10.17.2025 QUARTERLY CALL AGENDA

- Welcome & Announcements
- Institutional Profile Updates & Reminder
- New IREx Features
- Upcoming Features
- IREx Evaluation


HAPPY FALL!

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

Next Quarterly Call

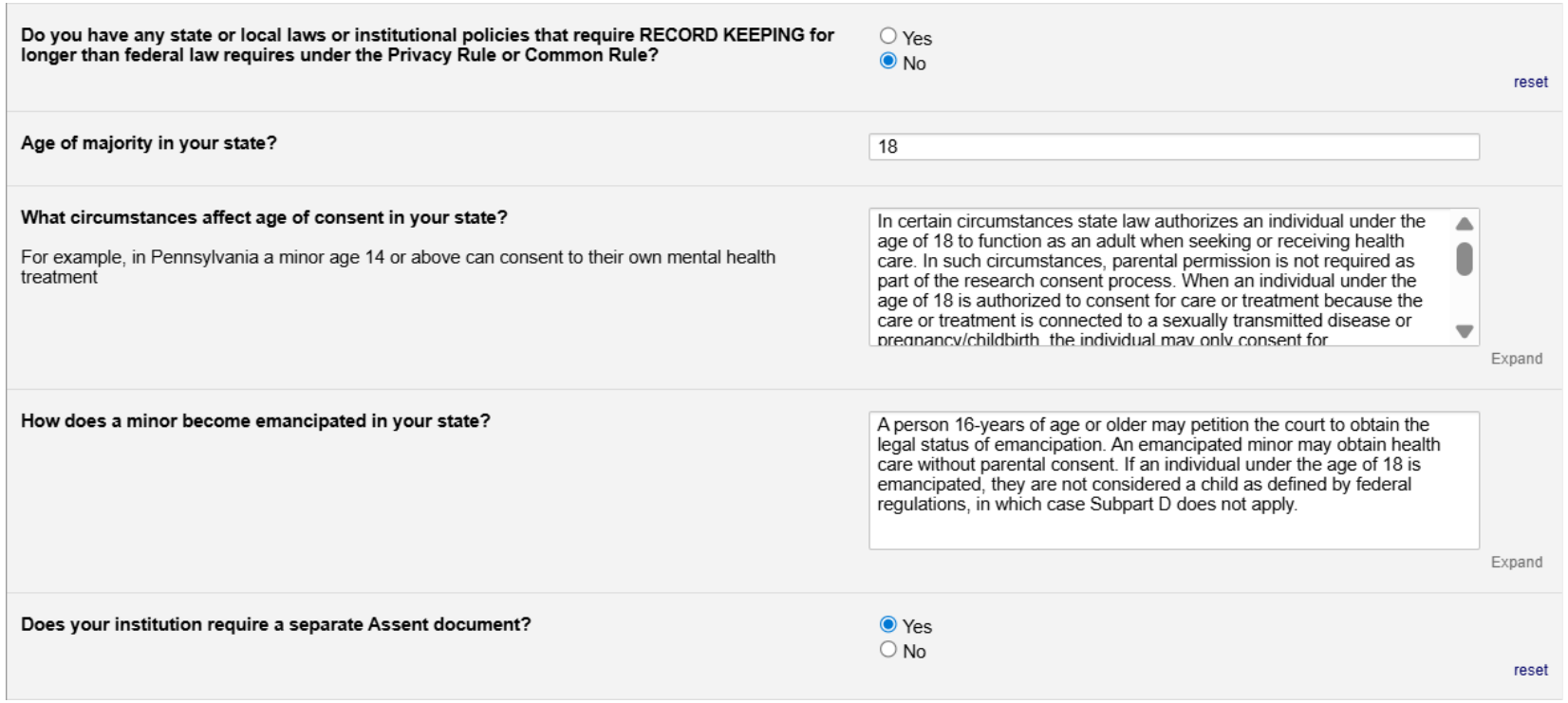
January 16, 2026

- **NEW Registration Link:** https://zoom.us/meeting/register/Feqe9Ug-QX2YeL-71mDNVw

Institutional Profile (IP) Updates

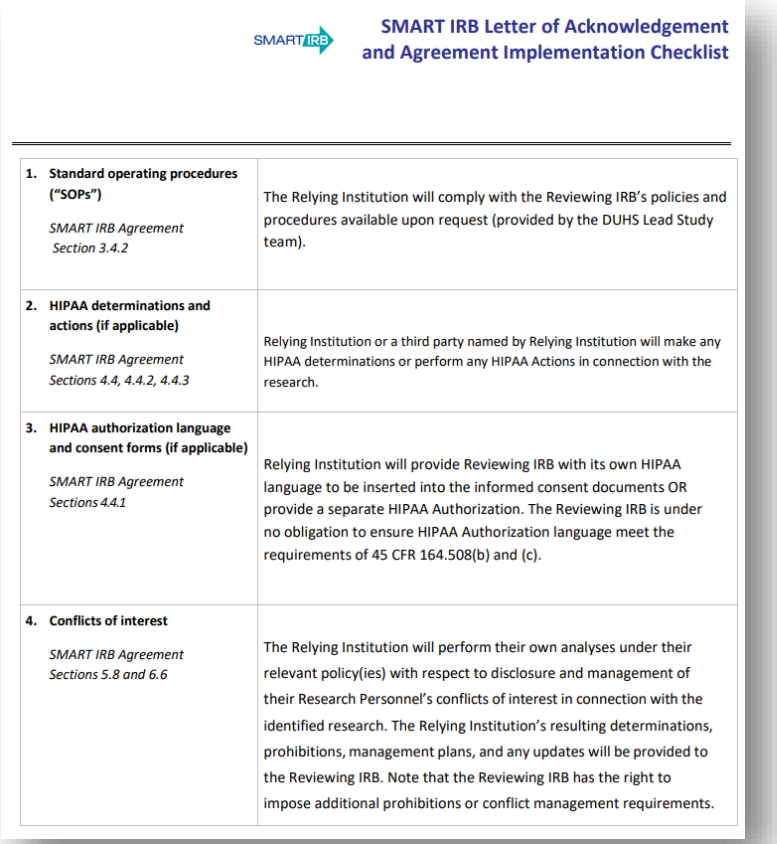
IP Reminder

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  - Minimizes out of date information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



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 Letter of Acknowledgement and Agreement Implementation Checklist

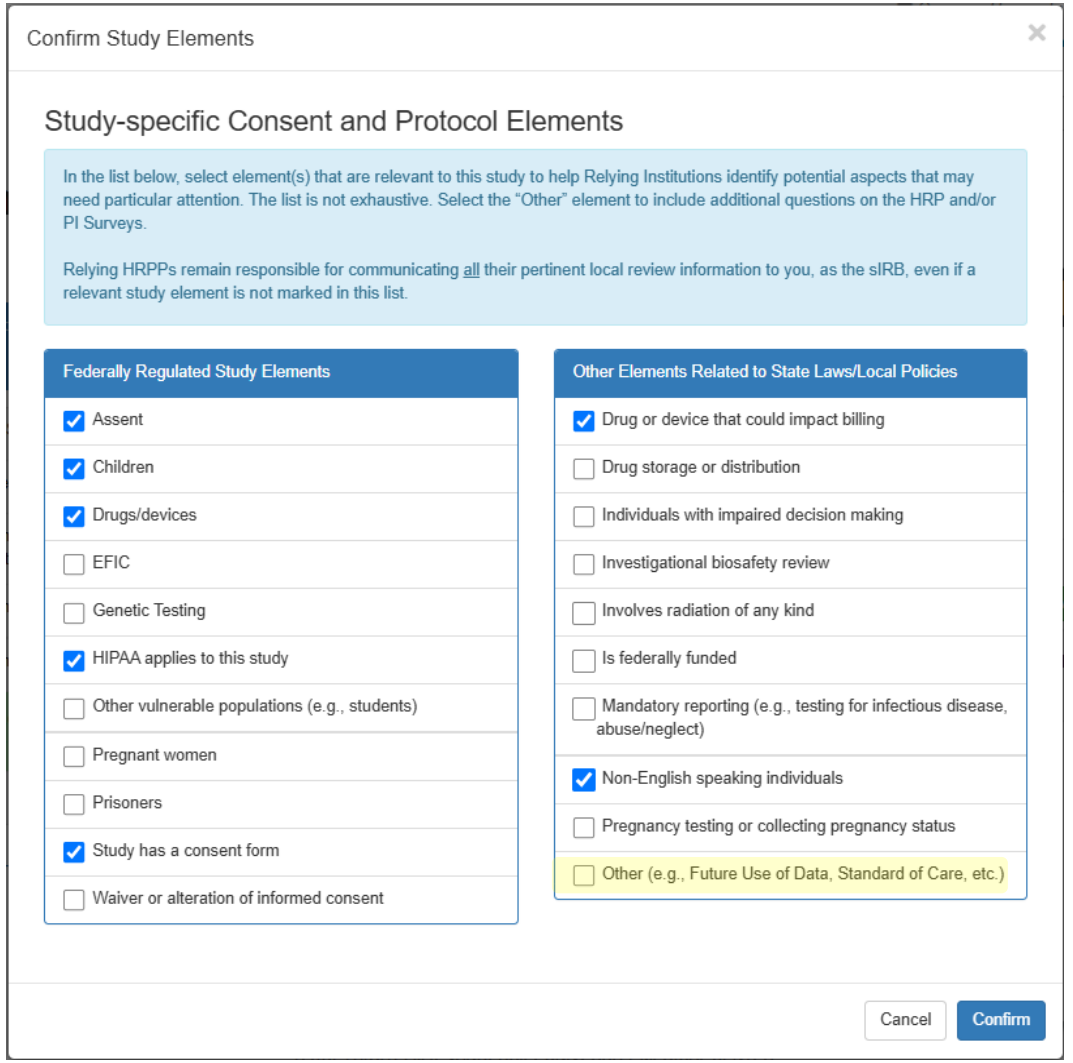
1. Standard operating procedures ("SOPs") *SMART IRB Agreement Section 3.4.2*	The Relying Institution will comply with the Reviewing IRB's policies and procedures available upon request (provided by the DUHS Lead Study team).
2. HIPAA determinations and actions (if applicable) *SMART IRB Agreement Sections 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.

New IREx Features:

Automating Local Considerations; IREx Project ID More Visible

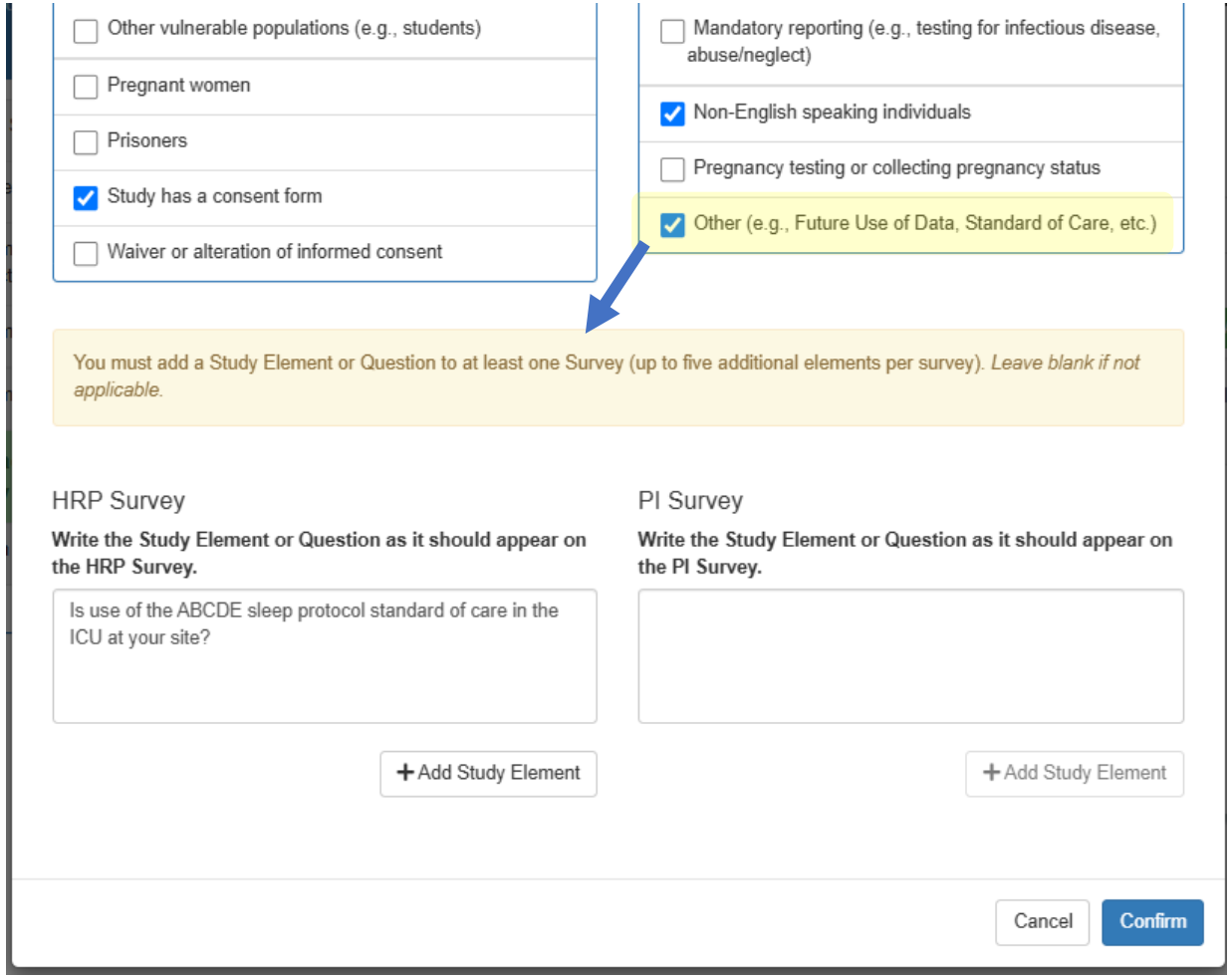
Automating Local Considerations – Study Setup [sIRB]

- Reviewing IRBs indicate study elements that apply to the study
- Reviewing IRBs can also add specific questions to the HRP and/or PI Survey (e.g., *Is use of the ABCDE sleep protocol standard of care in the ICU at your site?*)



Automating Local Considerations – Study Setup [sIRB]

- Reviewing IRBs can add up to five additional questions per survey

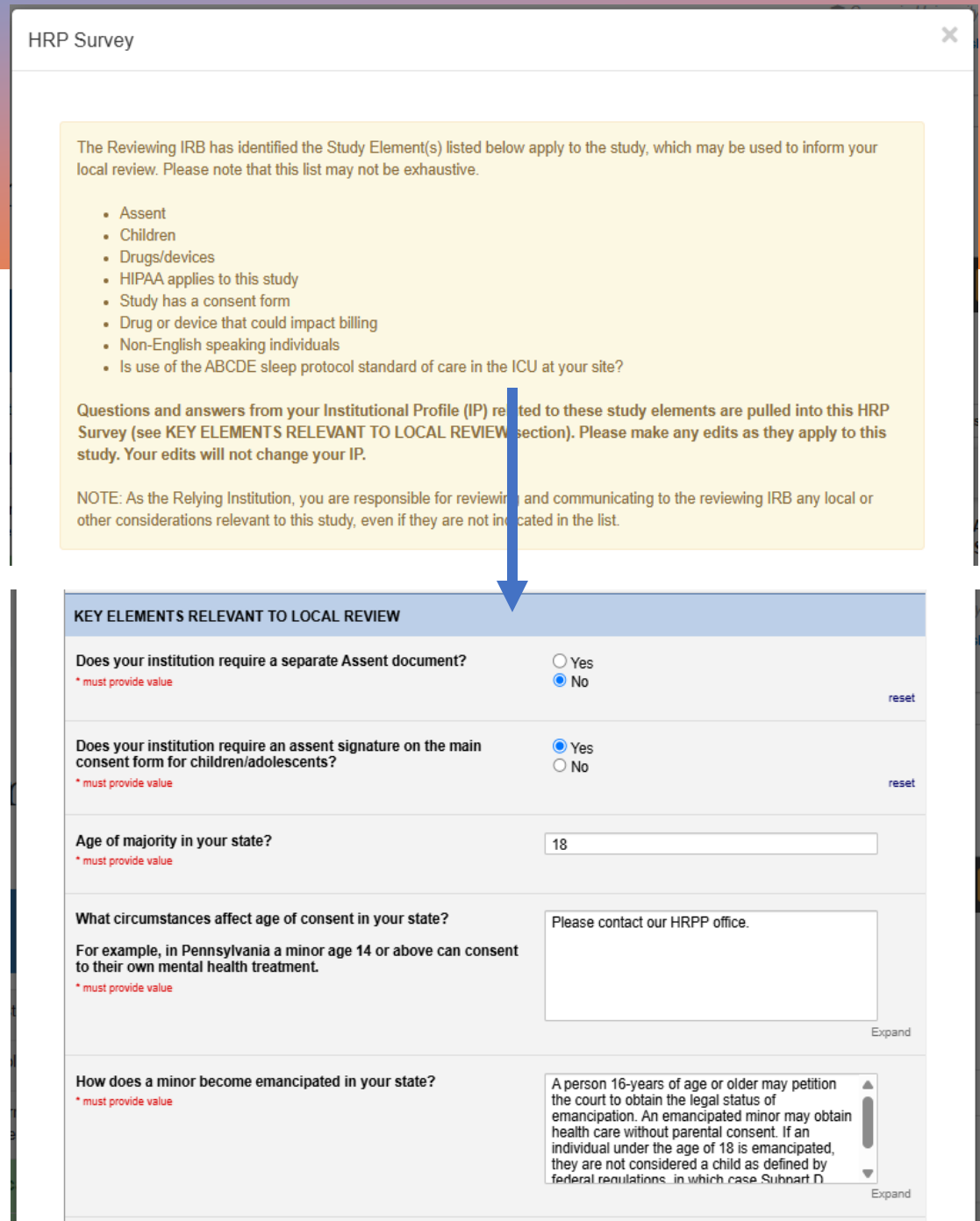


Automating Local Considerations – HRP Survey [Relying HRPP]

Institutional Profile (IP) questions & answers related to the study elements will **pipe into the HRP Survey** for Relying HRPPs to:

- Confirm response OR
- Tailor response to the study

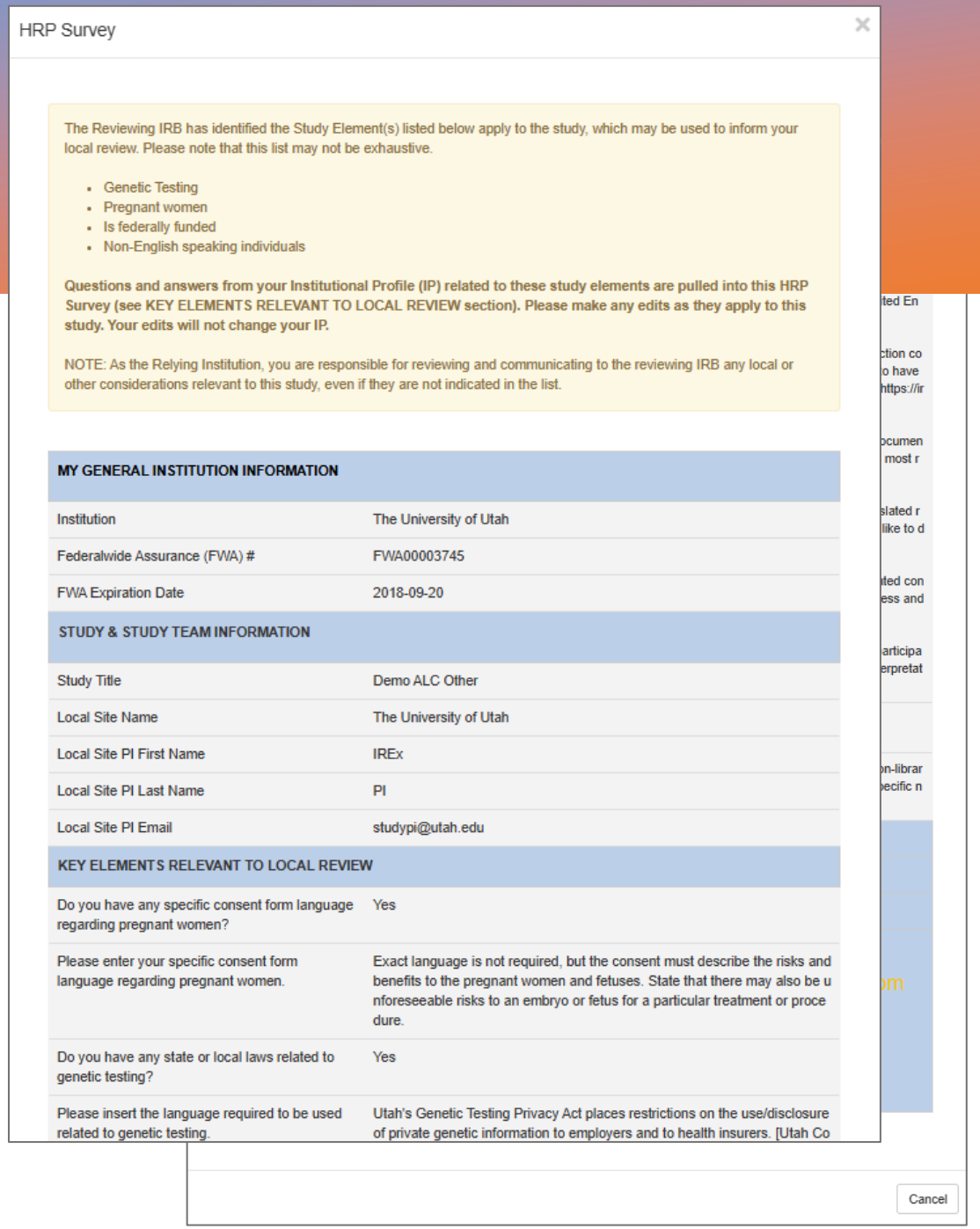
Minimize duplication & streamline reporting of local context!



Automating Local Considerations – LC Export [Study Manager]

- All relevant study information will be on a single form (HRP Survey) for review
- The full IP will no longer export with local considerations

Minimize inconsistencies between the IP & HRP Survey


HRP Survey

The Reviewing IRB has identified the Study Element(s) listed below apply to the study, which may be used to inform your local review. Please note that this list may not be exhaustive.

- Genetic Testing
- Pregnant women
- Is federally funded
- Non-English speaking individuals

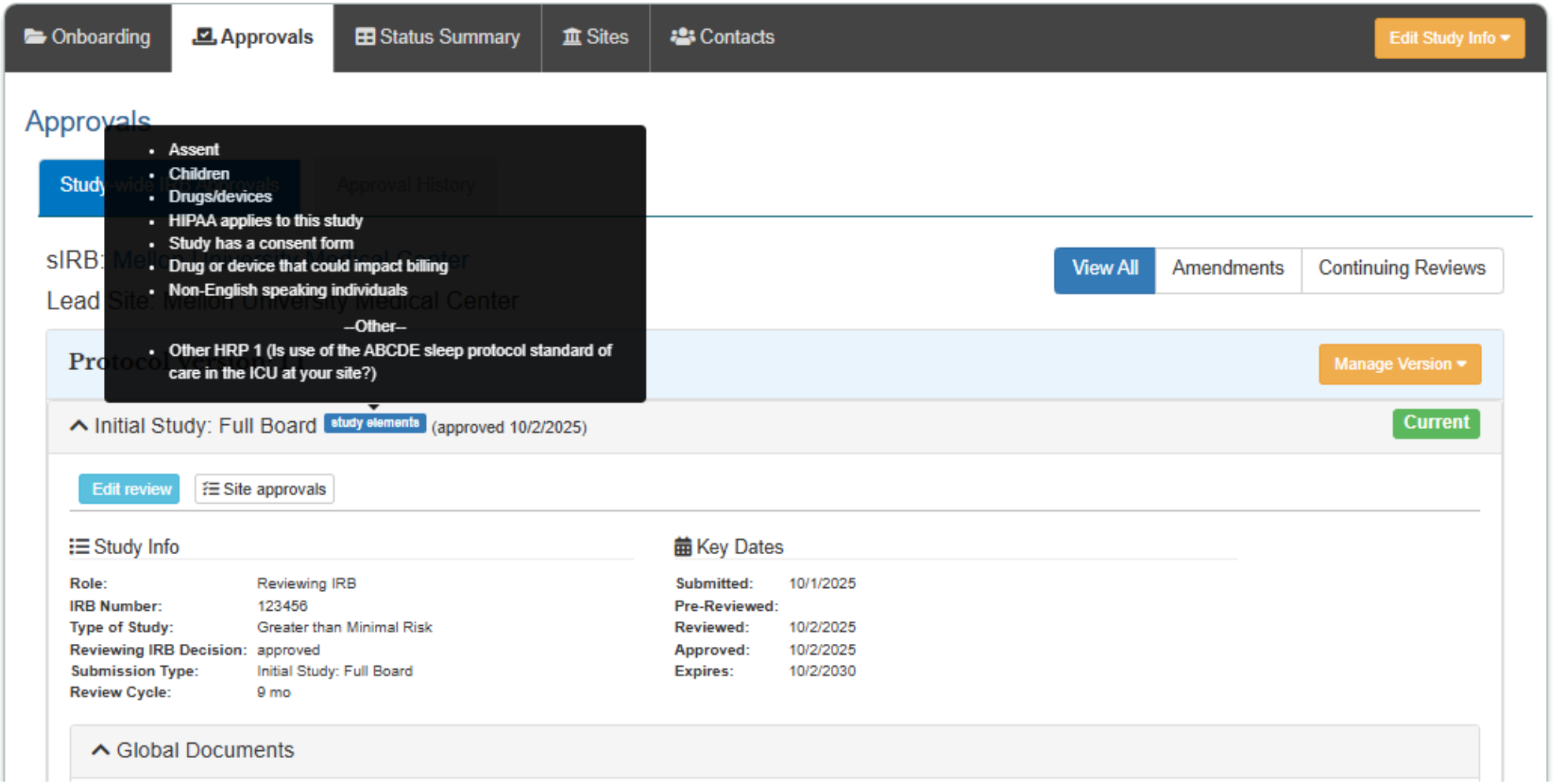
Questions and answers from your Institutional Profile (IP) related to these study elements are pulled into this HRP Survey (see KEY ELEMENTS RELEVANT TO LOCAL REVIEW section). Please make any edits as they apply to this study. Your edits will not change your IP.

NOTE: As the Relying Institution, you are responsible for reviewing and communicating to the reviewing IRB any local or other considerations relevant to this study, even if they are not indicated in the list.

MY GENERAL INSTITUTION INFORMATION	
Institution	The University of Utah
Federalwide Assurance (FWA) #	FWA00003745
FWA Expiration Date	2018-09-20
STUDY & STUDY TEAM INFORMATION	
Study Title	Demo ALC Other
Local Site Name	The University of Utah
Local Site PI First Name	IREx
Local Site PI Last Name	PI
Local Site PI Email	studypi@utah.edu
KEY ELEMENTS RELEVANT TO LOCAL REVIEW	
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 u nforeseeable risks to an embryo or fetus for a particular treatment or proce dure.
Do you have any state or local laws related to genetic testing?	Yes
Please insert the language required to be used related to genetic testing.	Utah's Genetic Testing Privacy Act places restrictions on the use/disclosure of private genetic information to employers and to health insurers. [Utah Co

Cancel

History of Study Elements Per Approval Version



Updated Materials Related to Automating Local Considerations

PDFs Available on the IREx Website

- How to Upload a Study-Wide Amendment
- IREx Benefits for Single IRBs
- Automating Local Consideration Overview
- Multi-Site Liaison HRPP Quick Guide
- Participating Site HRPP Quick Guide
- Reviewing IRB Quick Guide

Videos Available on the IREx YouTube Channel

- How to Create a New Study
- How to Upload a Study-Wide Amendment

Update your IP & Complete the New Questions!

Two sIRBs' Experiences (so far) with Automating Local Considerations:

Junie Hildenbrandt (UCSF) & Jacque van Audenhove (VUMC)

Automating Local Considerations

Study Elements in IREX

UCSF User Experience

Junie Hildebrandt PhD, CIP

Reliance Coordinator, UCSF

10/21/2025

Junie's Observations

5 different levels of input (UCSF reviewing)

- **Reviewing Site HRPP– Me!**
  - To complete Study Element: Review IRB application, outcome information, and IRB approval letters(s)
  - Select the appropriate elements in IREX
  - Finish IREX Set up, turn over IREX to the Study Manager
- **Study Manager – Lead PI**
  - When should the study manager review the elements?
  - Is this decision a local site process or an IREX process?
- **Participating (relying site) HRPP**
  - They fill it out, but do they check against the submitted materials?
  - What if they need to change their entry?
- **Participating (relying) PI**
  - Do they even notice?
- **Reviewing Site HRPP – Analyst (not me)**
  - Checking for consistency before approving site

What I fill out

Confirm Study Elements

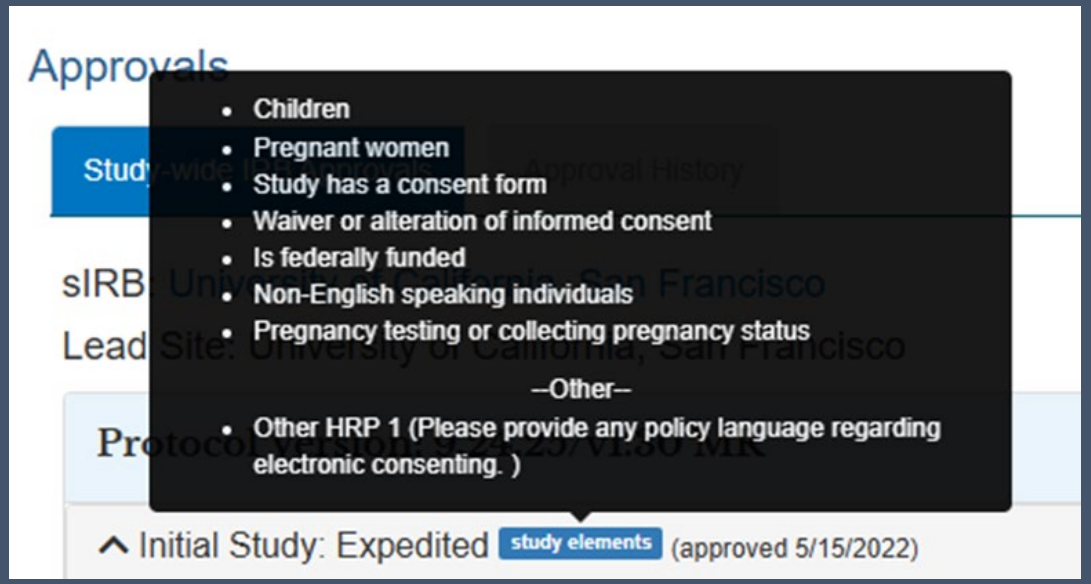
Study-specific Consent and Protocol Elements

In the list below, select element(s) that are relevant to this study to help Relying Institutions identify potential aspects that may need particular attention. The list is not exhaustive. Select the "Other" element to include additional questions on the HRP and/or PI Surveys.

Relying HRPPs remain responsible for communicating all their pertinent local review information to you, as the sIRB, even if a relevant study element is not marked in this list.

Federally Regulated Study Elements	Other Elements Related to State Laws/Local Policies
☐ Assent	☐ Drug or device that could impact billing
☐ Children	☐ Drug storage or distribution
☐ Drugs/devices	☐ Individuals with impaired decision making
☐ EFIC	☐ Investigational biosafety review
☐ Genetic Testing	☐ Involves radiation of any kind
☐ HIPAA applies to this study	☐ Is federally funded
☐ Other vulnerable populations (e.g., students)	☐ Mandatory reporting (e.g., testing for infectious disease, abuse/neglect)
☐ Pregnant women	☐ Non-English speaking individuals
☐ Prisoners	☐ Pregnancy testing or collecting pregnancy status
☐ Study has a consent form	☐ Other (e.g., Future Use of Data, Standard of Care, etc.)
☐ Waiver or alteration of informed consent	

What the study team sees



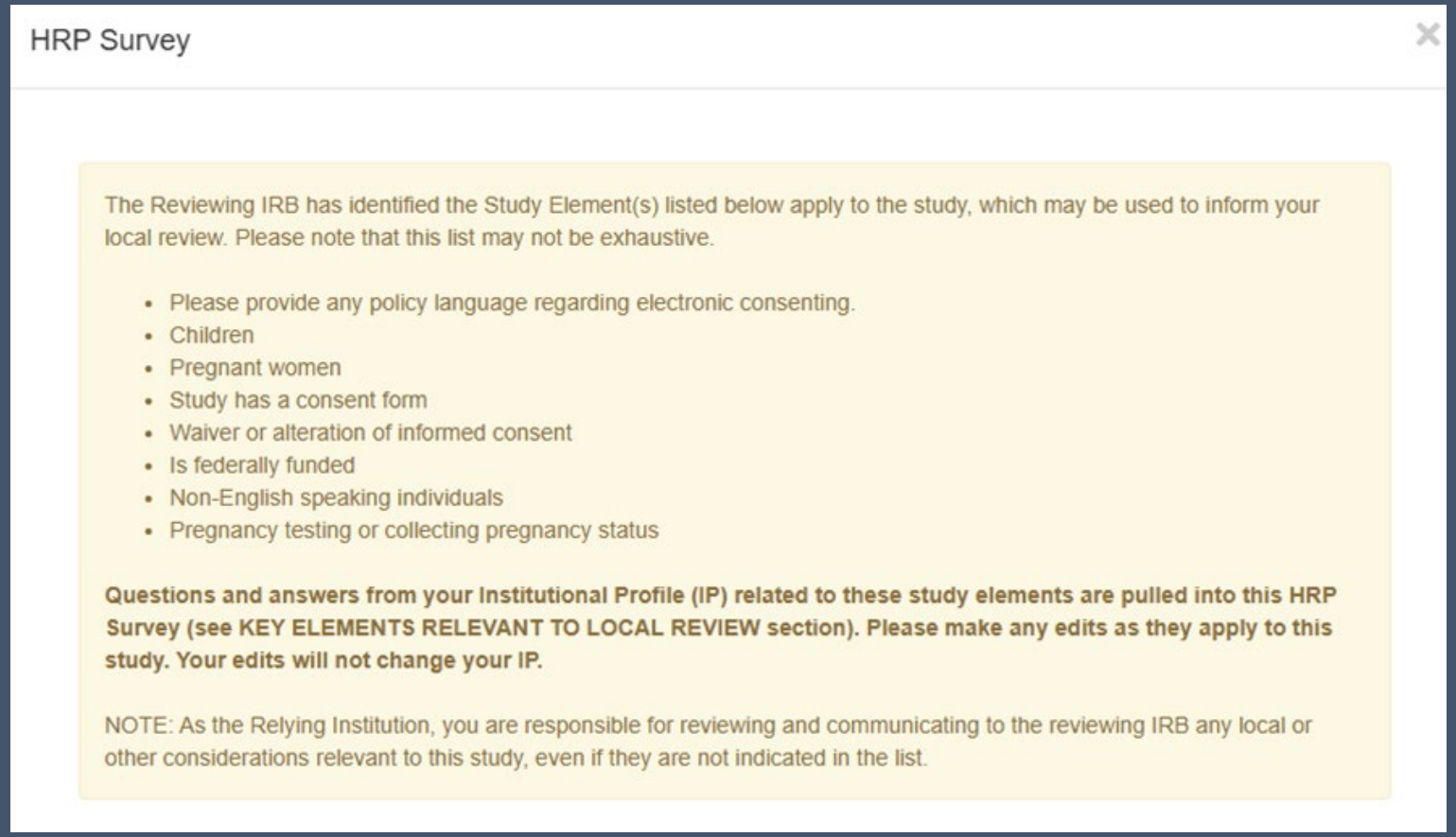
Study Team questions/observations

- Children vs Children/Minors
- Federal Elements v Local Elements
- Explanation to the study teams about the elements???

When should I go over the elements with the study team?

What the relying site sees?

Q: what does the relying PI see??



<u>Working with Relying site:</u>

- If I need to edit the elements, how can I communicate this to the relying site?
- Confirmation that the relying site has “agreed” to the elements?
- What if the relying site doesn’t agree?

What the reviewing analyst sees

Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:	I have verified these personnel do not have any financial interests to disclo se
KEY ELEMENTS RELEVANT TO LOCAL REVIEW	
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	Under Indiana law, a parent or guardian does not have to provide consent f or a minor to participate in research in the following special circumstances: • Minors who are at least 17 years old may donate blood without parental p

STUDY-SPECIFIC LOCAL REQUIREMENTS	
Date Submitted for Local Review*	2025-10-01

<u>For approval of the site:</u>

- Submission of Local Context forms
  - IP is no longer included in the export.
  - All the key Elements *might* not be relevant
  - We utilize more information other than the Key Elements

Note: the “naming” of these elements isn’t 100% consistent

study-specific...elements
Study elements
Key elements

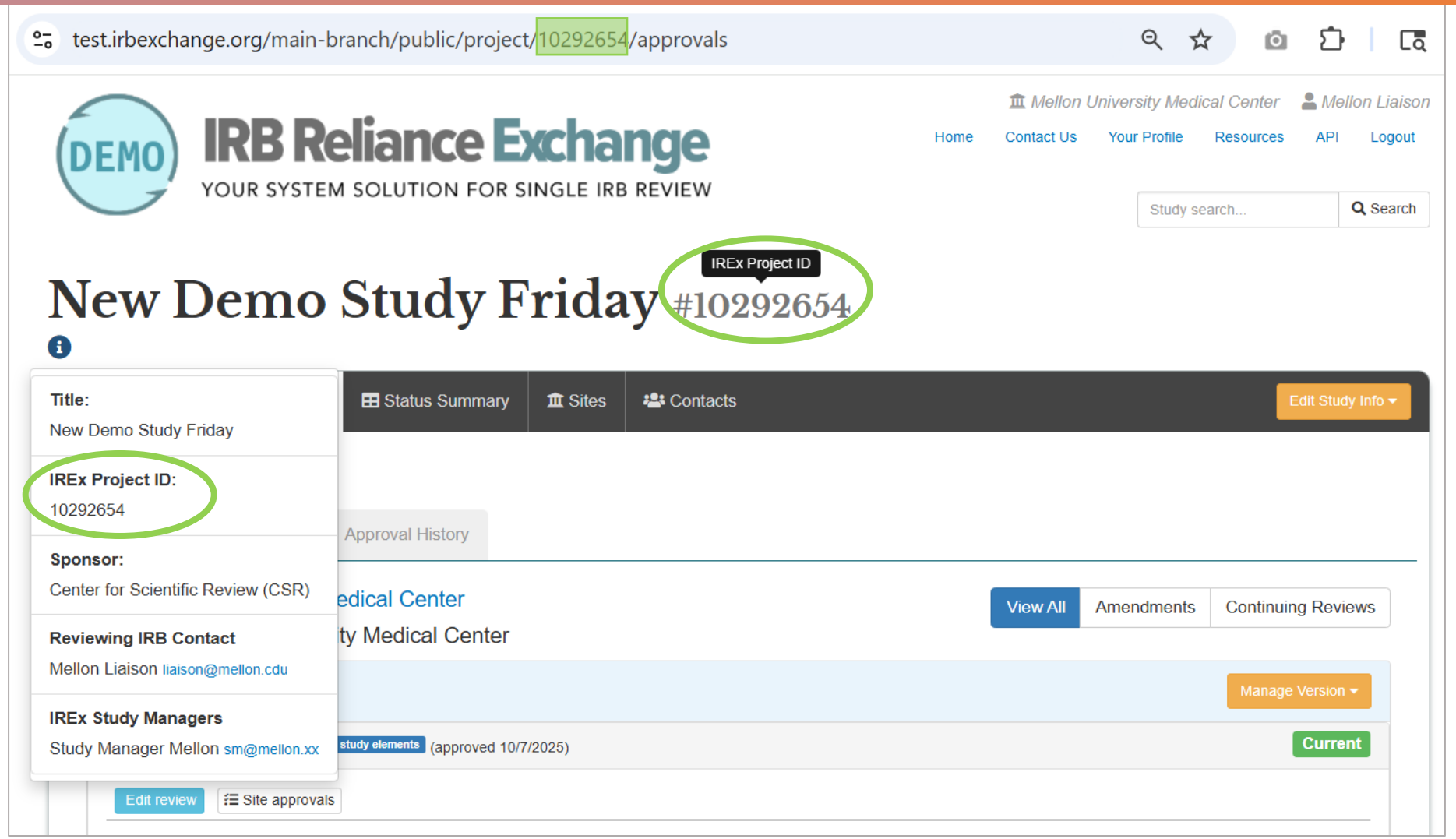
Getting Acquainted - Study Elements in IREx

Q:Who is responsible for completing study elements form?
A: Process flows vary across institutions. Need to identify and educate those who may be responsible and discuss expectations.

Q: When is the appropriate time to complete?
A: Some flexibility until the study is approved, then the form is locked (at time of overall study approval/Lead Site approval). If HRP survey is completed prior to initial study approval and updates are made to study elements after that, those changes will not be noticed by the Lead site. (This may happen when lead site is not Reviewing IRB.) Changes may need to be communicated to that relying site. *Study elements may be editable at time of a Global amendment.

Q: How can we use the "other" option?
A. Less common elements can be added and questions which will populate in either the HRP survey or PI survey.

New: IREx Project ID Visible from Study Page



Current Feature Development

Allowing for Multiple Indemnification Agreements in IREx

- Track SMART IRB Indemnification Addendum in IREx
- Archive existing indemnification agreements
- Allow multiple indemnification agreements on a study

We Want to Hear From You!

IREx Evaluation (Lead Study Teams)

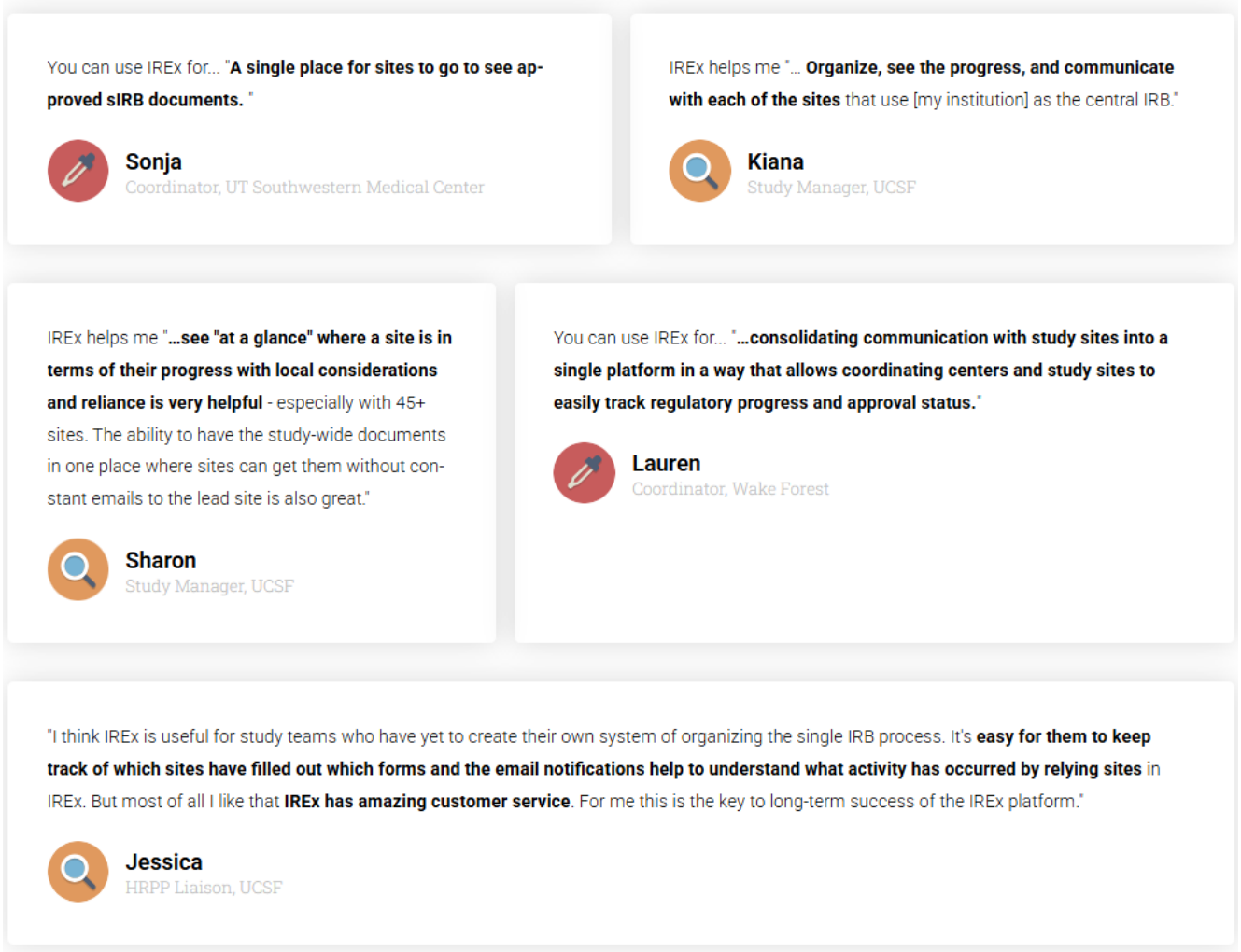
Who?	Lead Study Team personnel (Study Managers & PIs) with studies created in IREx after 2023, who have 25-50% of sites with initial approval
What?	General satisfaction / feedback about the platform; what's going well, what can we do better
When?	NOW!
How?	REDCap Survey link sent via email
Why?	1) Assess whether study teams find that IREx is a) easy to use and b) helps streamline the sIRB process for their sites. 2) Get a sense for when study teams use IREx 3) Get a sense for what other resources are used to support sIRB processes 4) Obtain a smaller pool of interviewees

IREx Evaluation (Lead Study Teams)

Who?	Subset (n=12-15) of SMs who complete satisfaction survey
What?	30-minute interview about their experience with IREx and for what studies they use IREx
When?	Q1 2026
Why?	1) Gain general feedback and areas of improvement 2) Gain insight into the decisions behind how studies are chosen for IREx (or not)

Call for Testimonials

- Has IREx made your life easier?
- Want to share about your experience(s) with IREx?
- Email admin@irbexchange.org anytime!



You can use IREx for... "**A single place for sites to go to see approved sIRB documents.** "

Sonja
Coordinator, UT Southwestern Medical Center

IREx helps me "... **Organize, see the progress, and communicate with each of the sites** that use [my institution] as the central IRB."

Kiana
Study Manager, UCSF

IREx helps me "**...see "at a glance" where a site is in terms of their progress with local considerations and reliance is very helpful** - especially with 45+ sites. The ability to have the study-wide documents in one place where sites can get them without constant emails to the lead site is also great."

Sharon
Study Manager, UCSF

You can use IREx for... "**...consolidating communication with study sites into a single platform in a way that allows coordinating centers and study sites to easily track regulatory progress and approval status.**"

Lauren
Coordinator, Wake Forest

"I think IREx is useful for study teams who have yet to create their own system of organizing the single IRB process. It's **easy for them to keep track of which sites have filled out which forms and the email notifications help to understand what activity has occurred by relying sites** in IREx. But most of all I like that **IREx has amazing customer service**. For me this is the key to long-term success of the IREx platform."

Jessica
HRPP Liaison, UCSF

Next Call: January 16, 2026!