SIRB Question Guide
IRB chairs and administrators only (360° interviews) and IRB leadership (PRIM&R interviews)
Version 2.0
February 19, 2019

1. Interviewer Name	
2. Participant ID#	
3. Interview Date (mm/dd/yyyy)	|___|___|/|___|___|/|___|___|___|___|
4. Participant agrees for interview to be digitally recorded	Yes ..... ☐ No ..... ☐
5. Time Interview Began (hh:mm)	|___|___ | : |___|___| am/pm
6. Time Interview Ended (hh:mm)	|___|___| : |___|___| am/pm

Step 1: Complete Q1-3 above before starting the interview.
Step 2: Introduce yourself at the beginning of the interview. Thank participant for taking part in the interview.
Step 3: Read "Introduction and overview" below to participant.
Step 4: Ask for the participant's permission to record interview. Tick appropriate box in Q4 above.
Step 5: Turn on audio recorder if permitted. Document time interview begins in Q5 above, and conduct interview.
Step 6: At the end of the interview, thank the participant and ask if she/he has any further questions. Document time interview ended in Q6 above.
Step 7: Provide reimbursement and document appropriately.

Section 1: Introduction and overview

- Hello, thank you for taking time out of your busy schedule to speak with me today. My name is [Name], and I am a _____ with Duke University. (For telephone interviews: Is now still a good time to talk?)

- Before we begin, I'd like to tell you more about this interview and the research we're conducting.

- The Clinical Trials Transformation Initiative at Duke University– known as CTTI – is partnering with NIH to develop a framework for evaluating the implementation of NIH's single IRB policy.

- We are conducting interviews with IRB representatives, investigators and study coordinators to learn about their experiences with using the single IRB review process when their institutions serve the reviewing IRB or when they are a relying institution or both. We're also interested in hearing people's suggestions on realistic metrics on how the single IRB process can be evaluated

- The interview will take roughly 1 hour.

- With your permission, I would like to audio-record the interview. The audio-recording will be stored on a secure server and destroyed after the findings of this research are published. If you do not want the interview audio recorded, I will take detailed notes throughout the interview instead.

- Before I start asking questions, I'd like to highlight some terminology that I'll reference throughout the interview, as often different terms are used to describe the same idea. I know you are quite familiar with these terms but I want to make sure we're thinking of these terms in the same way.

- When I refer to a Reviewing IRB, which is also known as the single IRB, I mean the IRB of record for a particular multi-site study for the duration of the study.

- When I refer to a Relying institution, I mean the IRB or institution that will rely on an IRB from another institution to conduct the ethics review of a study that will be conducted at the relying IRB's institution. The NIH's single IRB policy refers to these institutions as "participating sites."

Are these the same terms you use—or do you use different terms?

- **Lastly, for all questions, we are only referring to NIH-funded, multi-site research.**

- Do you have any questions for me at this point?

[If yes, answer the participant's questions.]

Is it okay if I turn on the audio recorder now?

[If yes, begin audio recording now.]

[If no] That's okay, I'll take detailed notes as we talk.

Section 2: Development of the sIRB process map

Overview: A template sIRB process map has been developed by the CTTI team. This template process map will be modified as follows:

360° interviews: The template process map will be first reviewed by an IRB chair and an IRB administrator as part of the 360° interviews. Based on their feedback, the template will be modified so it depicts the process followed at each 360°university. Each university's modified sIRB process map will then be used in the subsequent interviews with IRB representatives at the university in order to gather details on the specific roles and responsibilities, input, and output of each representative, as it relates to the sIRB process. Additional modifications can be made to the process map during these interviews.

PRIM&R interviews: Modifications will be made to the template sIRB process map during the interviews so we can learn about the variety of sIRB processes followed across institutions of multiple sizes.

Interviewer instructions:

- Explain the purpose of the sIRB process map exercise to the participant:
  - *We are interested in learning about the flow of activities when your institution serves as a reviewing IRB and when it is the relying institution.*
  - *The CTTI team will use the process map to identify areas in which to focus metrics in the evaluation framework.*

- Show the template sIRB process map.
  - *This is a sample sIRB process map of how activities may occur when institutions implement the sIRB process at their university. Explain flow.*

- Ask questions below.
- Write any modifications directly on the process map.

Questions

1. Let's talk about when your institution serves as the *reviewing IRB*. How is the flow of activities at your university **different** from what is presented in this template map? *[Interviewer: Show the reviewing IRB map. Start at the beginning of the map and finish with the last step.)]*

2. Now let's talk the flow when your institution *relies on outside IRB* for ethics review. How is the flow of activities at your university, when it was the *relying institution*, **different** from what is presented in this template map? [*Interviewer: Show the relying institution map. Start at the beginning of the map and finish with the last step.]*

Section 3: Current and baseline metrics

Now I'd like to speak with you about IRB-related metrics.

1. What IRB-related metrics does your IRB currently collect? *[Probe about when these metrics were initiated—before or after the initiation of the NIH's sIRB process; any metrics related to time; IRB-related metrics planning to collect; quality, form, and completeness of the data]*

    a. What IRB procedures and tools were used before the new policy or used concurrently with the new policy? If SMART is used, when was it started? What was the workload prior?

2. *[If have metrics]* In thinking about how to evaluate the sIRB process, how could those metrics be used as baseline metrics, if at all?

    a. How could those metrics be improved upon so they could measure the sIRB process moving forward?

3. What suggestions do you have for the type of information that could be used as baseline metrics for evaluating the sIRB process?

Section 4: NIH sIRB goals

Now I'd like to speak with you about the NIH's goals for the sIRB process and learn about your institution's experiences as they relate to these goals.

Goal #1:

The first goal of NIH's sIRB policy is to "enhance and streamline IRB review for multi-site research."

In a moment, I'd like to hear your thoughts on whether or not this policy has enhanced and streamlined the IRB process for the review of NIH funded multi-site research at your university.

Let us first start with your thoughts on how this policy may have streamlined review—and then I'll ask you for your thoughts on how they may have not.

1. Based on your institution's experience, how has the implementation of NIH's sIRB policy *streamlined* your university's ethics review of the study protocol for NIH-funded, multi-site research? *[Probe about the specific areas that have been streamlined and exactly how those areas have been streamlined compared to the local IRB review model]*.

    a. What suggestions do you have on how these areas can be realistically measured to appropriately reflect the efficiencies of this new policy? *[Probe about each topic mentioned]*

2. How has the implementation of the sIRB policy fallen short of streamlining or simplifying your university's ethics review of the study protocol? *[Probe about the specific areas that have NOT been streamlined and exactly how those areas have NOT been streamlined compared to the local IRB review process]*.

    a. What suggestions do you have on how these areas can be measured to appropriately reflect the burden of this new policy? *[Probe about each topic mentioned]*

Now let's talk about the other activities that must take place at your university in order for research to proceed.

3. Based on your institution's experience, how has the implementation of NIH's sIRB policy *streamlined* your university's overall process for reviewing of NIH-funded, multi-site research, beyond the ethics review? This includes activities beyond the ethics review of the protocol, such as ancillary reviews and conflict of interest. *[Probe about the specific areas that have been streamlined and exactly how those areas have been streamlined compared to the local IRB review model]*.

    a. What suggestions do you have on how these areas can be realistically measured to appropriately reflect the efficiencies of this new policy? *[Probe about each topic mentioned]*

4. How has the implementation of the sIRB policy fallen short of streamlining or simplifying your university's overall review process beyond the ethics review? *[Probe about the specific areas that have NOT been streamlined and exactly how those areas have NOT been streamlined compared to the local IRB review process]*.

    a. What suggestions do you have on how these areas can be measured to appropriately reflect the burden of this new policy? *[Probe about each topic mentioned]*

Goal #2:

The second goal of NIH's sIRB policy is to "maintain high standard for human subjects protections." My next questions will be about this goal.

5. How would you define "high standards?"

6. Based on your institution's experience, I'd like to hear about any concerns you may have had regarding your institution's ability to maintain a high standard for human subject projections when using a sIRB process when you rely on another institution.

7. When your institution has served as the *reviewing IRB*, how did you gather local information relevant to the study from other institutions or sites particularly information related to vulnerable populations?

    a. How did your institution use the local information?
    b. What has worked well with this process?
        - What has not?

8. When your institution has been the *relying institution*, how did you gather local information relevant to the study, particularly information related to vulnerable populations?

    a. How was that information communicated to the reviewing IRB?
    b. To the best of your knowledge, how was that information incorporated into the IRB review?
    c. What has worked well with this process?
        - What has not?

9. What suggestions do you have for evaluating the collection and incorporation of local knowledge into the sIRB process for multi-site studies?

Goals #3 – #5:

Three other goals of NIH's sIRB policy are to allow "research to proceed effectively and expeditiously," "eliminate unnecessary duplicative IRB review," and "reduce administrative burdens."
We will now discuss topics related to these goals, specifically focusing on what has worked well, what hasn't, and how these items can be evaluated.

10. When your institution serves as *reviewing IRB*, how do you interact with the study PI and local investigators? *[Probe about direct communication or through the local IRB]*

    a. What has been efficient about this process, if anything?
    b. What has been burdensome about this process, if anything?
    c. How could this process be evaluated?

11. This question is similar to the last question, but now let's focus on when your institution has been the *relying institution*. How do you communicate information beyond local contextual information with the reviewing IRB?

    a. What has been efficient about this process, if anything?
    b. What has been burdensome about this process, if anything?
    c. How could this process be evaluated?

12. What, if any, regulatory responsibilities have remained with your institution when your institution has been the *relying institution*? (e.g., informed consent)

    a. Beyond ethics review, what regulatory responsibilities have shifted to the reviewing IRB when your institution has been the relying institution?
    b. What has worked well with this division of responsibilities?
    c. What has not?
    d. How could these divisions of responsibilities be evaluated?

13. When your institution has been the *relying institution*, what ethics reviews, if any, still take place?

    a. Why?

14. **What (other) activities have you found to be duplicative between the reviewing IRB and relying institution?**

15. What have you found to be the main administrative burdens when you have been the *relying institution*?
    a. How are these burdens different, if at all, from administrative burdens prior to the sIRB policy?
    b. How could administrative burdens be evaluated?

16. What have you found to be the main administrative burdens when serving as the *reviewing IRB*?
    a. How are these burdens different, if at all, from administrative burdens prior to the sIRB policy?
    b. How could administrative burdens be evaluated?

17. How, if at all, has the amount of time needed for providing IRB and other reviews and activities changed under the sIRB model compared to the local IRB model? *[Probe about specific aspects that have increased time and decreased time, and how this time investment may have changed over time].*

    a. How could we evaluate the time necessary for using the sIRB model in comparison to the local IRB model?

Goal #6:

The remaining NIH sIRB goal we'll discuss is to "prevent systemic inefficiencies."

18. Beyond what you have already shared, what systemic inefficiencies previously existed with the local IRB model, if any?
    a. How has the sIRB model improved upon these inefficiencies, if at all?
        - How has it not?
    b. How has the sIRB model created new inefficiencies, if at all?

Concluding Section

I have few remaining questions to wrap up our conversation today.

19. **How, if at all, does using a sIRB process improve the research experience for study participants?** ***[Probe to 1) identify the specific part of the sIRB process that is most impactful and why, and 2) the specific part of the participant experience that is most impacted by the use of a sIRB process]***
    a. ***[If identified participant improvements]*** **How could this be measured?**

20. Based on your experience, what do you think have been the top three benefits of using a sIRB process for multi-site studies? *[Probe about why these benefits were selected, if the benefit was not previously discussed, as well as how to measure them, if not previously discussed.]*

21. What do you think have been the top three burdens? *[Probe about why these burdens were selected, if the burden was not previously discussed, as well as how to measure them, if not previously discussed.]*

For the last two questions, please focus your answers on what you think your institution could reasonably do.

22. What are your top three suggestions for how to evaluate the day-to-day work that your institution does to implement the sIRB process—often referred to as process evaluation?

23. What are your top three suggestions for how to evaluate the impact of using a sIRB process for multi-site studies—meaning, how to evaluate whether the sIRB process is achieving NIH's sIRB goals?

24. Is there any topic that we haven't discuss yet that you'd like to mention?

Thank you for your time. May we contact you if we have any additional questions?