

SIRB Question Guide
IRB representatives other than IRB chairs and administrators only (360° 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 <input type="checkbox"/> No <input type="checkbox"/>
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 as the reviewing IRB or as 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 process map during the interviews so we can learn about the variety of sIRB process followed across institutions of multiple sizes.

Interviewer instructions:

- Explain the purpose of the sIRB process map exercise to the participant:
 - *We are creating a sIRB process map for each of the 360° case study universities so we can have a pictorial representation of the sIRB process followed at that university.*
 - *The map displays the flow of the position-specific roles and activities as they relate to the sIRB process.*
 - *The IRB chair and administrator at each university will start the process by modify the template specifically for their university.*
 - *The details of each role will then be gathered at the subsequent interviews with IRB representatives at each university.*
 - *The completed sIRB process maps will give insight to the CTTI team on the processes universities follow to implement the sIRB process.*
 - *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.*
 - *I'll now ask you questions about how your specific IRB role fits within this map from two perspectives: 1) when your intuition is the reviewing IRB and 2) when your institution is the relying institution. Then I'll ask you questions about how these process might change based on the type of protocol.*
- Ask questions below.
- Write any modifications directly on the process map.

Questions

Let us first start with the process when your IRB serves as the reviewing IRB.

1. Where is your role on this sIRB process map?
2. What specific activities do you do that relate to the sIRB process when your iRB serves as the reviewing IRB?
 - a. What do you need from others so you can do your role? *(Probe from whom/type of position).*
 - b. What is the outcome of your activities?
 - What is the next step after you fulfill your role?

Now let us talk about the process when your institution is the relying institution.

3. What specific activities do you do that relate to the sIRB process when your institution is relying on another IRB for the ethics review?
 - a. What do you need from others so you can do your role? *(Probe from whom/type of position).*
 - b. What is the outcome of your activities?
 - What is the next step after you fulfill your role?
4. How does your role differ, if at all, based on the type of research—for example a drug trial versus a low risk behavioral intervention versus a biospecimen study? *(Probe for any differences between when serving a s reviewing IRB or as a relying institution).*

Section 3: 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:

One goal of NIH’s sIRB policy is to “enhance and streamline IRB review for multi-site research.”

I’d like to hear your thoughts on whether or not this policy has enhanced and streamlined your role with reviewing multi-site research.

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 experience, how has the implementation of NIH’s sIRB policy *streamlined* your roles and responsibilities for reviewing or facilitating NIH-funded, multi-site research—as it relates to the ethics review of the research? *[Probe about the specific areas that have been streamlined and exactly how those areas have been streamlined compared to the local IRB review process].*
 - 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 your role and responsibilities in reviewing or facilitating NIH-funded, multi-site studies—as it relates to the ethics review of the research? *[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?

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 experience, how has the implementation of NIH’s sIRB policy *streamlined* the role you play in the overall review process, **beyond the ethics review**? *[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 measured to appropriately reflect the efficiencies of this new policy? *[Probe about each topic mentioned]*
4. Based on your experience, how has the implementation of the sIRB policy fallen short of streamlining or simplifying the role you play in the 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 realistically 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 experience in your role, I'd like to hear about the any concerns you may have had regarding your institution's ability to maintain a high standard for human subject projections when using a single IRB process.
 - a. Let's first start when your university has served as the *reviewing IRB* for multi-site research. What concerns, if any, related to maintaining a high standard for human subject projects have you had?
 - b. What about as the *relying institution*?

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.

7. What responsibilities have remained with your role when your institution has been the *relying institution*?
 - a. Which of your previous responsibilities, if any, 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?
8. **What (other) activities related to your role are duplicative between the reviewing IRB and the relying institution?**
9. What have you found to be the main administrative burdens, if any, in your role when your institutions has 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?
10. What have you found to be the main administrative burdens, if any, in your role 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?
11. How, if at all, has the amount of time changed for your role and responsibilities for providing IRB and other reviews and activities under the sIRB model compared to the local IRB model? [*Probe about specific aspects that have increased time and decreased time, how this time investment may changed over time*].
12. How do you think we could evaluate the time necessary for using the sIRB model in comparison time spent implementing the local IRB model?

Goal #6:

The remaining NIH sIRB goal we'll discuss is preventing systemic inefficiencies.

13. Beyond what you have already shared, with your role and responsibilities, what systemic inefficiencies have 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 with your role, if at all?

Concluding Section

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

14. 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?

15. 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]*

16. What do you think have been the top three burdens? *[Probe about why these burdens were selected, if the burden was not previously discussed]*

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

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

18. 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?

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