07.18.2025 QUARTERLY CALL AGENDA

- Welcome & Announcements
- New IREx Features
- Institutional Profile Updates & Reminder
- Upcoming Features
- Mid Year Metrics
- Using IREx as the Single IRB [Demo] & Resource Tour

Welcome –
About the IREx Quarterly Calls

hear • new • features

- You're busy.
- IREx is busy.
- Call in once a quarter to hear what's new!

learn • new • trends

- Who's using IREx?
- How are folks leveraging IREx on their sIRB studies?

share • your • voice

- Give your opinion
- Ask your questions
- Express your needs

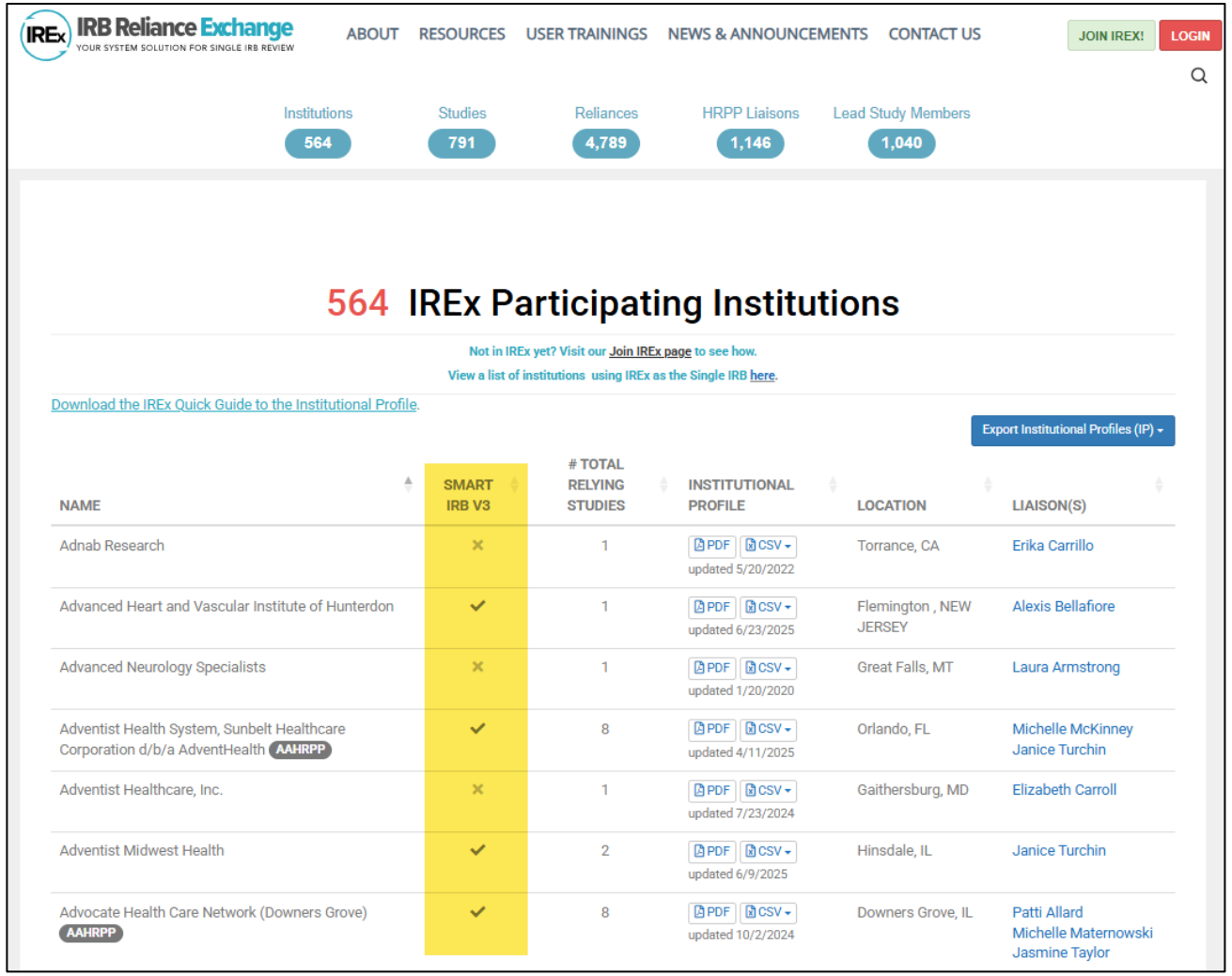
Remaining 2025 Quarterly Calls

October 17, 2025

Announcements

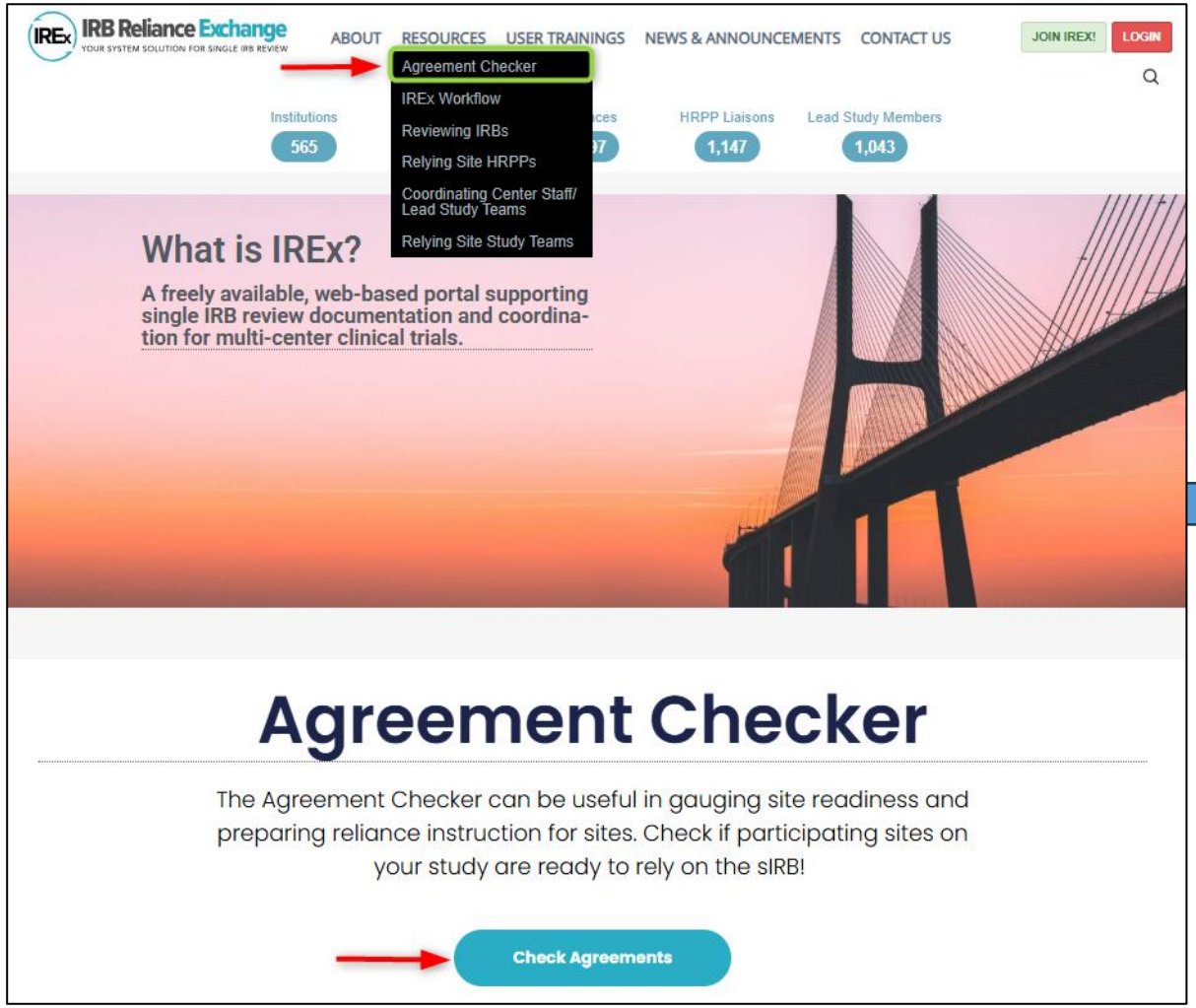
Website Updates - https://www.irbexchange.org/p/participants/

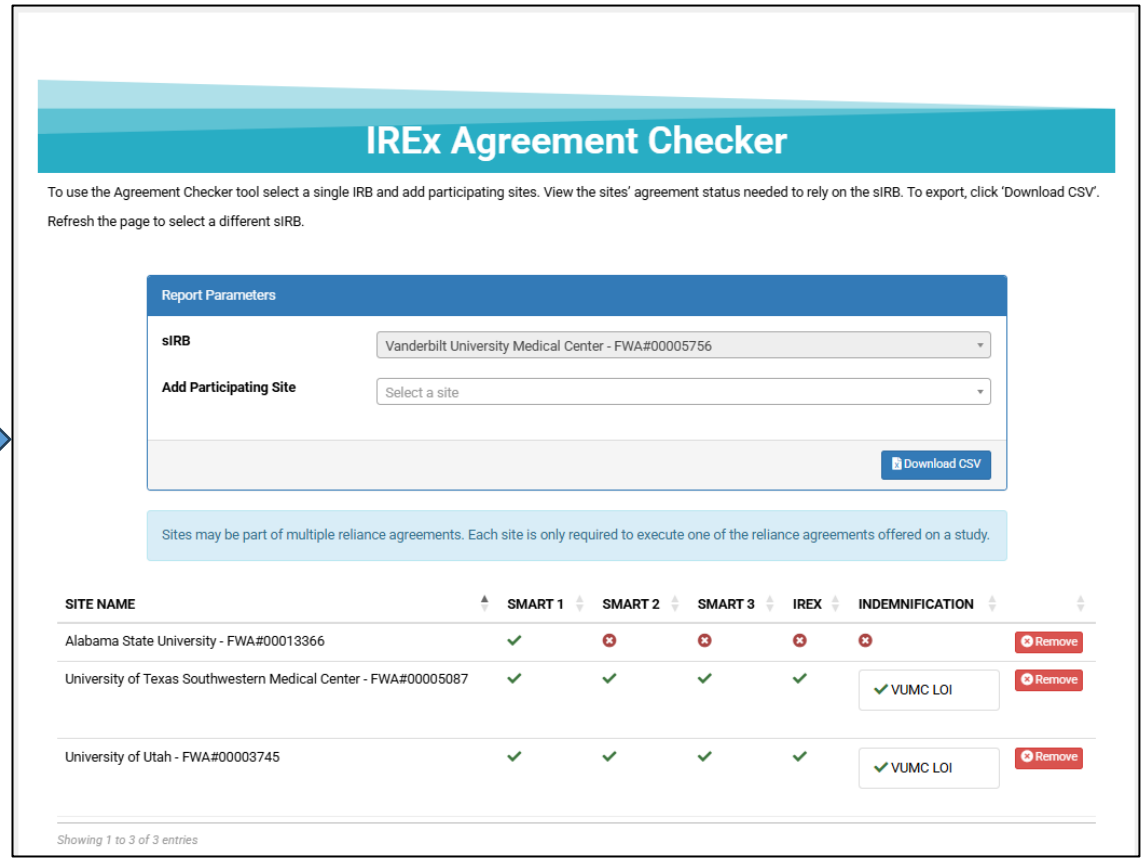
- SMART V3 status available on public **IREx Participating Institutions** page
- Improved load time



Website Updates -

https://www.irbexchange.org/p/agreement-checker/





Updated Materials Related to Reliance Agreements / SMART

PDFs Available on the IREx Website

- SSRP QG (PDF)
- Using IREx to Capture Local Considerations (PDF)
- Local Considerations Packet – non-EFIC Studies (PDF)
- Local Considerations Packet – EFIC Studies (PDF)
- Agreements Overview (PDF)

Videos Available on the IREx YouTube Channel

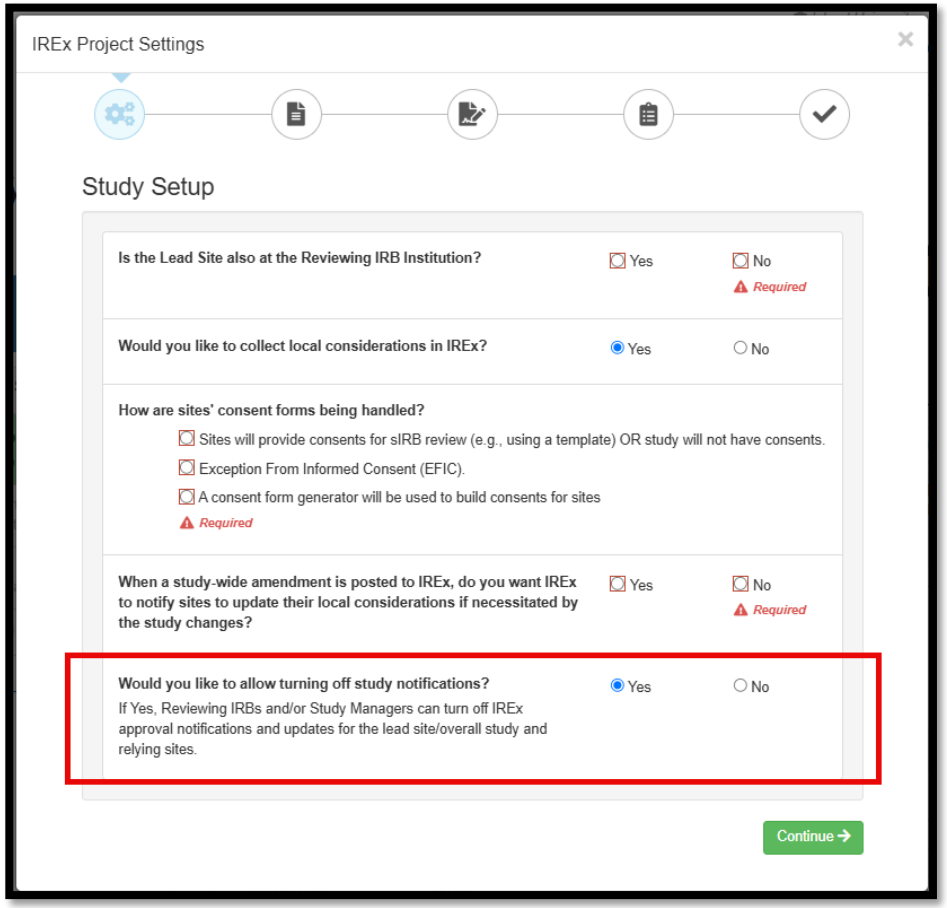
- Managing Agreements in IREx (video)
- How to Add Another Reliance Agreement to an Existing Study in IREx (video)
- What is the SSRP? (video)
- The Importance of Study-specific Local Considerations & Using IREx to Capture LCs (video)

New IREx Feature:

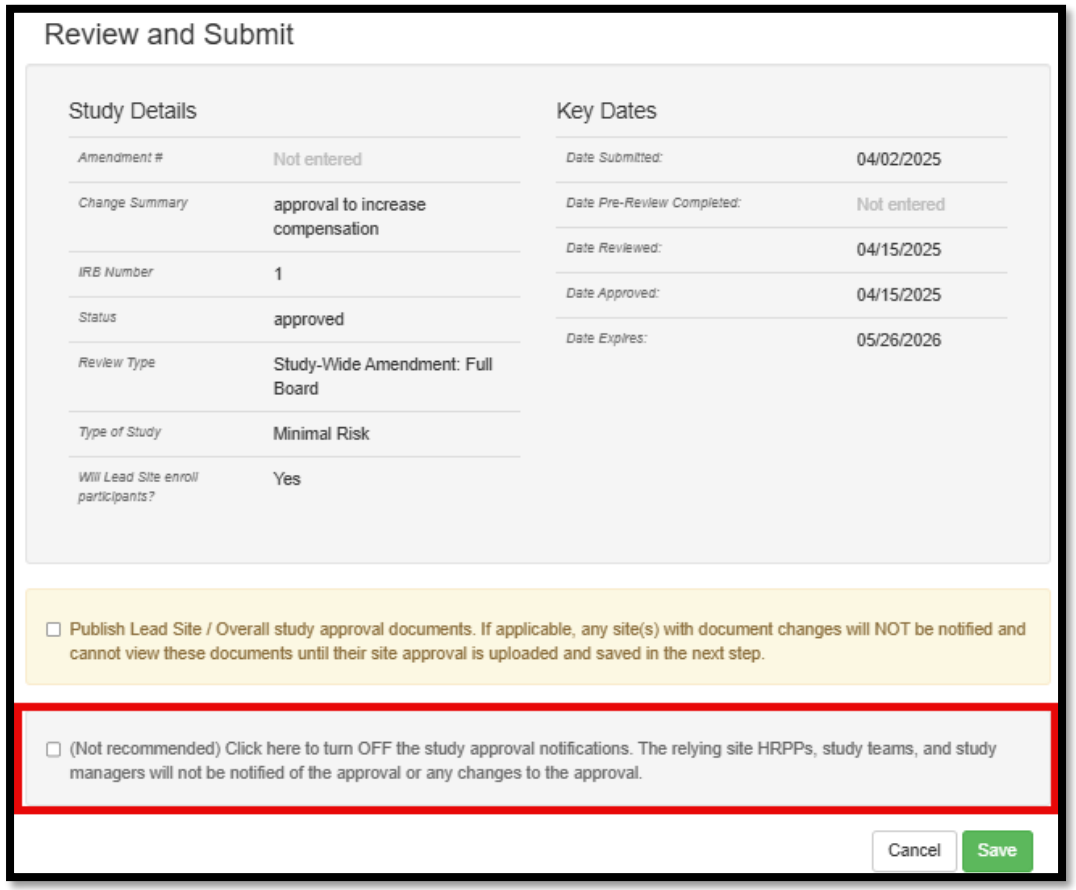
Turning Off Approval Notifications

Allow Reviewing IRBs & SMs to turn off approval notification emails

1. Single IRB will have option to allow Lead Study Team / CC to turn off approval notifications



2. If allowed, **Lead Study Team / CC** can check box to publish approval WITHOUT sending notifications



Updated Materials Related to Turning Off Notifications

PDFs Available on the IREx Website

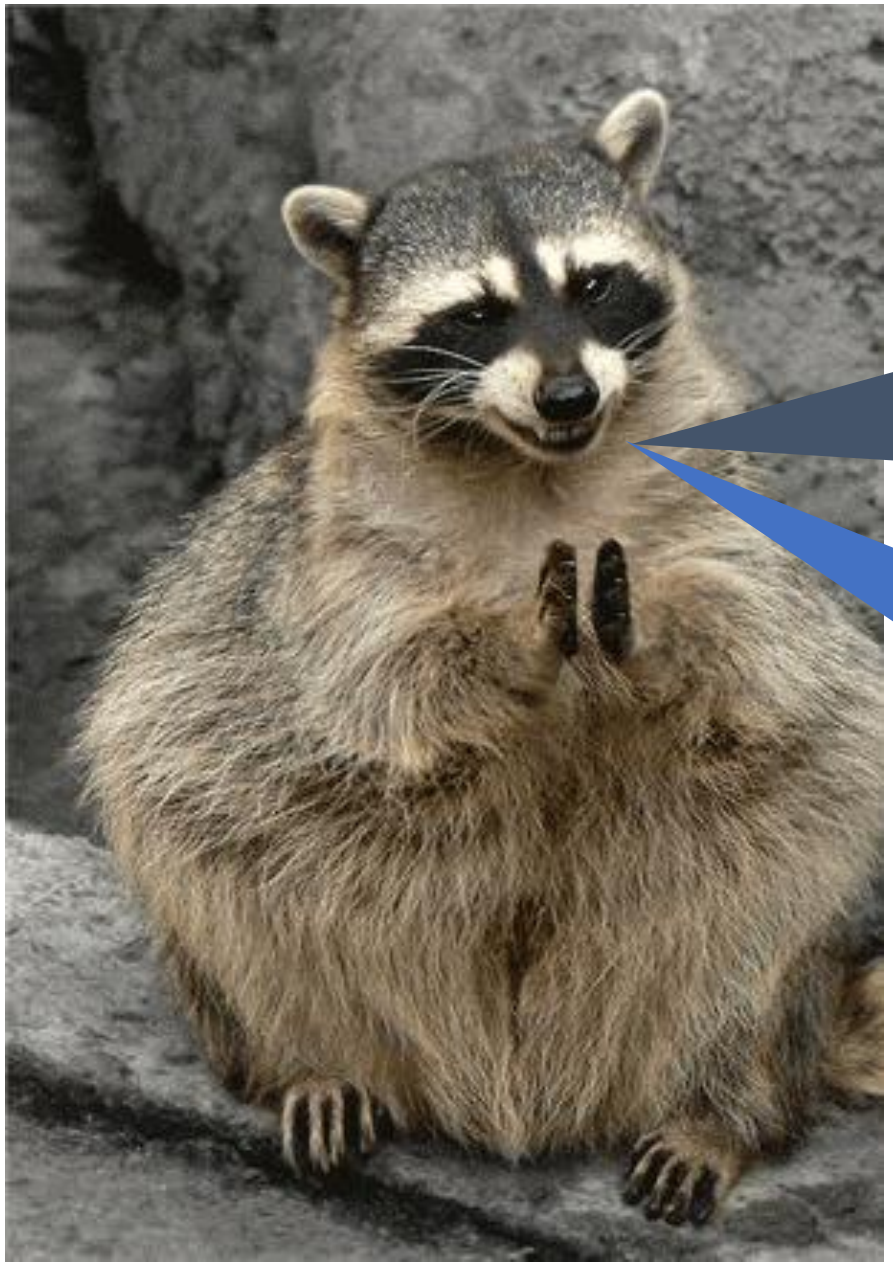
- How to Upload Site Amendments (PDF)
- How to Upload Initial Approvals for Relying Sites (PDF)
- IREx Study Manager Step-by-Step (PDF)
- IREx API Study Manager Step-by-Step (PDF) *(only use if your sIRB uses the IREx API)*
- Reviewing IRB QG (PDF)
- How to Upload the Lead Site / Overall Study Initial Approval (PDF)
- How to Upload a Study-Wide Amendment (PDF)
- How to Upload Continuing Review Approvals in IREx (PDF)

Videos Available on the IREx YouTube Channel

- How to Upload the Initial Approvals for Relying Sites (video)
- How to Upload the Lead Site / Overall Study Initial Approval (video)

PI Survey Updates

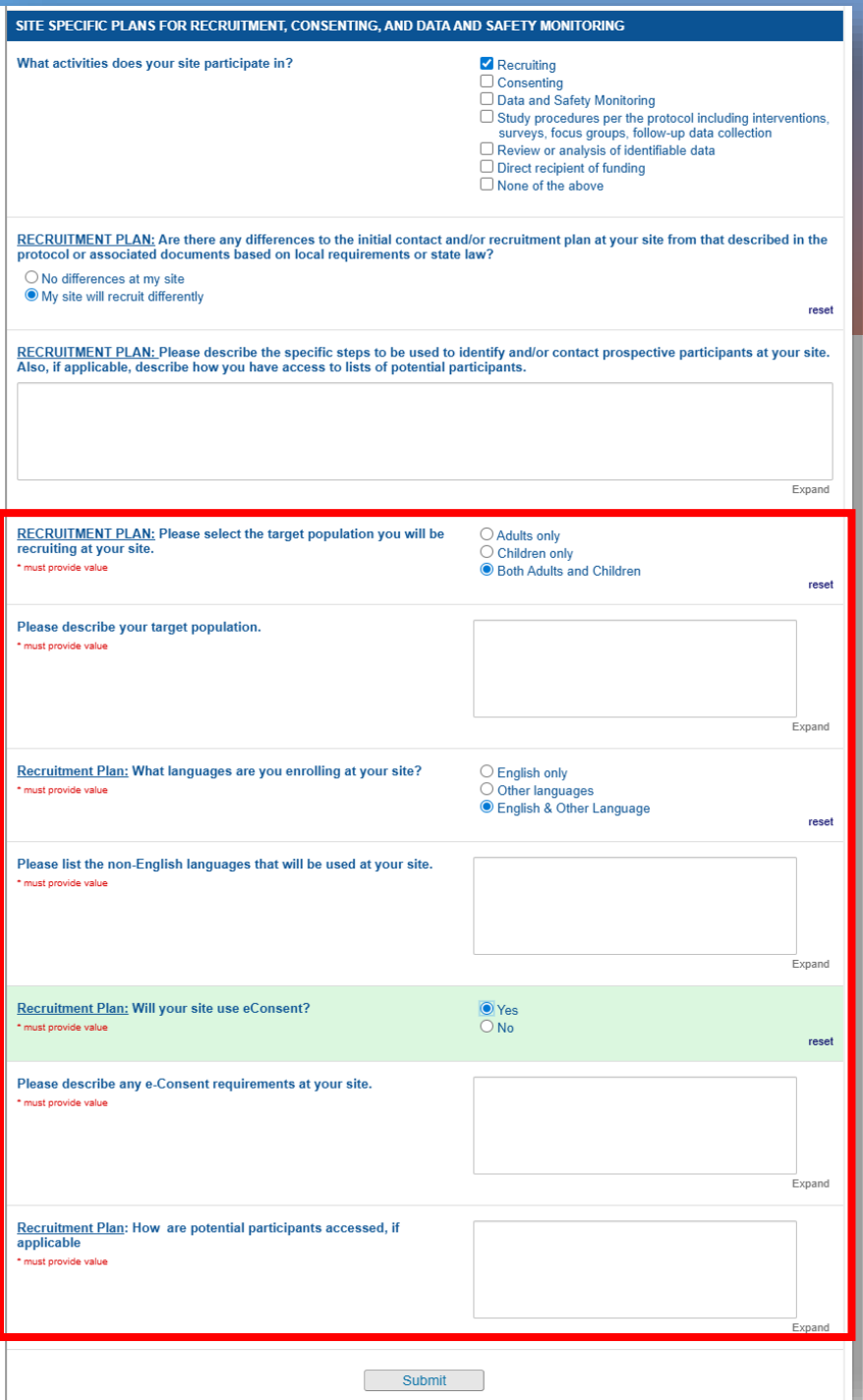
New questions to improve response quality

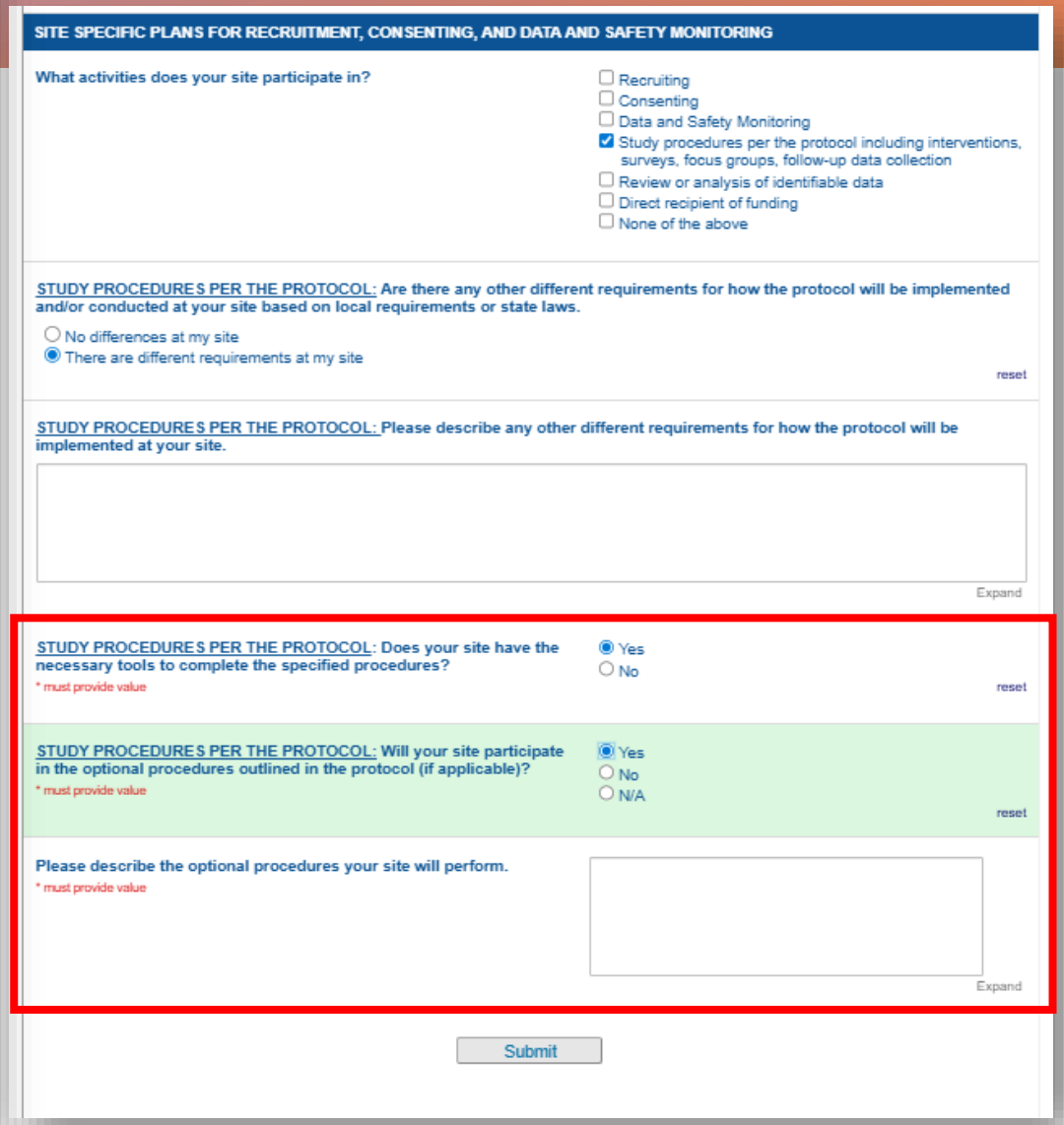


Thank you **Vanderbilt Coordinating Center** for the suggestions!

Thank you **IREx User Feedback Group** for review & additional thoughts!

New Question

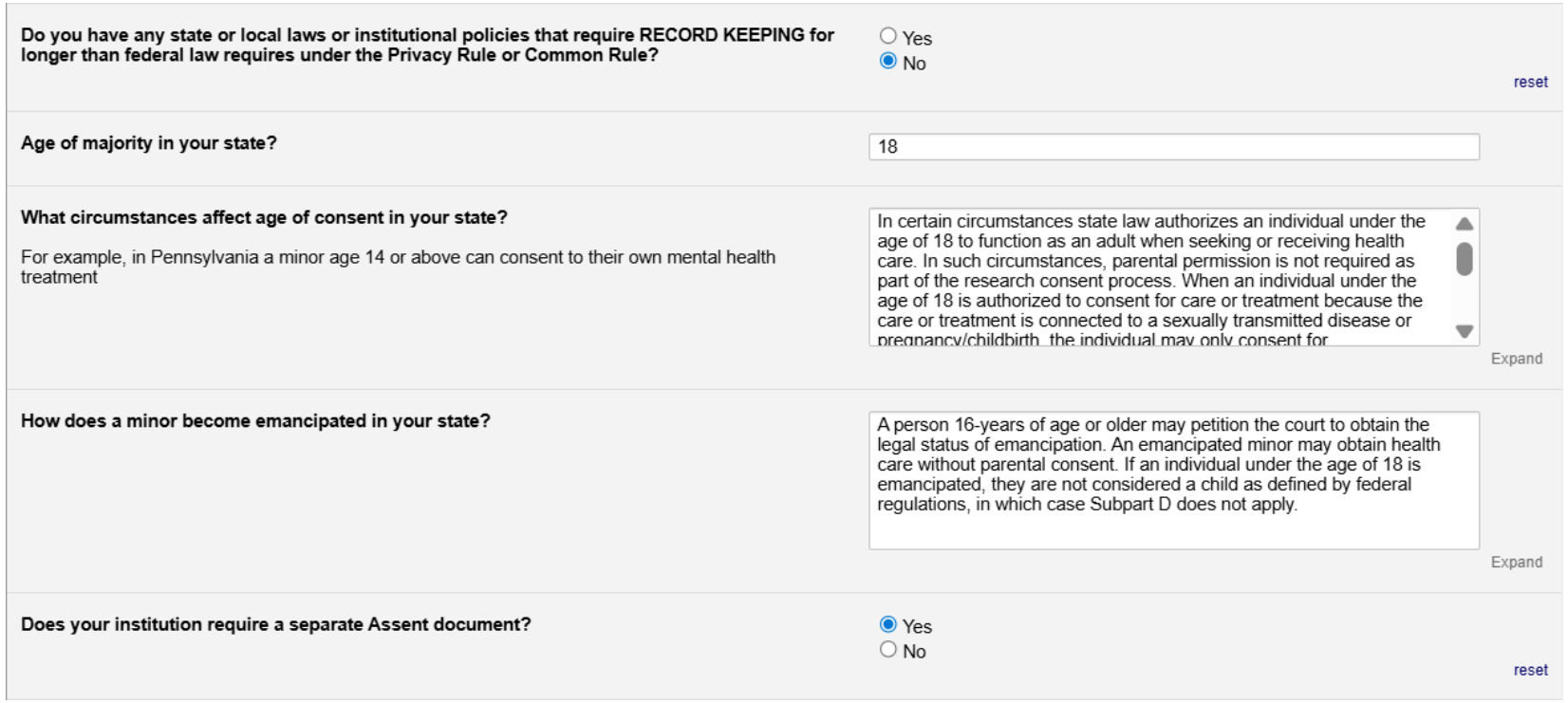




Institutional Profile (IP) Updates & Statistics

IP Reminder

- **No file uploads**
  - Simplify review
  - Minimizes out of date information
- **Line breaks to improve formatting!**



Do you have any state or local laws or institutional policies that require RECORD KEEPING for longer than federal law requires under the Privacy Rule or Common Rule?

○ Yes
◉ No

reset

Age of majority in your state?

18

What circumstances affect age of consent in your state?

For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment

In certain circumstances state law authorizes an individual under the age of 18 to function as an adult when seeking or receiving health care. In such circumstances, parental permission is not required as part of the research consent process. When an individual under the age of 18 is authorized to consent for care or treatment because the care or treatment is connected to a sexually transmitted disease or pregnancy/childbirth, the individual may only consent for

Expand

How does a minor become emancipated in your state?

A person 16-years of age or older may petition the court to obtain the legal status of emancipation. An emancipated minor may obtain health care without parental consent. If an individual under the age of 18 is emancipated, they are not considered a child as defined by federal regulations, in which case Subpart D does not apply.

Expand

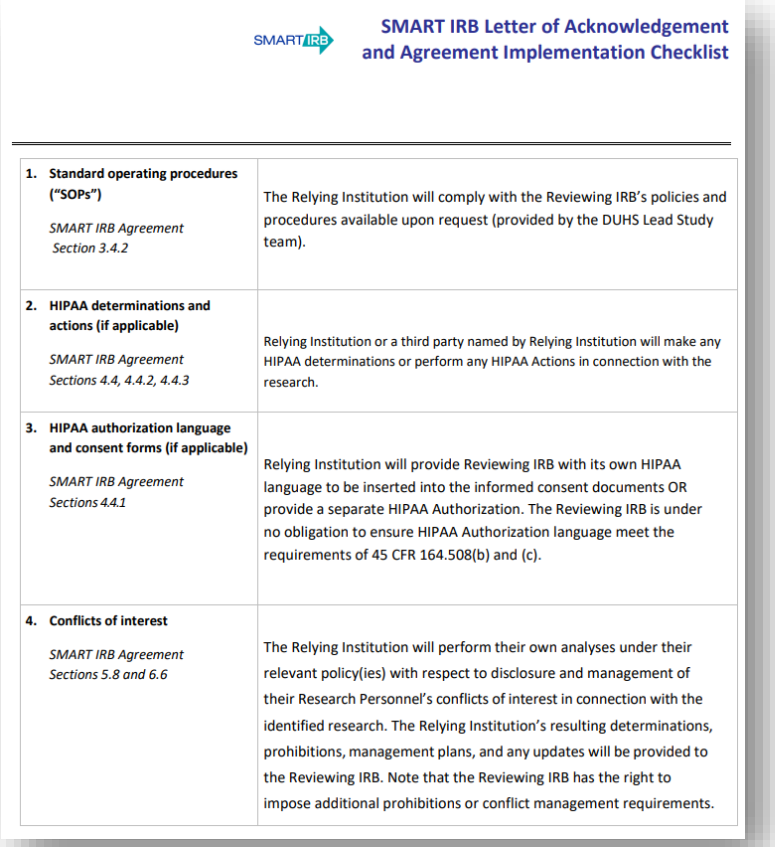
Does your institution require a separate Assent document?

◉ Yes
○ No

reset

About the New IP Fields

1. Align IREx's SSRP with the SMART IRB v3 Implementation Checklist
2. Capture additional state/local requirements that have standard implications for review or the consent form, for example:
   - Pregnancy testing
   - Text/email communication policies
   - Signature block requirements
   - Genetic testing



SMART IRB

SMART IRB Letter of Acknowledgement and Agreement Implementation Checklist

1. Standard operating procedures ("SOPs") *SMART IRB Agreement Section 3.4.2*	The Relying Institution will comply with the Reviewing IRB's policies and procedures available upon request (provided by the DUHS Lead Study team).
2. HIPAA determinations and actions (if applicable) *SMART IRB Agreement Sections 4.4, 4.4.2, 4.4.3*	Relying Institution or a third party named by Relying Institution will make any HIPAA determinations or perform any HIPAA Actions in connection with the research.
3. HIPAA authorization language and consent forms (if applicable) *SMART IRB Agreement Sections 4.4.1*	Relying Institution will provide Reviewing IRB with its own HIPAA language to be inserted into the informed consent documents OR provide a separate HIPAA Authorization. The Reviewing IRB is under no obligation to ensure HIPAA Authorization language meet the requirements of 45 CFR 164.508(b) and (c).
4. Conflicts of interest *SMART IRB Agreement Sections 5.8 and 6.6*	The Relying Institution will perform their own analyses under their relevant policy(ies) with respect to disclosure and management of their Research Personnel's conflicts of interest in connection with the identified research. The Relying Institution's resulting determinations, prohibitions, management plans, and any updates will be provided to the Reviewing IRB. Note that the Reviewing IRB has the right to impose additional prohibitions or conflict management requirements.

About the New Local Review Fields

Responses are general and should not be tailored to a study.

Does your institution require a separate Assent document?	Yes
Please describe specific requirements for a separate Assent document (e.g., separate consent for certain age groups).	Investigators must provide the IRB with information regarding the plan to obtain assent from children involved in the research. Because the IRB must evaluate the age, maturity, and psychological state of the children, it is important for the investigator to provide as much information about the children who will be recruited. Generally, the IRB requires assent from children 7 or older but this may vary depending on other factors. Once the IRB has enough information about the assent process, the IRB determines whether assent is a requirement of all children, some of the children or none of the children. **Under what circumstances is assent not required by the IRB?** If assent is NOT a requirement for some or all children, the IRB must make one (or more) of the following findings: • The children are not capable of providing assent based on the age, maturity, or psychological state. • The capability of the children is so limited that they cannot be reasonably consulted. • The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research. • The assent process is entirely waived consistent with the provisions for waiver of consent contained in 45 CFR 46.116 (consistent with the provisions for waiver of consent/parental permission). Note: The University of Utah IRB does not require investigators to complete waiver of consent form in ERICA. Once the assent process has been completed, an assent document will typically be used to document assent. If the investigator plans to document assent using another method or does not plan to document the assent process, the IRB must approve of such a plan. The assent document should be written in a way that is suitable for the child's age. Typically, the University of Utah IRB recommends one assent document to be written for younger children (7-11) and one assent document for older children (ages 12-17). In some cases, one assent document would be acceptable (e.g., the study is enrolling children ages 10-15 and uses one assent document). Reference: https://irb.utah.edu/investigator-guidance-series/, search "Parental Permission and Child Assent".
Does your institution require an assent signature on the main consent form for children/adolescents?	No
Do you have any specific consent form language regarding pregnant women?	Yes
Please enter your specific consent form language regarding pregnant women.	Exact language is not required, but the consent must describe the risks and benefits to the pregnant women and fetuses. State that there may also be unforeseeable risks to an embryo or fetus for a particular treatment or procedure.
Does your institution require an internal review for studies involving prisoners?	No
Do you have any specific consent form language regarding other vulnerable populations (e.g. students, LGBTQIA+, etc...)?	No

About the New Local Review Fields

It’s okay to include hyperlinks to policies and websites.

When possible, **also** include navigational tips and important notes.

Please insert your policy language related to translation of consent forms for non-English speaking individuals.	Please visit our Translations Library at: https://irb.utah.edu/translation-library/. Review the FAQ section for information related to your study's specific needs.
Does your site have an institutional policy for text and/or email communications for research purposes?	Yes
Please insert your policy language related to text/email communications.	https://regulations.utah.edu/it/rules/Rule4-004C.php. All devices storing, processing, creating, or transmitting University data, where technically feasible, shall be Encrypted.
Does your site require specific language in your consent around text and/or email communications?	No
Is your site able to use an e-Consent platform, if available for a specific trial? If yes, please indicate whether your study teams HAVE OR ARE ALLOWED TO USE the platforms below, if provided by the study.	Yes
DocuSign	Yes, but unsure of part 11 compliance
REDCap e-Consent Module	Yes, in part 11 compliant manner
AdobeSign	Yes, in part 11 compliant manner
SignNow	Yes, but unsure of part 11 compliance
Does your site require specific signature blocks (e.g., signatures for translators for folks who can't read or date and time)?	Yes
Please describe when a specific signature block is required at your site.	Reference: https://irb.utah.edu/informed-consent/forms-templates-cpt/ and search for "Signature Block Samples". We accept variations of the signature block, with the exception of the Legally Authorized Representative block, which has specific requirements related to Utah State law.

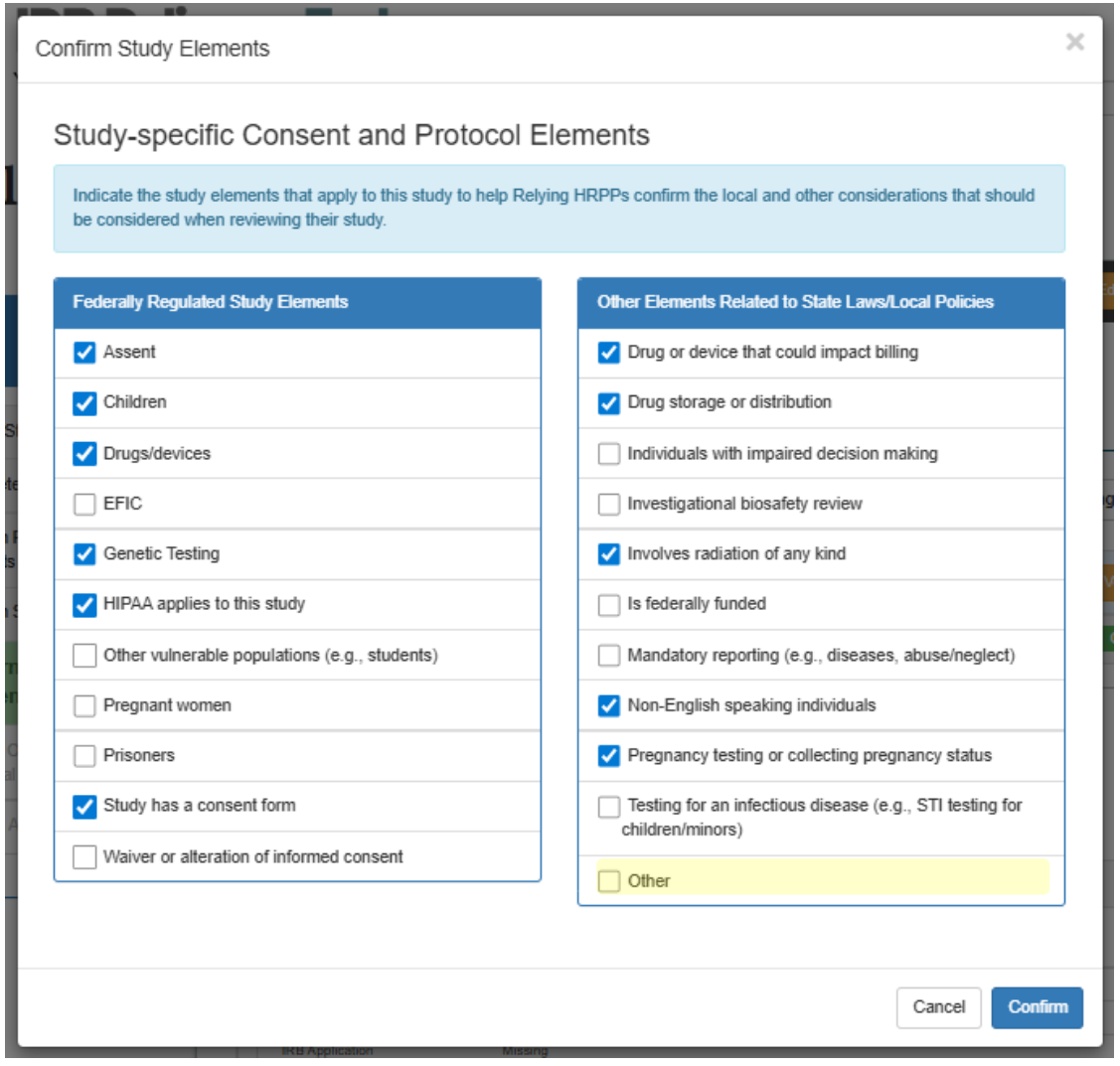

Why?

IREx is bringing automation to Local Context Reporting!

It's an investment in your future!

Coming soon for sIRBs:

- When sIRBs create a study, they will indicate study elements that apply to the study
- sIRBs can also add specific questions to the HRPP and/or PI Survey (e.g., *Is use of the ABCDE sleep protocol standard of care in the ICU at your site?*)

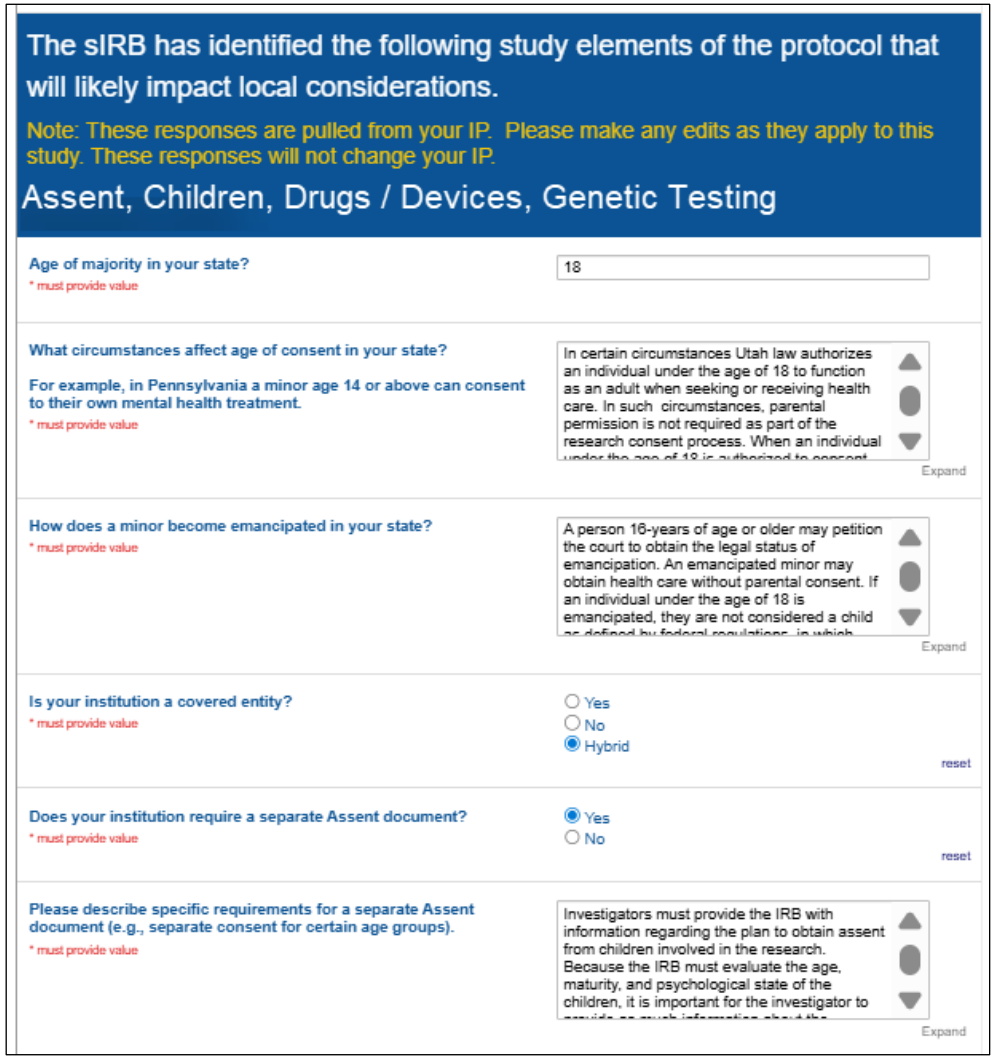


IREx is bringing automation to Local Context Reporting!

Coming soon for Relying Sites:

- **IP questions & answers** related to the study elements will **pipe into the HRP Survey** for relying HRPP to:
  - Confirm response OR
  - Tailor response to the study

Minimize duplication & streamline reporting of local context!

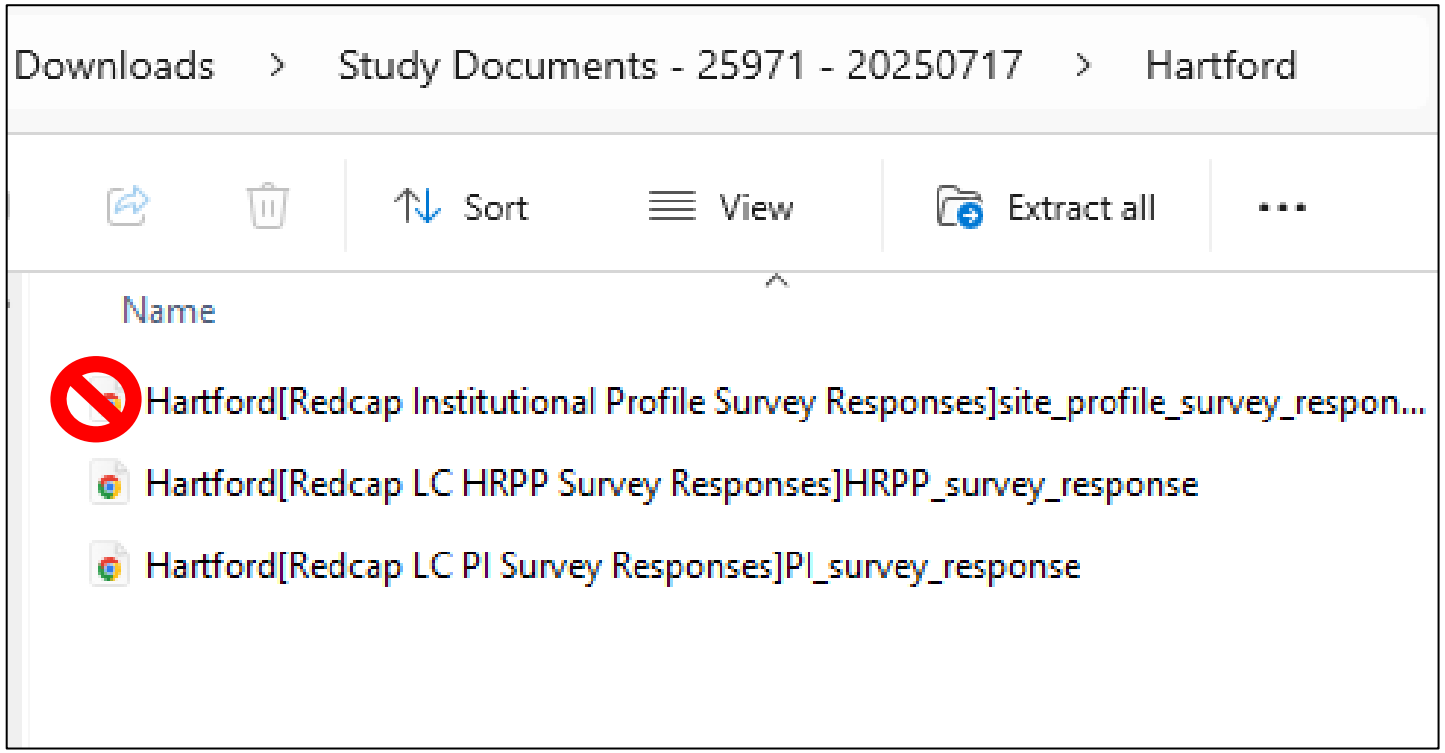


IREx is bringing automation to Local Context Reporting!

Coming soon for sIRBs:

- All IP & HRP Survey information will be on a single form for review.
- The full IP will no longer export with local considerations

Minimize inconsistencies between the IP & HRP Survey

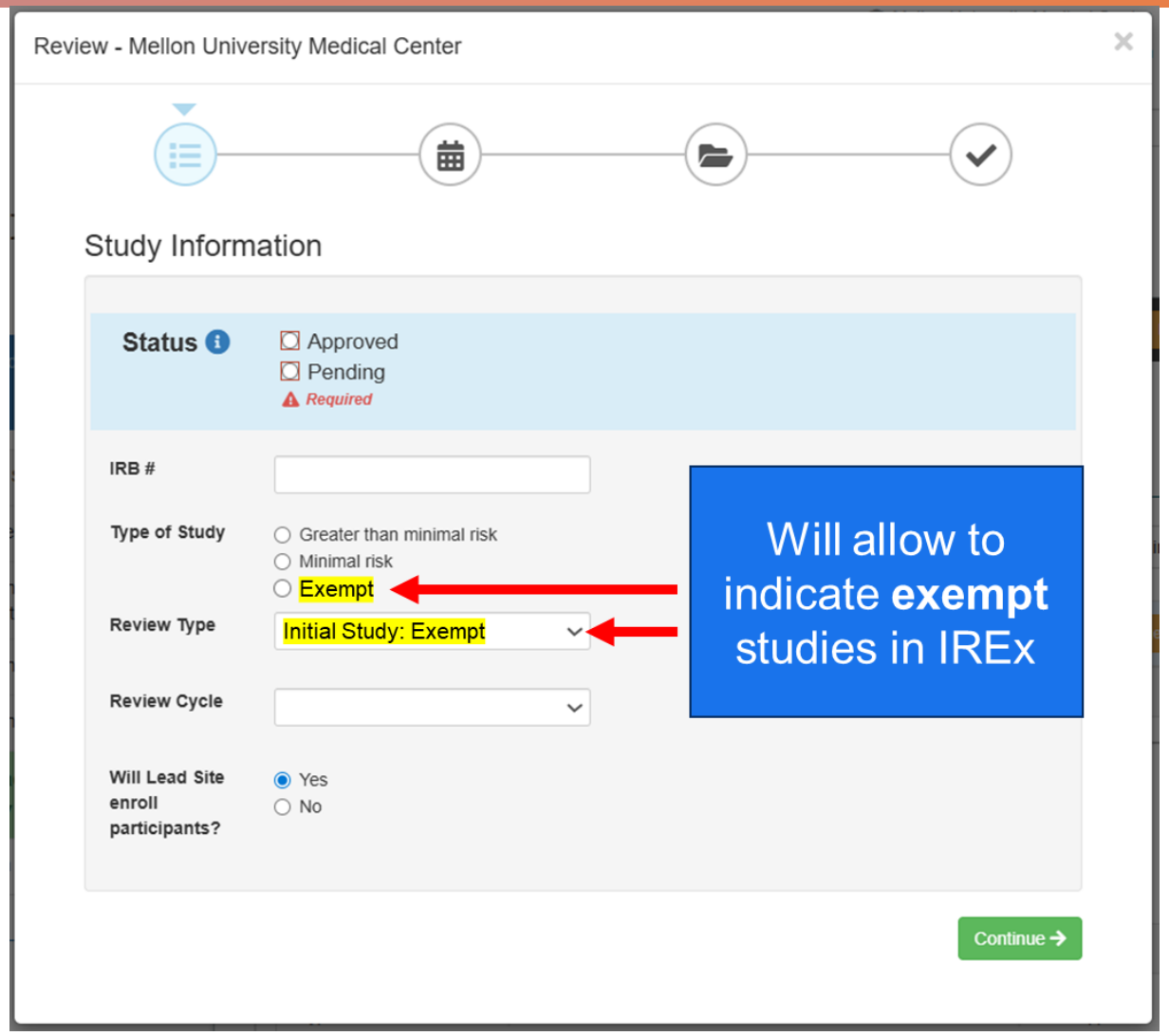


Update your IP & Complete the New Questions!

Upcoming Features

ETA –Fall 2025

‘Exempt’ Studies in IREx



Mid-Year Metrics Check

Notable Metrics

- **49 institutions** are using *IREx as the sIRB* for over **700** studies
- **70%** of single IRBs using IREx, continue to use it (have >1 studies in IREx)
- **68%** of studies have **1-5 sites** | **32%** of studies have **>5 sites**
- **40** sites have >40 studies in which they are relying
- Average of **10** studies per relying site
- **90%** of sites have made it through the sIRB process and received initial approval

Who’s next??

Using IREx as the Single IRB

IREx is proven useful for studies of all sizes

- **Centralizes** documentation for large studies
  - Helps capture document for many, many sites
  - Easy to track where sites are in the pipeline
  - Provides Transparency for coordinating centers or studies with large teams to onboard sites
- **Simplifies** the process for small studies
  - May not have a ‘study manager’ or coordinating center to manage communications
  - PIs may be new to multisite studies + sIRB → IREx is their guide to what needs to happen
- **Minimizes burden** on sIRB to answer operational/process questions
  - IREx Support Team offers 2 trainings per month to lead study teams
  - IREx Support Team monitors site onboarding ON ALL STUDIES to offer tips/answer questions

IREx and SMART Online Reliance System Differ

- **In IREx…**
  - PIs do not request an sIRB within IREx – they discuss **directly** with the sIRB (e.g., email, HRPP website)
  - **sIRBs creates the study shell + configure preferred settings**
  - Capture reliance decisions, the Implementation Checklist (SSRP), local context and Approvals
  - IREx local context and SSRP are dynamic – they can be edited and captured **for the life of the study**
  - IREx captures relying site approvals to streamline communications and centralize access **for the life of the study**
- The SAME: Study Teams add sites and contacts

IREx Workflow is Flexible

- **When should the study be created?**
  - ❑Prior to lead site approval – this gives study team time for training & adding sites + contacts
  - ❑After the lead site is approved
- **What features can I leverage?**
  - ❑Reliance agreements offered (SMART IRB and/or others)
  - ❑Track indemnification agreements in IREx, or not
  - ❑Use IREx **template emails** (instructions to sites, agreements to complete) or **upload custom templates**
  - ❑Capture Local Context for the life of the study or not
  - ❑*Allow* study manager to turn off approval notifications
- **How much do I want the Study Manager to do?**
  - All of it (other than study creation and setup)
  - A mix – sIRB screens local context and creates site add | SM adds sites and their sIRB approvals
  - **FWIW: Most offload all tasks the Lead Study Team!**

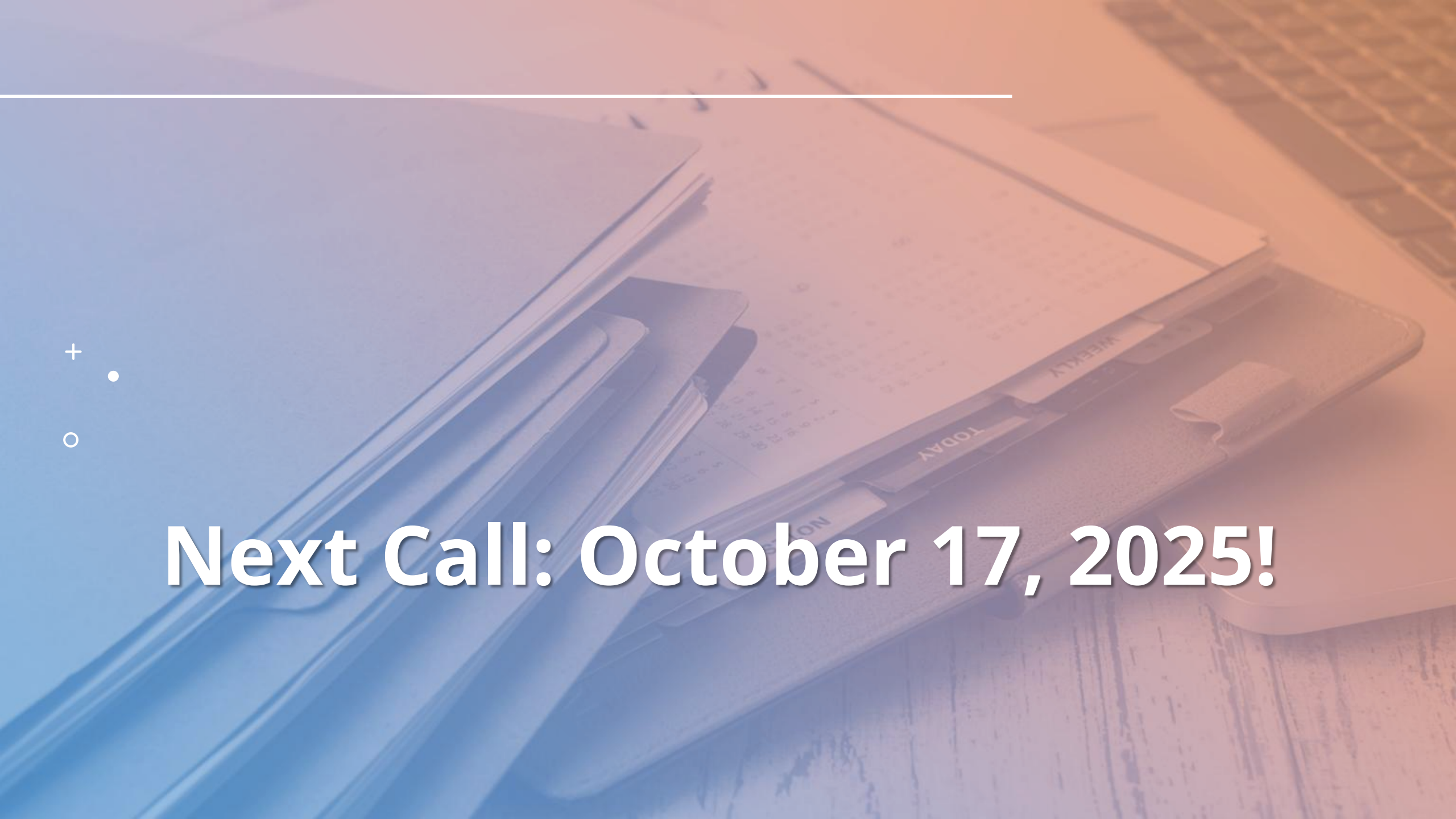
[Demo] Create a Study in IREx

IREx Resource & Navigation Tour

We Want to Hear From You!

How can we improve IREx?

- Other metrics or information we can make available on the public homepage?
- New features?
- Reports?



Next Call: October 17, 2025!