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IRB Reliance Exchange
YOUR SYSTEM SOLUTION FOR SINGLE IRB REVIEW

# USING IREx TO CAPTURE LOCAL CONSIDERATIONS

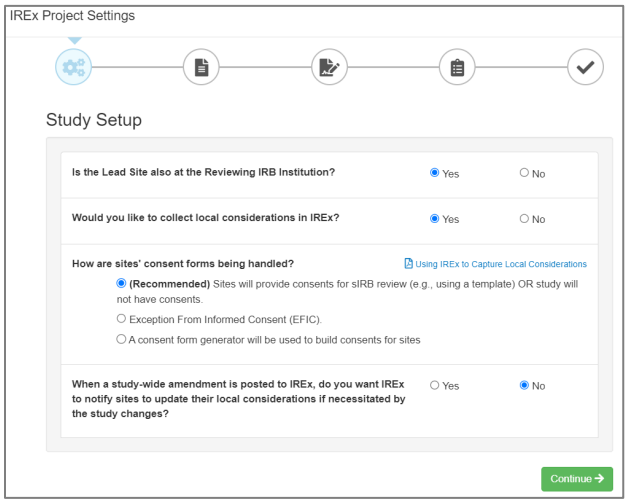
## BENEFITS OF USING IREx TO CAPTURE LOCAL CONSIDERATIONS

| For Single IRBs | For Lead Study Teams/ Coordinating Centers | For Relying Site HRPPs |
|---|---|---|
| • Standardize questions and align with national sIRB initiatives<br>• Minimize need for external study teams to submit directly to the sIRB's submission system<br>• Ensure sign off by the Relying Site HRPPs | • Track site progress<br>• Centralize site documentation of local considerations<br>• Enable pre-screening to catch errors or missing information and facilitate edits<br>• Provide user-friendly exports to streamline submission to the sIRB | • Reduces duplicative submission of site-specific/institutional local considerations<br>• Verify information submitted by your local study team to the sIRB<br>• Provides a historical record of local considerations submitted on a study-by-study basis |

## WHAT DO I NEED TO KNOW BEFORE USING IREx TO CAPTURE LOCAL CONSIDERATIONS?

1. Local considerations consist of THREE components in IREx:
   a. Site-specific Information – The Institutional Profile (IP): each HRPP completes an IP one time. The IP captures information about the FWA, legal components, and overarching state laws or institutional policies affecting *all research* at a site.
   b. Study-specific Information from the HRPP – The Human Research Protections Survey (HRP Survey): For each study, the site's HRPP must communicate any applicable state or local laws, regulations, institutional policies, standards, relevant consent language, or other local factors, including local ancillary reviews, relevant to the study being reviewed.
   c. Study-specific Information from the PI – The PI Survey: For each study, PIs are asked to provide information about the conduct of the study and any procedures that differ from the protocol. This information must be verified by the site's HRPP.
   d. Note: For Exception from Informed Consent Studies (EFIC), the **Community Consultation Plan Summary of Results** is also a part of each site's local considerations, for a total of FOUR local considerations components in IREx.

2. After creating a study, the Reviewing IRB sets up the study using **Complete IREx Setup** on the IREx checklist. After indicating you will collect local considerations in IREx, please indicate how site consents are being handled:
   - **(Recommended) Sites will provide consents for sIRB review (e.g., using a template) OR study will not have consents.** Select this option if sites will provide their locally required language in the consent form or a template the sIRB provides. Using this option, the study team enters their required language into the consent; submits it to their HRPP for sign off; and the HRPP will upload the consent to the HRP survey in IREx for sIRB review.
   - **Exception From Informed Consent (EFIC).** Select this option if the study is an EFIC study.
   - **A consent form generator will be used to build consents for sites.** Select this option if sites will provide their locally required language and consents will be created for the sites by the Coordinating Center, Lead Study Team, or sIRB, which may require significant resources depending on the number of sites and consents. In this option, the site HRPP and PI enter their required language into the HRP and PI surveys in IREx, rather than directly into a consent. The consent is then generated and submitted for sIRB review.




3. Submitting local considerations in IREx is NOT a submission to the sIRB. IREx is a mechanism to centrally capture and track local considerations from sites. However, after a site completes the local considerations, the IREx Study Manager (i.e., the lead coordinator or coordinating center) receives an email from IREx that local considerations is complete. The Study Manager then exports the information and submits it to the sIRB for review.

# The Institutional Profile

# (Sections 1 and 2 pertain to local considerations)

# IRB Reliance Exchange

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**Note: In order to show all possible questions on the Institutional Profile, this document does not include the branching logic, which cuts out certain questions based on your answer to a previous question(s).**

**ABOUT THE INSTITUTIONAL PROFILE**

**The IREx IP contains basic information about your institution that another institution might use to determine if they feel comfortable relying on, or serving as the Reviewing IRB for, your institution. The IP can also be used by IRBs and study teams to better understand one's institutional processes and requirements when using reliance.**

**This information will be visible to other users in IREx and publicly available as a downloadable PDF on the IREx Website here. This information is for general review purposes only. It may not be accurate and may be subject to change, withdrawn or revised at any time without notice. The Institutional Profile is not intended to serve as a complete record of an Institution's study-specific local considerations.**

*******

**Section 1: GENERAL HRPP INFORMATION**

| | |
|---|---|
| Institution | _____ |
| Federalwide Assurance (FWA) # | _____ (Enter FWA# and 8 digits, eg FWA#00000000) |
| FWA Expiration Date | _____ |
| Does your institution have an internal IRB? | ◯ Yes ◯ No |
| IRB Registry Number(s) | _____ (Insert 1 registry # per line) |
| Is the IRB AAHRPP accredited? | ◯ Yes ◯ No |
| Does your institution REQUIRE institutions to be AAHRPP accredited in order to serve as their IRB of Record (all the time)? | ◯ Yes ◯ No ◯ It depends |
| Describe any board specialties of your IRB. | _____ |
| Does your institution have an outstanding FDA Form 483 related to its IRB(s)? | ◯ Yes ◯ No |

| | |
|---|---|
| Comments on the outstanding FDA Form 483 | _____ |
| Has your institution been issued an FDA warning letter related to its IRB(s) in the past 12 months? | ◯ Yes<br>◯ No |
| Comments on the FDA Warning Letter | _____ |
| Is your institution a covered entity? | ◯ Yes<br>◯ No<br>◯ Hybrid |
| Additional Comments | _____<br>(Feel free to enter additional/clarifying info here) |
| Describe how your institution assessed the quality of its HRPP/IRB within 5 years of joining SMART IRB. | ☐ Third-party assessment (e.g., AAHRPP)<br>☐ Federal agency audit<br>☐ Self-assessment (e.g., OHRP Self Assessment)<br>☐ We have not joined SMART IRB |
| List the third party that completed your assessment | _____ |
| Please describe the scope and findings of the federal agency audit of your institution's IRB. | _____ |
| Please upload your self assessment.<br><br>For reference, the OHRP QA Self Assessment Tool is an acceptable self assessment tool. It is available as a PDF here: https://www.hhs.gov/ohrp/sites/default/files/ohrp/education/qip/ohrpqatool.pdf.pdf | |

## Section 2: SITE-SPECIFIC LOCAL CONTEXT

**This information may be helpful for a Reviewing IRB to understand when considering whether to serve as the Reviewing IRB for your organization.**

**Additional, study-specific information will be requested when a Reviewing IRB is reviewing a specific study for your site (e.g., COI, investigator training, study-specific consent requirements, state law or institutional requirements)**

To what state laws is your institution subject

List other names by which your institution is known.

_____

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

Please describe how long you are required to keep your records.

_____

Age of majority in your state?

_____

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

_____

Do you require specific language in your consent form to describe what requires mandatory reporting to authorities?

- ○ Yes, I will upload language in file
- ○ Yes, I will insert language in text box
- ○ No

Please upload the language required to be used around mandatory reporting to health authorities.

Please insert the language required to be used around mandatory reporting to health authorities.

_____

Does your institution have a posted policy for the following?

NOTE: Please only select those for which there is a posted institution policy; generally accepted practice and guidance are not policy.

- ☐ Consent Process for those with Impaired Decision-Making Capacity
- ☐ Use of short forms for non-English speaking individuals
- ☐ Translation of consent forms for non-English speaking individuals
- ☐ We do not have a posted policy for any of these

Is your site able to use an e-Consent platform, if available for a specific trial?

- ○ Yes
- ○ No

(If yes, indicate which can be used below)

| | Yes, in part 11 compliant manner | Yes, but unsure of part 11 compliance | Yes, but is not part 11 compliant | Unable to use |
|---|---|---|---|---|
| DocuSign | ○ | ○ | ○ | ○ |
| REDCap e-Consent Module | ○ | ○ | ○ | ○ |
| AdobeSign | ○ | ○ | ○ | ○ |
| SignNow | ○ | ○ | ○ | ○ |
| Other | ○ | ○ | ○ | ○ |

| | |
|---|---|
| Please describe other e-consent platforms your institution uses and, if you list multiple, please note whether each can be part 11 compliant, if needed by a specific trial. | _____ |
| If your site will enroll non-English speakers, does your site allow the use of a short form? | ◯ Yes<br>◯ No |
| How many times can the short form be used before needing a fully translated consent? You can also indicate no limit. | _____ |
| Does your site require a Translator/Witness to sign the Short form? | ◯ Yes<br>◯ No |
| Does your site require a Translator/Witness to sign the full English consent document?' | ◯ Yes<br>◯ No |
| Please upload additional policies related to the consent of non-English speakers, if needed. | |
| Does your site's consent process require any additional documents or riders? For example, Subject Bill of Rights. | ◯ Yes<br>◯ No |
| Please describe any additional documents or riders required. | _____ |
| For trials providing compensation, does your site have specific guidelines, policies, or language that will need to be incorporated into the consent? | ◯ Yes<br>◯ No |
| Please upload your compensation-related guidelines, policies or language. | |
| Please enter your specific consent form language regarding payment for research-related injury. | _____ |
| Please enter your specific consent form language regarding costs to participants to participate. | _____ |
| Does your site require a site-specific logo appear on consent forms and/or recruitment documents? | ◯ Yes<br>◯ No |
| Please upload the logo | |
| Does your institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects? | ◯ Yes<br>◯ No |
| Does your IRB require HIPAA authorization forms be a separate document from the Informed Consent Form? | ◯ Yes<br>◯ No |
| Please enter any special formatting your IRB requires for HIPAA authorization forms? | _____ |
| Please upload your template HIPAA Authorization language. | |
| Do you have any additional HIPAA Authorization language template documents? | ◯ Yes<br>◯ No |
| Please upload additional template HIPAA Authorization language documents | |
| Please upload a copy of your local informed consent template. | |

**LOCAL CONTEXT: Component Sites**

**As the FWA-holder of a component site, you are responsible for providing the relevant local considerations for component sites here, in the Institutional Profile, and for specific studies, as requested by the Reviewing IRB.**

**If your component sites have information that differs from that provided in the previous section, specify the site and what differs below.**

Do you have a component site on your FWA?

- ◯ Yes
- ◯ No

What is the name of this component site?

_____

If yes, the local context questions from section 2 are repeated for the component. Multiple component sites can be reported on in the site's Institutional Profile.

# Local Considerations: Study-specific Human Research Protections Reviews (completed by the HRPP Liaison)

*Confidential*



# Study-Specific Local Context Worksheet

Please have this form completed by someone at your local institution who has knowledge of the protocol and any local regulatory, policy or community considerations that may impact the approvability of the research at your site.

Study Title _____

Local Site Name _____

## STUDY TEAM INFORMATION

Local Site PI First Name _____

Local Site PI Last Name _____

Local Site PI Email _____

Please review the planned list of personnel who will be engaged in human subjects research.

Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?

- ◯ Yes
- ◯ No
- ◯ Our institution delegates this responsibility to the PI

NOTE: If all study personnel have not met the required training, please have them do so before submitting this application.

Additional Information regarding the verification that all training requirements are met.

_____
((optional))

Are all involved individuals at the institution for this protocol credentialed and/or appropriately qualified and meet the institution's standards for eligibility to conduct research?

- ◯ Yes
- ◯ No

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
- ◯ I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable
- ◯ Our institutional policy requires the researcher to disclose conflicts to another office/department and send the management plan to the Reviewing IRB

Where the conflict of interest management plan requires additional language in the consent form, please provide the language that is to be included in the consent form.

Where any financial conflicts of interest have been identified that require a management plan, please upload the relevant management plan.

Provide institutional point of contact for questions related to local management plan (this person should be someone in the office/entity who prepared the management plan).

_____
(Provide name, email and phone number)

## STUDY-SPECIFIC LOCAL REQUIREMENTS

Please review the protocol and template consent form and verify in the box below that there are sufficient resources available at your site to carry out the research as planned. If any changes are required to the study plan related to the resources available at your site, please outline the required changes below.

Please review the protocol and template consent, as provided to you by your local study team, and identify areas where there are unique state, local or federal regulatory requirements that apply to this study and describe any steps that must be taken to adhere to these requirements.

For Example: legally authorized representatives, state laws regarding confidentiality of specific types of health information, emancipated minors.

Please Note: In the box below, please outline any specific changes needed to ensure adherence with the requirements you have identified that are applicable to the conduct of this study at your site. This may include changes to the consent form to include any language required based on state law requirements [e.g. reportability of test results for infectious diseases].

If your site has no unique regulatory requirements, enter "None" below.

Please review the protocol and template consent, as provided to you by your local study team, and identify any institutional requirements (e.g., recruitment, data security, remuneration) that apply to this study and any steps that must be taken to adhere to these requirements.

Please Note: In the box below, please outline any specific changes needed to ensure adherence with the requirements you have identified that are applicable to the conduct of this study at your site. This may include changes to the consent form to include any language required based on local requirements [e.g. any specific local policy requirements related to consent for future use of biospecimens.

If your site has no specific changes, enter "None" below.

Please identify any ancillary reviews required at your site [e.g. radiation safety review, review for research with biospecimens, etc.] that will be required before this study may be initiated at your site.

If no ancillary reviews are required, please indicate "None" below.

Based on the ancillary reviews listed above, are there any site-specific ancillary reviews that may impact the IRB review?

◯ Yes
◯ No

What is the current status of the review and approval by that ancillary committee?

_____

Provide details here (i.e. outcome, anticipated date of review) or upload documentation below

_____

Upload documentation here (i.e. outcome, anticipated date of review) or provide details in text box above

## COMMUNITY CONSIDERATIONS

Please review the protocol and template consent and identify whether there are any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study. Please also outline any steps that must be taken to address these concerns.

It is possible that the Reviewing IRB may have additional questions about your local community. Please include the best contact below for additional questions about local context information.

Local Contact First Name

_____

Local Contact Last Name

_____

Local Contact Email

_____

Local Contact Phone

_____

**CONSENT FORMS: Please review the template consent form and, with consideration for any local site regulatory or institutional requirements, please ensure any local site required consent language is included before uploading the ICF(s) here.**

| | |
|---|---|
| Does your site have an informed consent(s) (including short forms, assent forms, permission forms, etc.) for this study? | ◯ Yes<br>◯ No |
| Number of ICF-related documents for your site | ◯ 1<br>◯ 2<br>◯ 3<br>◯ 4<br>◯ 5<br>◯ 6<br>◯ 7<br>◯ 8<br>◯ 9<br>◯ 10<br>◯ 11<br>◯ 12<br>◯ 13<br>◯ 14<br>◯ 15<br>(this informs the number of upload fields provided) |
| ICF 1 | |
| ICF 2 | |
| ICF 3 | |
| ICF 4 | |
| ICF 5 | |
| ICF 6 | |
| ICF 7 | |
| ICF 8 | |
| ICF 9 | |
| ICF 10 | |
| ICF 11 | |
| ICF 12 | |
| ICF 13 | |
| ICF 14 | |
| ICF 15 | |

## Additional Local Considerations

If the Reviewing IRB sent additional study-specific questions about your local context/local considerations, please upload your answers to those questions here.

## Section IV - Signatures/Attestations

IRB Point of Contact First Name

_____

IRB Point of Contact Last Name

_____

IRB Point of Contact Title

_____

IRB Point of Contact Phone

_____

IRB Point of Contact Email

_____

By signing below, I attest that the information fulfills the relying institution's responsibilities, as outlined in the reliance agreement, for the provision of local context information and to the accuracy and completeness of the information provided herein.

_____

# The PI Survey regarding Conduct of the Study at their Site

# Local Context PI Survey

Study Title

_____

Participating Site Name:

_____

## STUDY TEAM INFORMATION

Site Investigator's Name

_____

Site Investigator's Email Address

_____

Site Investigator's Phone

_____
(Consent Form contact information)

Lead Study Contact Name

_____

Lead Study Contact Email

_____

Lead Study Contact Phone

_____

Please review the planned list of personnel who will be engaged in human subjects research.

Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?

- ◯ Yes
- ◯ No
- ◯ Our institution delegates this responsibility to the HRPP

NOTE: If all study personnel have not met the required training, please have them do so before submitting this application.

Please attach the list of key study personnel associated with this study at this site.

Additional Information regarding the verification that all training requirements are met.

_____
((optional))

Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:

- ◯ I have verified there are no financial interests to disclose
- ◯ I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable
- ◯ Other

Where the conflict of interest management plan requires additional language in the consent form, please provide the language that is to be included in the consent form.

Where any financial conflicts of interest have been identified that require a management plan, please upload the relevant management plan.

Provide an institutional point of contact for questions related to local management plan (this person should be someone in the office/entity who prepared the management plan).

Please describe any alternative COI arrangements with the sIRB

**SITE-SPECIFIC CONSENT FORMS:**

**IF YOUR SITE HAS CONSENT FORMS, ANSWER 'YES' BELOW AND INDICATE THE # OF CONSENTS YOU WILL UPLOAD. Consent language should be verified by your local HRPP before uploading them here. If your HRPP has not yet verified your local consent language, skip this question, submit the survey, and return later to fill in this section of the survey.**

Does your site have an informed consent form(s) (ICFs), including short forms, assent forms, permission forms, etc., for this study?

◯ Yes
◯ No

**CONSENT FORMS**

Number of ICF-related documents for your site
(this will generate the appropriate number of file upload fields)

◯ 1
◯ 2
◯ 3
◯ 4
◯ 5
◯ 6
◯ 7
◯ 8
◯ 9
◯ 10
◯ 11
◯ 12
◯ 13
◯ 14
◯ 15

ICF 1

ICF 2

ICF 3

ICF 4

ICF 5

ICF 6

ICF 7

ICF 8

ICF 9

ICF 10

ICF 11

ICF 12

ICF 13

ICF 14

ICF 15

## SITE SPECIFIC PLANS FOR RECRUITMENT, CONSENTING, AND DATA AND SAFETY MONITORING

What activities does your site participate in?

- ☐ Recruiting
- ☐ Consenting
- ☐ Data and Safety Monitoring
- ☐ Study procedures per the protocol including interventions, surveys, focus groups, follow-up data collection
- ☐ Review or analysis of identifiable data
- ☐ Direct recipient of funding
- ☐ None of the above

RECRUITMENT PLAN: Are there any differences to the initial contact and/or recruitment plan at your site from that described in the protocol or associated documents based on local requirements or state law?

◯ No differences at my site
◯ My site will recruit differently

RECRUITMENT PLAN: Please describe the specific steps to be used to identify and/or contact prospective participants at your site. Also, if applicable, describe how you have access to lists of potential participants.

CONSENTING PLAN: Does the consent plan for your site differ in any way from that outlined in the protocol?

◯ No differences at my site
◯ My site will consent differently
◯ This study has a waiver of consent

CONSENTING PLAN: Please describe the specific steps for obtaining informed consent and the procedures that will be utilized to protect the privacy of individuals.

CONSENTING PLAN: Does the person obtaining consent have an existing relationship with the participant(s)?

◯ Yes
◯ No

CONSENTING PLAN: Please indicate/describe the relationship(s) and how you will protect against undue influence or coercion.

DATA AND SAFETY MONITORING PLAN: Does the data and safety monitoring plan for your site differ in any way from that outlined in the protocol?

◯ No differences at my site
◯ My site's data and safety monitoring plan differs

DATA AND SAFETY MONITORING PLAN: Describe plans for monitoring the progress of trials and safety of participants at your site.

STUDY PROCEDURES PER THE PROTOCOL: Are there any other different requirements for how the protocol will be implemented and/or conducted at your site based on local requirements or state laws.

◯ No differences at my site
◯ There are different requirements at my site

STUDY PROCEDURES PER THE PROTOCOL: Please describe any other different requirements for how the protocol will be implemented at your site.

REVIEW OR ANALYSIS OF IDENTIFIABLE DATA: Provide any additional information, if necessary.

DIRECT RECIPIENT OF FUNDING: Provide any additional information, if necessary.

Please provide information on your site's role in the study.

## SIGNATURES/ATTESTATIONS

By signing below, I attest to the accuracy and completeness of the information provided herein.