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: Selecting a reviewing IRB

To start, I’d like to speak with you about your institution’s sIRB selection and reliance process, specifically.

1. Please describe the process you have followed to identify a sIRB for your multi-site studies.
   a. Who was involved in that process? We are interested in the type of personal and not personal names.
   b. What roles did each person play?
   c. Who made the final decision about which IRB to use as the reviewing IRB?
2. What did you find to be easy about the process?
   a. What did you think was difficult about the process?
3. About how much time and effort did it take to complete the sIRB selection and reliance process, from identifying the reviewing IRB and finalizing agreements between your institution and the reviewing IRB?
4. What would be indicators that would suggest that the sIRB selection and reliance process is a success?
   a. What indicators would suggest that this process was not a success?
   b. Is there anything that you would do differently NEXT time?

Section 3: NIH goals

Now I’d like to speak with you about the NIH’s goals for the sIRB process and learn about your experiences with the sIRB process 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.”
I’d like to hear your thoughts on whether or not the sIRB has enhanced and streamlined the IRB process for the review of your 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 the sIRB policy streamlined the entire review process for your multi-site research? This includes the IRB review of your protocol as well as other reviews and activities needed to be completed for your protocol to be approved to start data collection. [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 the entire review process for your multi-site research? This includes the IRB review of your protocol as well as other reviews and activities needed to be completed for your protocol to be approved to start data collection. [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.

3. How would you define “high standards?”

4. Based on your experience, what concerns have you had regarding your institution’s ability to maintain a high standard for human subject projections when using a single IRB process?
   
   a. How could those concerns be evaluated?

5. When your institution was the relying institution, how did you communicate local information relevant to the study population to the reviewing IRB, particularly about vulnerable populations?
   
   a. What has worked well with this process? [Probe: how sufficiently local information was incorporated into review]
      - What has not?

6. 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.
7. When your institution has been the *relying institution*, how has the *reviewing IRB* communicated with you?
   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?

8. **What activities, if any, have you found to be duplicative between the relying institution and reviewing IRB?**

9. What have you found to be the main administrative burdens, if any, when your institution 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 these administrative burdens be evaluated?

10. What have you found to be the main administrative burdens for you, if any, when your institution serves as the *reviewing IRB* for your multi-site studies?
    a. How are these burdens different, if at all, from administrative burdens prior to the sIRB policy?
    b. How could these administrative burdens be evaluated?

11. How, if at all, has the amount of time taken from point of submission to point of approval 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 required for using the sIRB model in comparison to the local IRB model?

12. How has the sIRB process, if at all, impacted study start up time?
    a. How can this be evaluated?

13. How has the sIRB policy impacted your ability to conduct research efficiently? *[Probe about benefits, burdens, initial review, ongoing review, adverse event reporting]*
    a. [If not addressed above] How, if at all, has the sIRB process impacted your ability to recruit participants?

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?

**Goal 6:**

*The remaining NIH sIRB goal we'll discuss is to “prevent systemic inefficiencies.”*

15. In your opinion, what systemic inefficiencies have 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.

16. 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, as well as how to measure them, if not previously discussed.]

17. What do you think have been the top three burdens that did not exist with the local IRB review model? [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, 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.

18. 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?

19. 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?