



*This survey template can be sent by a Reviewing IRB to a relying institution SMART IRB Point of Contact (POC) to obtain key local context information.*

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## Potential Relying Site SMART IRB Point of Contact Survey

### *General Information*

1. Name of Study:
  
2. Overall Principal Investigator:
  
3. Proposed Reviewing IRB:
  
4. Name of Relying Institution:
  
5. Name and title of person completing this survey:
  
6. Has the institution's FWA (federal wide assurance) been extended to non-federally funded research?  
☐ Yes      ☐ No
7. Provide any other names the site is known by:
  
8. Please identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. Note: This information is collected to allow us to confirm that all sites engaged in the research are covered by a reliance arrangement and to identify relationships between institutions.
  
9. If any of the sites identified in question 8 are within a network or system, do they have a separate FWA?  
☐ Yes      ☐ No

10. If you answered “yes” to question 9, please identify the sites with the separate FWAs.
11. Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subjects research proposed at the site?
- ☐ Yes ☐ No
12. If the answer to question 11 was “yes”, please explain any investigations, audits or findings that may be relevant.
13. Does the institution have a post approval monitoring program or other regulatory oversight for ongoing research?
- ☐ Yes ☐ No
14. If the answer to question 13 was “yes”, does the post approval monitoring program or other regulatory oversight monitor studies that have been deferred to an external IRB?
- ☐ Yes ☐ No
15. If the answer to question 13 was “yes”, please provide a link (URL) to the post approval monitoring program/ regulatory oversight information, or paste information here.

### *Local Context Information*

1. Are there any state laws that the Reviewing IRB will need to consider when reviewing this study?
- ☐ Yes ☐ No
2. If the answer to question 1 is “yes”, please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).
3. Are there any community or cultural differences for the local population of subjects that require consideration?
- ☐ Yes ☐ No
4. If the answer to question 3 is “yes”, please describe the relevant information.

5. Is 18 the age of majority for the state in which your site is located?  
☐ Yes      ☐ No
6. If the answer to question 5 is “no”, please identify the age of majority.
7. Does the institution require approval of a waiver of authorization under HIPAA for review of medical records to identify eligible subjects (e.g., the institution does NOT consider this “Preparatory to Research” activities)?  
☐ Yes      ☐ No      ☐ Not applicable – the HIPAA Privacy Rule does not apply to this study or institution.

### Site Policies

1. Does the site 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.

☐ Age of Assent Policy

*If selected, please provide a link (URL) to the policy, or paste the policy below*

☐ Consent Process for those with Impaired Decision-Making Capacity

*If selected, please provide a link (URL) to the policy, or paste the policy below*

☐ Use of short forms for non-English speaking individuals

*If selected, please provide a link (URL) to the policy, or paste the policy below*

☐ Translation of consent forms for non-English speaking individuals

*If selected, please provide a link (URL) to the policy, or paste the policy below*

2. Please provide any institutionally-required consent form language for compensation in the event of research-related injury:
  
  
  
  
  
  
  
  
  
  
3. Please provide any institutionally-required consent form language for pregnancy testing in minors:
  
  
  
  
  
  
  
  
  
  
4. Please provide any institutionally-required consent form language for genetic testing:
  
  
  
  
  
  
  
  
  
  
5. Please provide any other consent form language required by site policy or state law: