single IRB with the agreement of the overall study PI, is there a process recommended for this?**

    This process wouldn't be much different currently than if the study needed to move to a different IRB. So the same process would be considered there. So the new single IRB of record would need to do the appropriate reviews and there needs to be appropriate documentation of that transfer.

33. **Next question: Does this apply to non-competitive renewals?**

    No, it does not. When those grants come up for their re-competition, so when they undergo the next funding cycle, then they will fall under the single IRB policy.

34. **Are foreign sites excluded as prime applicants or as participating sites or both?**

    So they're excluded as both. However, if they are domestic sites to a study with a foreign prime awardee, the domestic sites are expected to rely on a single IRB.

35. **So did I misspeak? I thought the IRB rule applied when the announcement came out not when the application is submitted.**

    So again, for the NIH's single IRB policy, the implementation date is January 25th, 2018, so that's for grants that are due on or after for grant review, that are due on or after January 25th, 2018 or R&D contracts that are responding to a contract solicitation that was published on or after January 25th, 2018. The NIH policy is not related to IRB review or the IRB review date. They're very separate things.

36. **Next question: If the protocol or research procedures are identical in all sites except that each site will study a different human condition or variable, is this considered as “conducting the same study” or under the single IRB policy?**

    So when there are variations in the study it really depends on what would be submitted to an IRB. So if a large protocol that includes every different condition is included in the IRB protocol and would be submitted to each individual site, then those sites would be expected to use a single IRB. However, if the different conditions require a separate protocol, then that study would not fall under the policy. There may be some discretion there and I would really recommend that

you work with your Program Officer if you're not sure if your study falls under the policy or not.

37. **Once the slides have been distributed they can be posted locally.**

38. **I understand that a single IRB of record is required, but can a site choose to submit materials to their own institutional IRBs as well as a single Central IRB? It seems that sites may be unwilling to completely forego their IRBs although they may be willing to submit to both.**

    So we strangely recommend that you involve your local IRB. The local IRB should be providing the single IRB with any local context, any additional information that's important to your particular or that particular site. NIH cannot or will not pay for local IRB review when there is a single IRB of record that the sites have agreed to rely on, but the local IRBs or the human research protection programs should very much be involved and informed in the study because they are providing additional information to the single IRB of record. The policy approximately is really just for the actual review of the protocol, but all other information or input should be gathered by local IRBs and HRPPs.

39. **So what is required of the single IRB plan if you're not asking for actual rosters and agreements? So is this just a Word document each site writes as it wants?**

    Yes. So it should be a succinct document that identifies a single IRB of record, indicates that all sites, even those selected or added after award, will rely on the single IRB, that all sites will sign the reliance agreement and are aware of the communication plan, and who is going to manage the information for the study. The single IRB plan will also include any exceptions. So if you have policy-based exceptions, if you have a site that involves a tribal community or population, that site then is excepted to the policy so that site can have local IRB review. If you have a time limited exception for ancillary studies, you want to identify that in your single IRB plan, or if you think you have one or more sites that need or require local IRB because they have a compelling justification. So those are the pieces to the single IRB plan. Also, all the instructions are available in the application instruction Guide, and there are links for that throughout the presentation, as well as easy Google.

40. **Returning to the questions of contracts that support multiple proposals: Does the proposal require multiple single IRB agreements and forms?**

    You would propose and have that based upon whether or not you would need multiple IRBs. Quite often you would be able to use one IRB to review multiple protocols. As long as the IRB is appropriate for the review and acceptable, you could have just one single IRB for all the protocols.

41. **Should the single IRB plan include letters of support from each institution's IRB office regarding willingness to utilize a single IRB?**

    That doesn't seem to be necessary based on the instruction, so I would say no at this time.

42. **So there's a follow-up on the same protocol question. So I'm concerned about what happens when we see a pragmatic trial or other clinical trial that has the 'same protocol' in the grant proposal, but the implementation at the sites is very different. Questions are the same outcome measures, are the same, but implementation -- implementing the study and perhaps intervention are going to vary greatly.**

    Again, if all of the levels -- everything that's being conducted under the protocol is written in the protocol and that one protocol is being shared at multiple sites, the expectation is that those sites will rely on a single IRB. If the protocol that's submitted to the IRBs are different, then that should would not fall under the single IRB policy.

43. **And someone's answered one of the previous questions and it's regarding the NCI Central IRB, so:**

    Turnaround time for the NCI Central IRB studies is usually 30 days. Thank you very much for that.

44. **Next question: Would a single award with two different protocols require each protocol to be reviewed by the single IRB separately or under one submission?**

    So this is the assumption that there are multiple sites that are conducting a shared protocol, that they're not just two different protocols and two different sites. So multiple sites are conducting the same protocol, but there are two or more protocols within that grant application. So again, all the protocols that are shared will be expected to use the single IRB. You can provide a different single IRB plan for each of the protocols if it's appropriate. So if the first protocol is using ABC IRB, then that plan should be uploaded for that protocol. And if the second protocol is using XYZ IRB then that plan should be uploaded for those study records.

45. **How will this work for medical devices work as the IRB surrogate?**

    The single IRB that's selected should also comply with FDA regulations. Many do. I'm not sure this is a huge barrier. But you want to make sure you're complying with both the IRB regulations along with any applicable FDA regulations.

46. **Someone is saying that I keep saying due date. I thought it was the announcement date.**
    Again it's the due date for the grant applications, January 25th, 2018. So our assumption is that you're now starting to work on those applications, which is why we're holding the webinar now to help you with the due dates on January 25th and after. So not all studies are going to come in on January 25th. So after that date it's applicable then as well. And for R&D contracts it applies to the contract solicitations written on January 25th or after.

47. **Do other institutions have a plan to institute a similar plan to NCI?**

    Not at my knowledge, not at this time.

48. **How should we demonstrate site's willingness to sign an agreement to abide by the single IRB? Is this just a statement in the single IRB plan or do all officials need to provide documentation?**

    So once the single IRB plan is provided in the application and your institution signs off on the application, if a grant is awarded, reliance on the single IRB becomes a term and condition of the grant or the contract. So it now becomes a compliance piece in the funding. So if your institution violates that agreement, they're now out of compliance.

49. **Next question: Why does the single IRB review cost affect an institution's F&A cost negotiation?**

    This would affect your F&A cost negotiation if, for example, like some institutes have told us that they are actually pulling out all of their IRB costs from their indirect cost pools, so that could affect your rate. Other institutions are leaving some IRB costs, these routine costs for IRB in their rates so it really depends how your institution handles that.

50. **Next question: Does the single IRB charge the other institutions or is everything expected to be covered under direct costs?**

    So the site where the single IRB is located would be the site incurring the costs. So we would expect to see those costs on that site's direct cost budget. They wouldn't charge the other sites since they are the ones performing the single IRB activities and incurring the associated costs.

51. **If sites have different protocols and can therefore use different multiple IRBs, do you have to ask for an exception?**

    No. So if you go into the Human Subjects and Clinical Trial Information forms, section 3.2, there's a question that asks basically if you -- this grant falls under

the policy. So if you answer ‘No’ to that question, you do not have to have a single IRB plan.

52. **If the NIH, such as a clinical center, is one of the sites, will they accede review to an academic IRB, or will they be serving as the IRB?**

    So we can't answer that. That would be up to the IRB to determine. But again, communication is your friend, so talk early with the IRB. They may be willing to serve, but they would have to -- you would have to ask them if that's the case.

53. **And will there be any reporting on any single IRB in annual reports?**

    I think the IRB reporting will be handled as it currently is, so I don't believe that there's a mandatory reporting, but if your Program Officer or Contracting Officer has questions, they can ask for additional information.

And that would be our last question.

Thank you so much for your time and attention. If there are any additional questions at the end of this webinar, please email singleIRBpolicy@mail.NIH.gov.

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