SINGLE IRB & EXCEPTIONS PROCESS WEBINAR

LIVE WEBINAR SCRIPT

Slide 1
Good morning or afternoon and welcome to the NIH webinar on the single IRB policy and the exceptions process. My name is Dr. Petrice Brown-Longenecker and I am with the Office of Extramural Research. Today's webinar is being presented by various members of the NIH extramural staff to talk about their area of expertise. Each speaker will introduce themselves individually. Their name and address are located on the title slide of their portion of the presentation.

Before we begin I would like to go over a few housekeeping items. First mute your phone, computer or device. There's a PDF copy of the slides available to you now in the handout tab of the go-to webinar menu bar. Please feel free to download a copy.
We will be taking questions throughout the webinar. If there are relevant questions about a section just presented we will try to take a few in the transition between speakers and we will take as many as time allows at the end.

In the next couple of days after the presentation we will reach out to you with additional information regarding where to find the recorded webinar and slides. We ask you to please participate in a few polls for us to get an idea of who has joined us today or to test your knowledge. You won't be graded. You should see them come up under the poll tab of the go-to webinar menu bar. Let's try the first one. Please submit your answer. I'll give you a few moments to respond. Okay. I am closing the poll. Thank you for responding.

Slide 2
Let's go over today's learning objectives. First we would like to recognize the key aspects of the NIH single IRB policy, understand the requirements for compliance with the policy, understand the process for requesting an exception to the policy for individual sites, and know where to find key information and resources.

Slide 3
Because there are several speakers, we wanted to show you the organization of today's presentation. First we'll give you an overview of the NIH single IRB policy. Next the implementation guidance for both grants and R&D contracts. Then, the single IRB exceptions process for both grants and R&D contracts. The grant application budgets, and then the sIRB under R&D contracts specifically. And lastly we'll end with resources.

Our next poll before we start the presentation do you apply for funding through grants or contracts? I'm launching now. Okay. Thank you very much. Now we'll move on to an overview of the Single IRB Policy with Ms. Deysi Duque.

Slide 4

Good morning or good afternoon. This is Deysi Duque and I'm with the Office of Extramural Research and I'll be presenting an overview of the NIH Single IRB policy.

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I'll start with the goals of the Single IRB Policy.

- First it is intended to enhance and streamline the IRB review for multi-site research.
- Maintain high standards for human subjects protections.
- Allow research to proceed effectively and expeditiously.
- Eliminate unnecessary duplicative IRB review.
- Reduce administrative burden.
- Prevent systemic inefficiencies and
- To be compatible with final revised Common Rule requirement to use single IRBs for multi-site studies. This will be implemented in 2020, so I wanted to point out the distinction between the single IRB policy and the revised Common Rule.

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I'll go through the policy itself, just an overview. It's for all NIH funded multi-site domestic studies involving non-exempt human subject research and are expected to use a single IRB. Sites must be conducting the same protocol. It applies to all human subjects, not just clinical trials. Applies to all new and re-competing applications and proposals currently being funded.

Also for research funded through grants and research and development contracts.
The policy does not apply to:

- Foreign sites,
- Career development, K. Institutional training, T, and fellowship awards, F, and
- Current awards.

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I'll go through the different exceptions. There are three types of exceptions:

- First policy-based exceptions. When Federal, state, tribal, local laws, regulations, policies require local review. For example, tribal regulations and policies are given specific consideration in order to ensure the importance of their role is recognized. They do not require NIH exceptions review committee approval.
- Second, time limited exceptions. This is when ancillary studies are part of ongoing studies or parent studies. We would like to highlight that these exceptions do not require single IRB until the parent study is expected to comply with the single IRB policy. This is to ease some concerns about ongoing research without a single IRB.

Slide 8

- Third, we have compelling justification or other exceptions. This is when there is a compelling justification for local IRB review. They require NIH exceptions review committee approval. For clarity, presenters will be referring to compelling justification exceptions, but the term is exactly the same as other exceptions.

Slide 9
On this slide, we have some links for the full policy for the single IRB. We have some other Guide notices that talk about cost scenarios, implementation and exceptions. We want to highlight that the effective date of the policy has been extended from September 25th, 2017 to January 25th, 2018. So again, all competing grant applications, and this includes new, renewal, or resubmission. This applies to application due dates on or after January 25th, 2018. This applies to proposals solicitations issued on/after January 25th, 2018.

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Next we have Dr. Petrice Brown-Longenecker.
Thank you, Deysi.

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I would first like to do an introduction of the difference between a single and Central IRB. The two words are a little confused and used interchangeably. So we want to make sure that we're talking about the same thing.

- A single IRB is typically selected on a study-by-study basis. It's usually an existing IRB at an institution that agrees to serve as the IRB of record for a particular study.
- Conversely, a Central IRB is typically set up or created to review all sites that are participating in a study for a particular study. So all sites participating in a program that usually includes more than one multi-site study. So the Central IRB is usually created specifically for the study as opposed to a single IRB as an existing IRB that has agreed to be the IRB of record.

So unless the FOA (or Funding Opportunity Announcement) or contract solicitation that you are applying to specifies the creation of a Central IRB, you do not have to create one. For your study, you can identify the single IRB of record you would prefer to use, and we'll talk a little bit more on what that means.

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There are three broad possible IRB models that we've identified. And any of these will work with the policy.

- So the first being an existing IRB at an institution that's one of the sites. So this could be the awardee site or a participating site. So that IRB has agreed to serve as the IRB of record for the study.
- Or the investigator can decide to use an independent or unaffiliated IRB. We typically refer to these as commercial IRBs.
- And third is the Central IRB that's been organized specific to review those projects.

And please note that the single IRB of record that's chosen does not have to be the parent site. It can be any of the sites or a commercial IRB as we've mentioned. It's really the best IRB for the study. NIH will not select the IRB for the award unless it's a cooperative agreement or a contract that is determined to do so.

So there are two elements that are required for the IRB, so please note:

- The single IRB selected must be registered with OHRP and must have membership for the study.

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When choosing the single IRB of record it's important to take in mind the type of study and the sites that are conducting the research. So unless the FOA or solicitation has specific requirements, the investigators can choose their own single IRB. I'd like to reiterate that, you can contact NIH for help with identifying the appropriate IRB, but it usually is up to the investigator. That element of NIH's involvement will not change.

- If you have a multi-site study where at the time of application or proposal all the sites are known, you know who is working with who and where, you can identify the IRB of record either as a participating site, the lead site, or an independent IRB. That can be done ahead of time. So those two instances are when there's one single award with multiple sub-award sites. So the same proposal is being conducted at multiple sites. Or if you have multiple awards, so linked awards where all sites, and therefore, all awardees are conducting the same study. So that one is fairly straightforward. You can identify the best IRB for the study.
- Alternatively, if sites are not known until after review, so think of large network awards where the identification of sites is not done until after the institution has received funding:
    - You have multiple sites, plus an award for a central coordinating entity, the applicant or investigator may want to use the central entity or the coordinating entity to be either the site of the single IRB or they can coordinate choosing the single IRB.
    - Alternatively, if there are multiple awards without a central coordinating entity -- so for cooperative agreements -- we would recommend that the IC work with the awardee to determine the best single IRB of record or require that the sites create a Central IRB. So whichever is best for the study.

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So again, NIH isn't usually going to select the IRB, it's the best IRB for the study. And how do you know which is the best IRB? So that's a study-by-study decision. But we suggest that participating sites work together ahead of time to determine the best IRB for the study. Make sure that all reliance agreements and communication plans are in place and up to date either while you are writing the application or soon after the just-in-time area of award. And it may include working with your local IRBs at the participating sites to determine, A, the best IRB, and B, to make sure that all relevant local context, policies and information are gathered ahead of time.

Slide 15

I'd like to take a minute just to introduce to you one of the changes that NIH is embarking on with the January 25th due date. So if you have not heard, here is a word that for all applications due on or after January 25th, you must also complete FORMS-E

in the application. It includes the PHS Human Subjects and Clinical Trial Information form. So if you're conducting human subjects research you will have to also fill out FORMS-E in your application. There's a lot of information about FORMS-E online, including a video tutorial. I'm not going to go too much into FORMS-E, but I want to make sure that you're aware it's occurring, where you can find information. So I have the link to the application Guide there on this screen and this lets you know where to put your single IRB plan. So this includes all human subjects research and there's some clinical trials information. So if you haven't heard of FORMS-E, please familiarize yourself with it. And includes structured data, so particularly elements are now removed from certain parts of the application that you may have been used to putting them in different places. They're now located here, so again, familiarize yourself with this form.

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But specific to the single IRB policy is that there is a specific question in FORMS-E so section 3.2 asks is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site? So this question asks does this application fall around the NIH policy. The answers are yes, no and not applicable. If you mark yes, you must add a single IRB plan as an attachment. It's a separate attachment. I'll talk more in a minute. Only F's and K's grants can mark the N/A. It's only for those awards that are excluded from the policy.
If you mark yes, you have to include a plan and that should be created ahead of time. And this is where you want to work with all of your co-investigators.

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Here's a single IRB plan:

- When possible, or when known it should, include the name of the single IRB of record, so the IRB that has been selected. You want to indicate that all sites, including any added after award, agree to rely on the single IRB of record.
- You want to indicate that sites will sign the reliance agreement and that the reliance agreement will include a communication plan.
- And you want to indicate who will maintain the records of this agreement. You do not need to include your reliance agreement or the communication plan. The single IRB plan should be fairly succinct.
- If you have identified individual sites that you believe requires an exception to the single IRB policy, you want to include that in your single IRB plan too.
    - First, you will include any policy-based exceptions. Again, we'll talk in more detail what those are in just a moment. But these are those that require local IRB because of legal or regulatory requirements. And so you want to provide the specific citation so that law, policy or statute that requires local IRB and indicate which sites are impacted.
    - The second type of exception is the time-limited exception for ancillary studies. So if you have multi-site ancillary studies that are linked to a parent award, you want to provide the parent study information.

- And then thirdly is the exception with compelling justification. So compelling justification exception. And you want to identify the sites that are impacted and provide the justification.

I'm going to note here that when you create your budget, you want to budget as if there were no compelling justification exception because you have not been granted one yet. The compelling justification exception must be approved by NIH. Once it has been approved by NIH and granted to the award, the budget can then be adjusted. So at the time of budgeting, you want to budget with all of the sites you need for your single IRB of record. So I'll rephrase. If you believe that a site will require a compelling justification exception, budget as if it's to be included in your single IRB of record. Because if you are granted that exception after review of it, it will no longer be part of the single IRB of record budget, but will have its own local IRB funded through indirect cost. If there are questions on that, please let us know.

Additionally there's some information on the squares at the bottom here. In your FORMS-E, your human subjects and clinical trial form, you need a single IRB plan for every study record that involves a multi-site study. You may use the same plan, you may have to rename the document one, two or three, a unique name to use it repeatedly, or you can refer back to the original plan in study 1.

If your study is considered delayed onset, you will not get to section 3 of the form, of the PHS Human Subjects and Clinical Trial form, instead you will have a delayed onset justification. Please provide a statement that indicates that you will adhere to the policy, if funded, and you will provide the single IRB information or plan prior to starting your human subjects research.

And then, I've provided the Application Guide Instructions on this slide. It's a live link.

Slide 18
A little information about the single IRB plan attachment that's a part of 3.2 in the human subjects and clinical trial form,

- It's an uploaded attachment.
- There are no page limits.
- The single IRB should be identified by the applicant or offeror in the plan as appropriate or as available.
- You do not need to include your reliance agreements or communication plans.
- And again, if the study is delayed onset and your delayed onset justification, you will indicate that you will follow the single IRB policy.

Slide 19
And then lastly for my section, just brief information about peer review:

- The information provided in your single IRB plan is not considered in the overall score of your application, or in the overall rating -of protection of human subjects research. So these are -- so it's not scored -- as review criteria.

- Peer reviewers may note if an application appears to be applicable to the policy and there is no single IRB plan, they'll note that in your Summary Statement, but it should not be used or scored against you in either overall scoring or the human subjects section.
- And for grants, we are advising peer reviewers are encouraged to allow flexibility in budget requests while single IRB costs are still being assessed.

Slide 20
And with that, Dr. Sarah Dunsmore will talk about the exceptions process.

Slide 21
Good afternoon or good morning. My name is Sarah Dunsmore and I am from the National Institute of General Medical Sciences. I'm going to give you a bit more detail on what you need to put in your grant application for requesting a single IRB exception.
To review what you've heard previously in the webinar, as the single IRB policy is launched, there will be three types of exceptions:

- Policy-based exceptions,
- Time-limited exceptions, and
- Compelling justification exceptions or other exceptions.

The policy-based and time-limited do not require NIH exceptions review committee approval. They will be dealt with at the level of the institute, the funding institute, or at the level during the contract negotiation. The compelling justification exceptions will require an extra step, and this is internal review by a NIH Exceptions Review Committee.

Slide 22
For policy-based exceptions, in the single IRB plan, which is a separate PDF attachment of your grant application. Please identify the sites that are eligible for a policy-based exception, and please cite the law or policy that requires local IRB review.

- The budget should be prepared as if the policy-based exception site will use local IRB review and do not include policy-based exception sites in the single IRB budget.

- If you do choose to add policy-based exception sites after the time of award, you should notify the Program Director or the -- or someone assigned to handle your contract.

Slide 23
For time-limited exceptions, these are for ancillary studies to ongoing research that are not presently using a single IRB.

- These studies will not be required to use a single IRB until the parent study comes in for competing continuation or for peer review.
- These exceptions must be documented in the single IRB plan, and please cite the parent study and ideally the source of funding for that parent study.

- And there's a Guide notice, it's numbered 18-003, and this is an active link, and it will give you more guidance on exceptions to the NIH single IRB policy, including the time limited exceptions.

Slide 24
For compelling justification or other exceptions, in the single IRB plan, which is a separate PDF attachment of a grant application, please identify the site or sites for which a compelling justification exception is requested and please provide your compelling justification for local IRB review. However, this is a bit tricky. Please budget as if this exception is not going to be granted. So include these sites in the single IRB budget in the grant application.
And if you do choose to add compelling justification exceptions sites after the time of award, prior approval from your Program Director and from the funding institute is required in addition to review by this trait NIH exceptions review committee.

Slide 25
And a bit more detail about what to expect in terms of contacts and timing:
- So if you're requesting a compelling justification exception, after peer review if the IC chooses to fund it or if the contract is in the competitive range, this exception will be evaluated by an internal NIH exceptions review committee.
- Feedback from this committee goes to the Program Director or the CO, not to the grant applicant. So you will obtain all your information for all aspects of this compelling justification exception from either your Program Director or your CO. They will be your point of contacts.
- These exceptions are intended tore rare, so please don't anticipate that your request will be granted,
- but we do hope to provide case studies, FAQs, educational material in the public domain so you will get some idea of what types of compelling justification exceptions will be approved and what types will not be granted.

Thank you for your time and attention. And I will turn this over to Samantha Tempchin.

Slide 26
Thank you, Sarah. Hi, everyone. I'm Samantha Tempchin. I'm in the division of grants compliance and oversight in the Office of Policy for Extramural Research Administration. And I'm going to talk a little bit about grant application budgets and single IRB costs.

Slide 27
So the Single IRB Policy allows single IRB costs to be direct charged under certain circumstances, however, it's not required to direct charge single IRB costs.
- Single IRB costs may be charged direct if:
    - Your institution can differentiate which costs should be charged direct versus which should be charged indirect, and

    - If costs incurred for the same purpose in like circumstances are treated consistently as either direct or indirect according to the long-standing clause in the cost principles.
- So it's up to the individual institutions to determine if the single IRB costs are appropriately classified as direct or indirect according to your institutional policies. We've had some questions from some institutions that are planning to implement the policy a little early, and they've asked if they use a single IRB prior to the NIH implementation date if they're allowed to charge direct cost for single IRB.
- And since the cost principles are not changing with regard to this, yes, institutions may use single IRB early and you may include direct costs prior to the NIH implementation date if you choose.

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So last year when we published the single IRB policy we also published a campaign on Guide Notice providing some guidance for the single IRB. In that Guide Notice we provided a framework for thinking about the different activities that an IRB may perform and the costs associated with those activities. So we have:

- Primary activities, which we're thinking of as things that IRBs regularly do. The activities associated with conducting the ethical review of the proposed research protocol as required by regulation. So since these activities are usually routine, they tend to be included in an organization's F&A rate. If that's already negotiated into your rate.
- Secondary activities, however, are the additional activities that the IRB would perform specifically in its capacity as the single IRB of record. So that would be things like reviewing site specific considerations for all of the other participating sites. These would be project-specific activities that are above and beyond the review that the IRB routinely does. So in that case the secondary activities may be appropriately classified as direct charges for the single IRB costs.

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Over the past year since the policy has been published, we've been going out and talking to many of you about what your institutions are planning to do with the single IRB costs and how you're going to put them into your framework of costs at your institution. So some of the things that we've heard are on this slide:

- Some institutions are going through their costs and establishing a fee structure for single IRBs so that they can charge by project, by site, by year, those kind of fees put into a structure.
- Some of those fee structures may actually rise to the level of a recharge center or service center, and if that's the case for your institution, we would encourage you to look at the definition for specialized service facility provided in the cost principles.
- Some institutions have decided that they are actually going to remove all IRB costs from their F&A pool, not just single IRB costs. If your institution is considering that, we would encourage you to first get in touch with your rate negotiator at our cognizant Federal agency.

- Some institutions will be relying more heavily on independent or commercial IRBs instead of their institutional IRB.
- And finally, I just wanted to emphasize that this is not an all-inclusive list. Your institution may come up with some other costs that work for you and work within the cost principles.

Slide 30
So as for what to actually put in your grant application, if you are requesting direct costs for single IRB:

- The institution that is the one incurring the single IRB costs should include the single IRB costs on their detailed budget pages.
    - The other sites that are not serving as the single IRB we would not expect them to have IRB costs included in their direct cost budgets.
    - In that Guide Notice that I mentioned previously we have a table of examples of how the different arrangements might be set up depending on which IRB is serving as the single IRB.
- So for your detailed budget pages, the costs for your single IRB should be listed under whichever detailed budget category is the most appropriate for those costs, depending on how your institution decides to do that.
- For example, if you're doing some kind of fee for service arrangement or if you have an institutional fee structure that might go under the other direct cost category, but really any category that's appropriate we're not ruling out what's best for your institution.
- The key with the budget is really going to be providing support for any costs that you've included in your direct cost budget and your narrative budget justification pages. So I'm just really giving NIH an idea of how you've arrived at the figures for your budget requests.

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Finally, to touch on how to handle budgets with regard to exceptions, we've touched on this a little bit earlier in the presentation as well.

- For the policy-based exceptions and the time-limited exceptions for the ancillary studies, the applicant should account for that exception in your direct cost budget. Since those are standing exceptions, they do not require review by the NIH exceptions review committee. You can assume that those sites will be accepted. So if a site is not using a single IRB it should not be generating single IRB costs.
- However with the compelling justification exceptions, the proposed budget must reflect any necessary single IRB costs assuming that the exception will not be granted. So that way if the exception is approved, we can adjust the budget prior to award to remove any sIRB costs for the sites that receive the exception. If the exception is not approved then that should be fine because you will have included the single IRB costs for that site. Those are included in the Guide. I know it can get tricky, but that's a good place to refer if you have any questions.

These instructions are in the sections on the single IRB plan and there's also some material about single IRB costs in the budget page instructions as well.

So now I'm going to turn it over to Richard to talk about contracts.

Slide 32
Good afternoon. This is Richard Hartmann. I'm with the National Institute of Allergy and Infectious Diseases. And we're going to talk about contract implementation.

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- This policy will apply to all solicitations issued on or after January 25th, 2018 for any NIH-funded multi-site research involving nonexempt human subjects research. Unlike the grants policy where the grants -- the application is arriving after January 25th, it's the solicitation. So if a solicitation is issued prior to January 25th, but proposals are received after January 25th, it will not apply. It's only to those solicitations issued after January 25th of 2018.
- The RFP will state and the contract will require the sIRB, and
- The same policy-based and time limited exceptions are allowed and must be specified in your proposal.
- Compelling justification exceptions are expected to be rare and infrequent.

Slide 34
For contracts, we anticipate that there are three potential types of sIRB models:
- The first one is where we issued a request for proposal for a single study or clinical trial, for example, and if an offer comes in with one -- and the contractor proposes multiple contract sites.
- The second scenario is one in which we would anticipate making multiple contract awards and we will issue one RFP for the sites and then we will issue a second RFP for a Contract Research Organization or coordinating center. And in that solicitation we will state that the CRO or coordinating center would be responsible for the sIRB.
- The third one is where we issue a solicitation for multiple contract sites to perform a study, but we will have a separate IRB in place either through a standing contract. An example of that would be the NIH NCI centralized IRB, or we would capital making a separate IRB award only for the Institutional Review Board, either through a standalone contract or a task order.

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So in the first scenario the single contract award with multiple sites, you will have:
- A single contractor. They may have one, five, 10 subcontractors all performing activity.
- The sIRB is the responsibility of the contractor.
- And the sIRB may be that prime contractor. They may select in agreement with one of their subcontractors for the subcontractor to be the sIRB or they may also issue a separate subcontract to a commercial IRB.

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When you have multiple contract awards with a CRO or a coordinating center:

- The statement of work and the contract for the CRO or contract coordinating center will state that they are responsible for the sIRB. Contractors with the individual sites –
- Contracts with the individual sites will require them to accept the CRO or coordinating center as the sIRB.

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And finally, with multiple contracts with a separate IRB IRB, as I state willed earlier:

- The sIRB may be an existing sIRB, it can be a separate contract or task order.
- Contracts with individual sites will require them to accept that Government provided sIRB.

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Single versus multiple contractors:

- In a single contractor, our contract will have the HHSAR clause 352-270-4-A. That proposal will need to address the sIRB. The sIRB must be registered with OHRP. And the proposed membership of the sIRB must be adequate for review of the study.
- The Contracting Officer Representative and the Contracting Officer will consider the acceptability of the sIRB plan.

If we have multiple contractors anticipated:

- Our RFP and the contract will use the Alternate I language of HHSAR 352-270-4-A, and
- Proposal will need to state that the contractor agrees to the sIRB provisions stated in the request for proposal.

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In your proposed sIRB plan for a single award you will need:

- To name your sIRB of record.
- You will document that all sites accept that sIRB. You will need to make sure that they accept such procedures such as the composition of the sIRB, how you will maintain the records, your reliance agreements, how you're going to get your IRB approvals.
- Exceptions:
    - If you have a policy-exception you will indicate the affected site and the law or regulation requiring the local IRB.
    - If it is time limited, you're going to indicate the parent study.
    - And finally, if you have a compelling justification for another exception, you're going to need to provide the rationale.

Slide 40
We'll jump into sIRB costs. Your sIRB costs may be direct or indirect. They should be billed in accordance with your accounting system and your negotiated indirect cost rate. So each organization you have an established system for how you're accounting for

these costs, and you just need to be sure that you maintain your records and your costs in accordance with those systems. Obviously because this is a contract, you will need to comply with FAR parts 30 and 31.

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Exceptions under the contracts as stated. You will need to identify the site and cite the law or policy that requires the local IRB for policy-based exceptions. If it's a time-limited exception, you will need to identify the parent study. For compelling justification exceptions, you need to identify the site, you will need to provide your compelling justification. Exceptions will only be considered for proposals that are selected for the competitive range and they must be reviewed and approved by the NIH Exceptions Review Committee. And we'll go back through this but as with grants you should budget your proposal as if no compelling justification exception is approved.

Slide 42
Budget proposals. As I just stated, do not budget for a compelling justification. Budget may be adjusted if exception is granted and we would do that during negotiations. And a compelling justification exceptions for those offers in the competitive range must be submitted to the NIH exceptions review committee by the contracting officer. And we will adjust your costs during negotiations. In the review of the sIRB for peer review under contracts, we will not affect the overall scoring or the overall rating of protection of human subjects in the human subjects section.

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Peer reviewers may note if this policy appears applicable to the proposed research, but you did not include an sIRB plan.

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In summary, compelling justification exceptions. You must identify the exception site. You must offer a compelling justification. And again, budget as if there is no justification exception granted. And we will only consider compelling justification exceptions for those offerors in the competitive range.

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In the process that we are going to use, the Contracting Officer will submit the compelling justification exception to the NIH Exceptions Review Committee.
The NIH Exceptions Review Committee will make the decision based upon the justification and supporting documentation provided in the proposal and by the Contracting Officer. The request may be denied based upon the NIH Exceptions Review Committee's past precedent. The Contracting Officer will be your point of contact and they will communicate the NIH Exceptions Review Committee's decision and we would do that during negotiations. The budget negotiations may be impacted by the NIH Exceptions Review Committee's decision. For example, if they do accept the justification and you have obviously not budgeted for that exception.

So we will now go back to our next speaker, Deysi.

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Hi, good morning -- good afternoon, this is Deysi Duque again and I'm with the Office of Extramural Research. I'll be going through some challenges for single IRB and some resources or tools that are available to you.

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First, I'll go through the different challenges that the research community may have with single IRB.

- sIRB issues with infrastructure technology, a single IRB should have the capacity to facilitate tracking and sharing of sIRB related documents across multiple sites.
- There may be challenges with negotiation of reliance or other authorization agreements. Participating sites must be willing to use a master agreement and there should be clear roles and responsibilities for single IRB and local IRBs.
- Also, there could be budget development challenges as costs vary across sites.

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On this site we have some tools and resources from NCATS, which is a National Center for Advancing Translational Sciences, which is one of the 27 institutes at NIH. Some of the resources they have is, for example, the single IRB authorization agreement that eliminates time and effort required to negotiate different agreements for a new study. They have national collaboration for different institutions that have signed into SMART IRB. So far they have over 240 institutions. NCATS provides guidance and resources such as guides, tools and checklists to help with implementation. They have expertise across the nation and areas of research, such as medical, social, behavioral, and observational studies regardless of funding. Another tool that the SMART IRB has is an online sharing system, which is a centralized system to support the different reliance arrangements or negotiations. Currently in a pilot study. And finally they have the Trial Innovation Network for Central IRBs to help implement single IRB. They also provide SMART IRB agreements and SOPs. On this slide you have the different emails that you can access for additional information or questions. They also have a newsletter that you can sign up to receive additional information that provides some webinars on SMART IRB and single IRB implementation.

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On this next slide we have one of the NCATS tools, which is called SMART IRB Exchange. It's a web-based platform developed to support implementation of single IRB review from study start-up to study close. The tool allows for the documentation and tracking of the different reliance agreements and relationships between the different sites. And it helps manage all these documents for all participating sites. It helps streamline and automate the study related notifications to the participating sites. So that's some of the highlights for this SMART IRB exchange tool. If you have any interest or additional information, questions on SMART IRB exchange, please access the links on the right side of the screen.

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Some key takeaway messages: Just to highlight the effective date of the policy is January 25th, 2018 for all competing grant applications and research and development contract solicitation publications. Again, it applies to domestic sites conducting the same non-exempt human subjects research protocol. It does not apply to K's, T's and F's and foreign sites.

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Take away messages for the exceptions process, and the exceptions types. Three types of exceptions: policy-based that have legal requirement for local IRB. NIH should be informed. The law should be cited in the single IRB plan that's uploaded with the grant application or proposal. There are time limited exceptions. Again, NIH should be informed of these types of exceptions. And you should cite the parent study. The last exception is the compelling justification exceptions that require NIH approval and must have a compelling justification documented in the single IRB plan.

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For the process we have some highlights that we want to emphasize that the applicant or offeror should identify the exception requests in the single IRB plan. Policy-based exceptions are automatic. Time limited exceptions allowed for ancillary studies with ongoing parent studies. Compelling justification exceptions must be approved by NIH. Requests may be denied based on NIH's past precedent.

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For peer review, the single IRB plan does not factor into the score or overall rating in human subjects section. Reviewers and SROs will note if single IRB plans are not addressed in the single IRB or proposal.

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Lastly, we have some additional resources for you on this slide. For example, we have the policy web page for grants.nih.gov with additional details on the policy. We have some Guide Notices. We have the full policy. We have the extension policy. We have the Guide Notice for costs and implementation. We have the exceptions process Guide Notice. There's also the OSP web page for additional information on implementation FAQs, cost FAQs. There is the OER webinars page where you can access any recorded webinars, past webinars, and any additional information.

There are two mailboxes where you can ask for additional information such as the singleIRBpolicy@mail.NIH.gov and the grants compliance email. There are two links here for SMART IRB: One is for the website; one is for the tool: the SMART IRB Exchange tool.

Finally, we have the Clinical Trials Transformation Initiative, CTTI, which provides an additional template for the authorization agreement, and it only applies for clinical trials.

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Thank you for your attention. We will now take questions. So we have quite a few questions in the question tab of your menu. So if you have a question, feel free to type one in there. I want to remind everyone that there's a PDF version of the slides and they're available now if you click into the handout tab in the go-to meeting menu, there's the PDF version of the slides that we presented today. Also a captioned recording and slides of this webinar will be made available in a few days. You will get that information via email of a link that you can go to.