JEFFERSON—Office of Human Research

# Local Context Questionnaire for a Site Relying on Jefferson IRB

**Version Date – FOR OHR USE: 3/18/19**

Please have this form completed by the relying site and emailed directly to Crystal.Lijadu@Jefferson.edu in the Office of Human Research.

**General Information**

1. Name of Study:

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1. Overall Principal Investigator:

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1. Name of Relying Institution:

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1. Contact information of person completing this survey:

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1. Has the institution’s FWA (federal wide assurance) been extended to non-federally funded research?

[ ]  Yes [ ]  No

1. Provide any other names the site is known by:

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1. Please identify any affiliations this site has relevant to this study, such as a university, clinic, or hospital. If any of the sites are within a network or system, and have a separate FWA, please identify the sites with the separate FWAs. 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.

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1. Please describe 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. (If not applicable, please indicate as “N/A”)

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1. Does the institution have a quality assurance program or other regulatory oversight for ongoing research?

[ ]  Yes [ ]  No

1. If the answer to question 9 was “yes”, does the quality assurance program or other regulatory oversight monitor studies that have been deferred to an external IRB?

[ ]  Yes [ ]  No

1. If the answer to question 10 was “yes”, please provide a link (URL) to the quality assurance/regulatory oversight information, or paste information here.

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**Local Context Information**

1. Are there any state laws that the Reviewing IRB will need to consider when reviewing this study? (If the reliant site is in PA, please skip this section)

[ ]  Yes [ ]  No

1. 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).

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1. Are there any community or cultural differences for the local population of subjects that require consideration?

[ ]  Yes [ ]  No

1. If the answer to question 3 is “yes”, please describe the relevant information.

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1. What is the age of majority for the state in which your site is located?

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1. 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

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[ ]  Consent Process for those with Impaired Decision-Making Capacity

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

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[ ]  Use of short forms for non-English speaking individuals

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

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[ ]  Translation of consent forms for non-English speaking individuals

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

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1. Please provide any institutionally-required consent form language for compensation in the event of research-related injury:

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1. Please provide any institutionally-required consent form language for pregnancy testing in minors:

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1. Please provide any institutionally-required consent form language for genetic testing:

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1. Please provide any other consent form language required by site policy or state law:

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