

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>

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Institutional Profile (IP) Updates



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 - Minimizes out of date information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 Letter of Acknowledgement and Agreement Implementation Checklist	
1. Standard operating procedures ("SOPs") <i>SMART IRB Agreement Section 3.4.2</i>	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) <i>SMART IRB Agreement Sections 4.4, 4.4.2, 4.4.3</i>	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) <i>SMART IRB Agreement Sections 4.4.1</i>	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 <i>SMART IRB Agreement Sections 5.8 and 6.6</i>	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.

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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?*)

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

☒ Assent

☒ Children

☒ Drugs/devices

☐ EFIC

☐ Genetic Testing

☒ HIPAA applies to this study

☐ Other vulnerable populations (e.g., students)

☐ Pregnant women

☐ Prisoners

☒ Study has a consent form

☐ Waiver or alteration of informed consent

Other Elements Related to State Laws/Local Policies

☒ Drug or device that could impact billing

☐ Drug storage or distribution

☐ Individuals with impaired decision making

☐ Investigational biosafety review

☐ Involves radiation of any kind

☐ Is federally funded

☐ Mandatory reporting (e.g., testing for infectious disease, abuse/neglect)

☒ Non-English speaking individuals

☐ Pregnancy testing or collecting pregnancy status

☐ Other (e.g., Future Use of Data, Standard of Care, etc.)

Cancel

Confirm

Automating Local Considerations – Study Setup [sIRB]

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

The screenshot displays the 'Study Setup [sIRB]' interface. At the top, there are two columns of checkboxes for local considerations. The left column includes: 'Other vulnerable populations (e.g., students)', 'Pregnant women', 'Prisoners', 'Study has a consent form' (checked), and 'Waiver or alteration of informed consent'. The right column includes: 'Mandatory reporting (e.g., testing for infectious disease, abuse/neglect)', 'Non-English speaking individuals' (checked), 'Pregnancy testing or collecting pregnancy status', and 'Other (e.g., Future Use of Data, Standard of Care, etc.)' (checked). A blue arrow points from the 'Other' checkbox to a yellow warning box below. The warning box contains the text: 'You must add a Study Element or Question to at least one Survey (up to five additional elements per survey). Leave blank if not applicable.' Below the warning box, there are two sections: 'HRP Survey' and 'PI Survey'. The 'HRP Survey' section has a text input field containing 'Is use of the ABCDE sleep protocol standard of care in the ICU at your site?' and a '+ Add Study Element' button. The 'PI Survey' section has an empty text input field and a '+ Add Study Element' button. At the bottom right, there are 'Cancel' and 'Confirm' buttons.

☐ 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	

You must add a Study Element or Question to at least one Survey (up to five additional elements per survey). Leave blank if not applicable.

HRP Survey

Write the Study Element or Question as it should appear on the HRP Survey.

Is use of the ABCDE sleep protocol standard of care in the ICU at your site?

+ Add Study Element

PI Survey

Write the Study Element or Question as it should appear on the PI Survey.

+ Add Study Element

Cancel

Confirm

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!

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.

- Assent
- Children
- Drugs/devices
- HIPAA applies to this study
- Study has a consent form
- Drug or device that could impact billing
- Non-English speaking individuals
- Is use of the ABCDE sleep protocol standard of care in the ICU at your site?

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.

KEY ELEMENTS RELEVANT TO LOCAL REVIEW

Does your institution require a separate Assent document?
* must provide value

☐ Yes
☒ No

reset

Does your institution require an assent signature on the main consent form for children/adolescents?
* must provide value

☒ Yes
☐ No

reset

Age of majority in your state?
* must provide value

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.
* must provide value

Expand

How does a minor become emancipated in your state?
* must provide value

Expand

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 unforeseeable risks to an embryo or fetus for a particular treatment or procedure.
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

Onboarding

Approvals

Status Summary

Sites

Contacts

Edit Study Info

Approvals

Study-wide IRB Approvals

Approval History

IRB: Melion University Medical Center

Lead Site: Melion University Medical Center

Protocol: HRP 1

View All

Amendments

Continuing Reviews

Manage Version

Initial Study: Full Board

study elements

(approved 10/2/2025)

Current

Edit review

Site approvals

Study Info

Key Dates

Role: Reviewing IRB

IRB Number: 123456

Type of Study: Greater than Minimal Risk

Reviewing IRB Decision: approved

Submission Type: Initial Study: Full Board

Review Cycle: 9 mo

Submitted: 10/1/2025

Pre-Reviewed: 10/2/2025

Reviewed: 10/2/2025

Approved: 10/2/2025

Expires: 10/2/2030

Global Documents

- Assent
- Children
- Drugs/devices
- HIPAA applies to this study
- Study has a consent form
- Drug or device that could impact billing
- Non-English speaking individuals
- Other
- Other HRP 1 (Is use of the ABCDE sleep protocol standard of care in the ICU at your site?)

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!

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- + . **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

Approvals

Study-wide IRB Approval History

sIRB University of California, San Francisco

Lead Site: University of California, San Francisco

Protocol Version: 1.0.0 (25/11/2022)

- Children
- Pregnant women
- Study has a consent form
- Waiver or alteration of informed consent
- Is federally funded
- Non-English speaking individuals
- Pregnancy testing or collecting pregnancy status
- Other—
- Other HRP 1 (Please provide any policy language regarding electronic consenting.)

Initial Study: Expedited **study elements** (approved 5/15/2022)

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??

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.

- Please provide any policy language regarding electronic consenting.
- Children
- Pregnant women
- Study has a consent form
- Waiver or alteration of informed consent
- Is federally funded
- Non-English speaking individuals
- Pregnancy testing or collecting pregnancy status

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.

Working with Relying site:

- 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 disclose
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 for 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

electronic consenting.

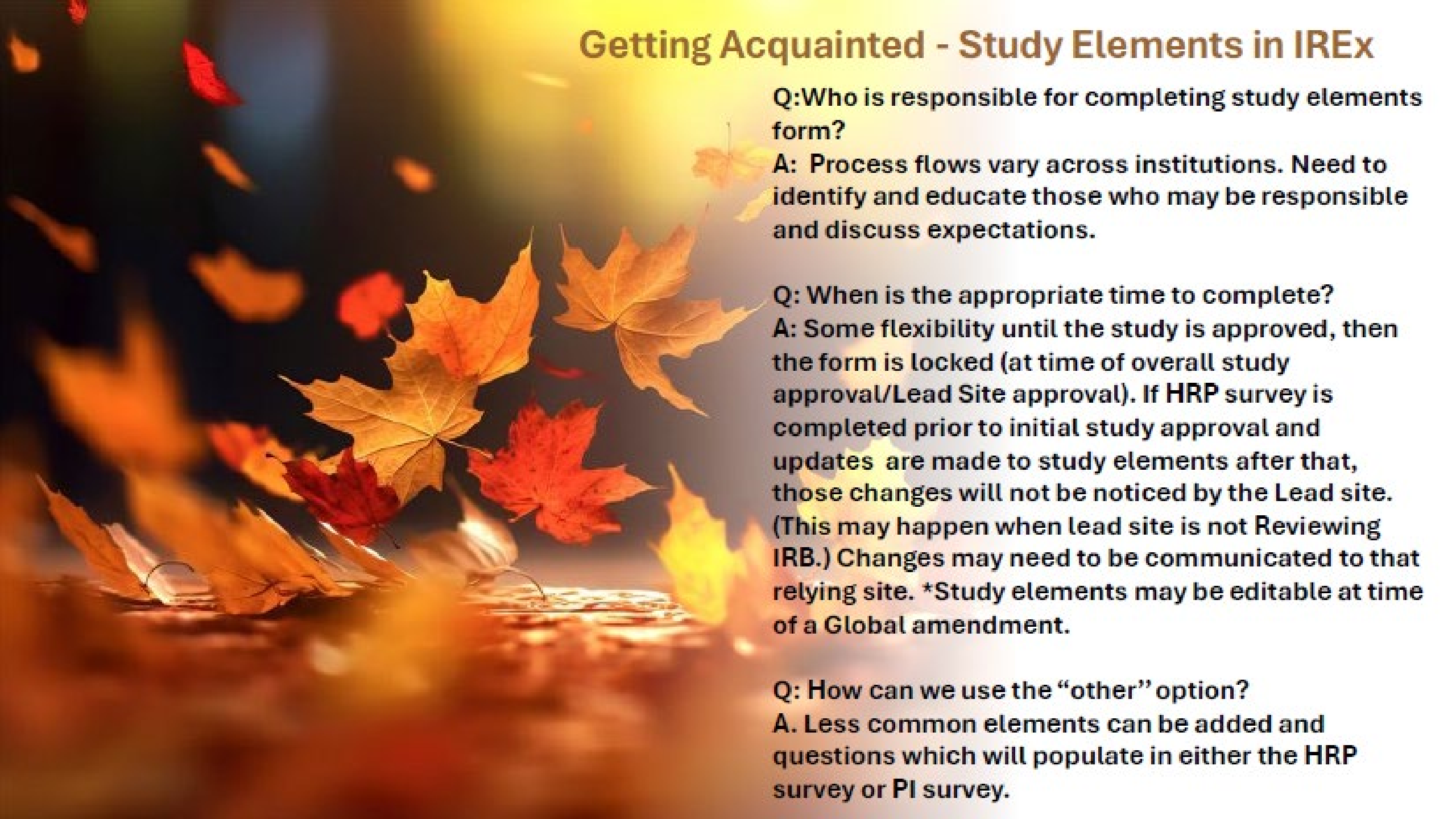
STUDY-SPECIFIC LOCAL REQUIREMENTS	
Date Submitted for Local Review*	2025-10-01

For approval of the site:

- 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

The screenshot displays the IREx Reliance Exchange web application. The browser address bar shows the URL `test.irbexchange.org/main-branch/public/project/10292654/approvals`, with the project ID `10292654` highlighted in green. The page header includes the IREx logo (a blue circle with 'DEMO' and 'IRB Reliance Exchange' text) and the tagline 'YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW'. Navigation links for 'Home', 'Contact Us', 'Your Profile', 'Resources', 'API', and 'Logout' are present, along with user information for 'Mellon University Medical Center' and 'Mellon Liaison'. A search bar is located on the right. The main content area features the title 'New Demo Study Friday' with the project ID '#10292654' circled in green. A side panel on the left provides details about the study, including the title, sponsor, reviewing IRB contact, and study managers. The project ID is also highlighted in green in this panel. The main content area includes tabs for 'Status Summary', 'Sites', and 'Contacts', and a 'Manage Version' button. A 'Current' status indicator is visible at the bottom right.

test.irbexchange.org/main-branch/public/project/10292654/approvals

DEMO IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

Mellon University Medical Center Mellon Liaison

Home Contact Us Your Profile Resources API Logout

Study search... Search

New Demo Study Friday #10292654

IREx Project ID

Title:
New Demo Study Friday

IREx Project ID:
10292654

Sponsor:
Center for Scientific Review (CSR)

Reviewing IRB Contact
Mellon Liaison liaison@mellon.cdu

IREx Study Managers
Study Manager Mellon sm@mellon.xx

Status Summary Sites Contacts Edit Study Info

Approval History

Medical Center
ty Medical Center

View All Amendments Continuing Reviews

Manage Version

study elements (approved 10/7/2025) Current

Edit review Site approvals

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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

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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!**

