Local Context PI Survey

Return URL

_____

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

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).

_____

SITE-SPECIFIC CONSENT FORMS:

AFTER YOUR LOCAL HRPP HAS VERIFIED THE LOCAL LANGUAGE YOU INSERTED INTO THE CONSENT FORM(S), UPLOAD THEM HERE. If your HRPP has not yet verified your local consent form, 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

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

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?

◯ Yes
◯ No

How does the recruitment plan differ?

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?

◯ Yes
◯ No
◯ This study has a waiver of consent

How does the consenting plan differ?

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

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

◯ Yes
◯ No

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?

◯ Yes
◯ No

How does the data and safety monitoring plan differ?

Describe plans for monitoring the progress of trials and safety of participants at your site.

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?

◯ Yes
◯ No

Please describe any other different requirements for how the protocol will be implemented at your site.

_____

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

_____