This survey template allows the Overall Principal Investigator/Lead Study Team to obtain information from the relying site study team to determine whether particular regulatory or institutional requirements should be communicated to the Reviewing IRB.

Potential Relying Site Study Team Survey

General Information

1. Name of Study:

2. Overall Principal Investigator:

3. Name of Relying Institution:

4. Site PI Name, Degree, and Contact Information:

5. Main contact for this research at site other than PI – Name and Contact Information:

6. Name and title of person completing this survey:

Special Procedures and Populations

1. Does the study involve any of the following special procedures or considerations?

   ☐ The study team may enroll subjects with impaired decision-making capacity.

   If selected, describe below how the study team will verify someone is qualified to be the potential subject's Legally Authorized Representative.

   ☐ The study team may enroll wards of the state (e.g., foster children).

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☐ The study team may enroll prisoners.

If selected, describe below how the study team will verify someone is qualified to be the potential subject's Legally Authorized Representative.

☐ For studies that involve a drug, biologic, and/or device,

Describe: a) the specific location where study drugs/devices/biologics will be stored

b) how storage location will be secured

c) who is responsible for study drug or biologic preparation

d) who will dispense subject drug or biologic to the subject

Site Specific Study Protocol Differences

1. Describe any differences between what is stated in the protocol and what activities will or will not be conducted at your site (e.g., Arm B of the protocol will not be conducted at our site).

2. Describe how and when people will be recruited to participate in the study. Specify who and how investigators will be involved in recruitment and the consent process. Explain how people will be approached, what recruitment material will be used (flyers, internet, letters, phone screening scripts), and how long the person has to decide to participate.

3. Describe the consent process (include who conducts the process and where).

4. How many subjects do you intend to enroll at your site?

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Medical Records

1. Will medical records be accessed prior to written consent, or with a waiver of consent?
   ☐ Yes ☐ No ☐ Not applicable – no medical records will be accessed for this study

   If the study does not involve medical records, please skip to the next section.

2. Describe how the PI will gain access to the records.

Data Handling and Storage

1. How and where will data (e.g., electronic, paper, audio) be stored at your site?

2. Who will have access to the data?

3. How is subject confidentiality protected?

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