

**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 20B

**SOP Title: NIH IRB RESPONSIBILITIES WHEN REVIEWING LOCAL CONTEXT
CONSIDERATIONS FOR OFFSITE RESEARCH**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators**

Approval:



Deputy Director for Intramural Research



Date

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SOP 20B- NIH IRB RESPONSIBILITIES WHEN REVIEWING LOCAL CONTEXT CONSIDERATIONS FOR OFFSITE RESEARCH

TABLE OF CONTENTS

20B.1 PURPOSE	1
20B.2 POLICY	1
20B.3 DEFINITIONS	1
20B.4 GENERAL CONSIDERATIONS FOR REVIEW OF RESEARCH CONDUCTED AT NON-NIH SITES.....	2
20B.5 LOCAL CONTEXT CONSIDERATIONS.....	3
20B.6 NIH IRB REVIEW OF HUMAN SUBJECTS RESEARCH CONDUCTED AT INTERNATIONAL SITES.....	4
20B.7 EXAMPLES OF METHODS BY WHICH AN NIH IRB CAN EVALUATE LOCAL CONTEXT	5
20B.8 NIH IRB REVIEW OF RESEARCH CONDUCTED AT NATIVE AMERICAN RESERVATIONS OR AT AN ENTITY THAT FOCUSES ON NATIVE AMERICAN POPULATIONS	5
REFERENCES.....	7
LIST OF APPENDICES	7
APPENDIX A: POINTS TO CONSIDER WHEN CONDUCTING RESEARCH IN AN INTERNATIONAL SETTING	9
APPENDIX B: INITIAL REVIEW LOCAL CONTEXT WORKSHEET	13
APPENDIX C: CONTINUING REVIEW LOCAL RESEARCH CONTEXT WORKSHEET	19

SOP 20B - NIH IRB RESPONSIBILITIES WHEN REVIEWING LOCAL CONTEXT CONSIDERATIONS FOR OFFSITE RESEARCH

20B.1 PURPOSE

This SOP states how local context should be addressed when an NIH IRB reviews protocols implemented at non-NIH sites, or when an NIH IRB is the central IRB for a multi-site study.

20B.2 POLICY

NIH complies with OHRP (45 CFR 46) and, when applicable, FDA (21 CFR 56) requirements for approving and overseeing human subjects research that involves NIH investigators conducting research at other sites or when other institutions rely upon an NIH IRB. When an NIH IRB reviews human subjects research conducted at non-NIH sites, the NIH IRB should ensure that it possesses sufficient knowledge of the local research context to satisfy the requirements of 45 CFR 46.111, i.e., that subject selection is equitable; subjects' privacy and confidentiality is protected; informed consent is sought in language understandable to the subject and under conditions that minimize the possibility of coercion or undue influence; and that appropriate safeguards are in place to protect the rights and welfare of vulnerable subjects. Local context review is applicable when there is an agreement to rely on an NIH IRB by a non-NIH institution and when there is dual IRB review. Consideration of local context must be documented in the deliberations of the NIH IRB when reviewing and approving research conducted at non-NIH institutions (see **Sections 20B.4 and 20B.5** below).

20B.3 DEFINITIONS

Authorization Agreement (also known as a "Reliance Agreement"): An agreement between NIH and one or more institutions involved in the same cooperative research (see definition, below) that assigns regulatory responsibilities to a specific IRB. The terms "authorization agreement" and "reliance agreement" are used interchangeably in this SOP. At NIH the preferred term is "reliance agreement." **The following terms and phrases are frequently used in the context of authorization/reliance agreements:**

Central IRB: The IRB responsible for reviewing a research protocol for multiple performance sites engaged in the same project. The Central IRB assumes responsibility

as the IRB of Record for the performance sites relying on the Central IRB for review of the research project. (See also definition of Centralized IRB Review Process in SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH. This "Central IRB" may also be called the IRB of record.

Cooperative Research: Research in which more than one institution is engaged in human subjects research. 45 CFR 46.114 states in part: "Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy."

Federalwide Assurance (FWA): A Federalwide Assurance is a written commitment by an institution to comply with the protection of human subjects regulations of 45 CFR 46. The FWA is filed with the DHHS Office for Human Research Protections (OHRP).

Local Context: In this SOP, this term refers to unique legal requirements, cultural or religious values or other site-specific variables that exist at a site where subjects are enrolled in research protocols. NIH expects IRBs to evaluate "local context" when approving and overseeing a research protocol because matters such as consent, privacy and confidentiality may necessitate specific requirements by the IRB before research can begin.

20B.4 GENERAL CONSIDERATIONS FOR REVIEW OF RESEARCH CONDUCTED AT NON-NIH SITES

Local context should be considered when there is an agreement to rely on an NIH IRB by a non-NIH institution or when there is dual IRB review. In order to make certain that local context issues are properly considered, NIH may choose to have dual IRB review, e.g., by a joint IRB agreement (see SOP 20-NIH HRPP Requirements for Collaborative Research).

An IRB also should evaluate whether researchers at the non-NIH site are engaged in human subjects research for the particular protocol. If engaged, those researchers must be part of an FWA holding institution, or have the NIH FWA extended to cover their research activities unless, for foreign sites, OHRP determines that the procedures prescribed by the non-NIH institution afford protections that are at least equivalent to those provided in 45 CFR 46. OHRP may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy (45 CFR 46)

however, thus far, OHRP has not determined that such protections are at least equivalent to 45 CFR 46.

Additionally, those researchers must have IRB approval through either an IRB affiliated with their FWA or through a reliance agreement between the NIH and their institution, to rely on the NIH IRB. Unless the study has a coordinating center responsible for validating that FWA's for all sites remain current, the NIH IRB should confirm that the PI has completed the section of the continuing review application confirming that the relying sites have an active FWA.

20B.5 LOCAL CONTEXT CONSIDERATIONS

IRBs must be mindful of the communities in which research will be carried out. Community issues may vary and IRBs should consider the following factors, as applicable:

- A. State and local laws: IRBs should be aware and mindful that Federal law, i.e., 45 CFR 46, may, in some instances, diverge from state and local law. While 45 CFR 46 must be met for research to be approved, varying state and/or local requirements that are not inconsistent with 45 CFR 46 need not be considered problematic. In the event of real or apparent conflict, the IRB may consult the NIH Office of the General Counsel for further assistance.
- B. Local attitude(s) towards medical research or research in general;
- C. Language barriers, illiteracy or lack of a written language;
- D. Variability in the age of majority;
- E. Research subjects' potential cultural differences/sensitivities, such as stigma associated with the health issue under study, gender roles or privacy issues (e.g. modesty concerns during protocol procedures);
- F. A study site that differs significantly from other sites because of variable ethnicity or national origin, religion or customs;
- G. If the research activities involve greater than minimal risk to subjects and investigators at the outside site are interacting with subjects, the NIH IRB must document the manner in which it has obtained appropriate information about the

local research context. Possible options for doing this include, but are not limited to:

1. One or more of the IRB members has knowledge of the local research context gained through direct experience with the non-local research site, the subject populations, and the local community;
2. A knowledgeable consultant participates in the IRB Committee discussion of the study or provides a prior written review and is available during the IRB meeting;
3. An experienced PI with a history working with the local population/community.

IRBs may choose to use the Local Research Context Forms (**Appendix B-Initial Review Local Context Worksheet and Appendix C-Continuing Review Local Context Worksheet**) for obtaining local context information from other sites.

20B.6 NIH IRB REVIEW OF HUMAN SUBJECTS RESEARCH CONDUCTED AT INTERNATIONAL SITES

When an NIH Investigator is planning to conduct research in a foreign country, the IRB should take into consideration the following issues:

- A. **Local Conditions:** The PI should provide information about the culture, economic and political conditions, and specify any risks to subjects specific to that site that may impact research.¹ The IRB may use consultants familiar with the population to aid in their deliberations. Consultants should include individuals with knowledge of the local research context (see also **20B.5 G** above).
- B. Dual Review:** In addition to the NIH IRB review, the research may also be subject to approval of a local IRB or Ethics Committee (EC). IRB/EC approval may be obtained from an institution/entity associated with that country that has a current approved FWA and an IRB/EC registered with OHRP. Some countries require approval from the Ministry of Health or other government entities or officials. For

1. While not an IRB responsibility, the PI should consider travel/business restrictions when the performance site is in a foreign country. There should be no U.S. Government restrictions about conducting research in that country. Additional information about such restrictions is available at the Division of International Relations at Fogarty International Center (see References below.)

more information, contact the Division of International Relations at Fogarty International Center (FIC) (see **References** below for the link to the OHRP website to search for foreign institutions holding FWAs and IRB registrations; for the OHRP International Compilation of Human Research Standards, and for the FIC contact information.) Additionally, the NIAID website, *ClinRegs*, provides an on-line database of country-specific clinical research regulatory information. (See **References** below for this link.)

- C. The NIH usually requires that the NIH IRB review and approve the protocol before it is submitted to the in-country IRB/EC.

IRBs should refer to Appendix A-Points to Consider When Reviewing International Research for more considerations.

20B.7 EXAMPLES OF METHODS BY WHICH AN NIH IRB CAN EVALUATE LOCAL CONTEXT

When an NIH IRB is engaged in collaborative research involving enrollment of subjects or data collection at non-NIH sites, the issue of local context must be addressed and documented by the IRB, using one or more of these methods:

- Non-NIH IRB review at the local site and feedback to the NIH IRB
- Information provided by the local lead investigator at a non-NIH site
- Completion of the NIH local context form by lead investigator non-NIH site (See **Initial Review Local Context Worksheet and Continuing Review Local Context Worksheet in Appendices B and C**, respectively.)
- Expertise of an NIH IRB member or an ad-hoc IRB consultant
- Long-standing or prior NIH IRB experience with the non-NIH site (i.e. NIH IRB expertise about that site)

20B.8 NIH IRB REVIEW OF RESEARCH CONDUCTED AT NATIVE AMERICAN RESERVATIONS OR AT AN ENTITY THAT FOCUSES ON NATIVE AMERICAN POPULATIONS

- A. When the performance site is located on a Native American reservation or an entity that focuses on Native American populations, an IRB should consider information about the culture, economic and political conditions, and risks specific to that site and applicable laws. Consultants familiar with the population

may aid in these deliberations. Consultants could include individuals with personal knowledge of the local research context, such knowledge having been obtained through extended experience with the research institution, its subject populations and/or its surrounding communities.

- B. All human subjects research conducted in Indian Health Service (IHS) facilities, in Tribally managed, Urban facilities (sites for Urban Indian Health Programs) or with IHS staff or resources must be approved by an IHS IRB (all of which fall under the IHS federal-wide assurance FWA00008894). The *sole* exception to this is that urban or Tribally managed facilities may obtain their own independent FWA with OHRP. In that case, the Tribe may use an IHS IRB or any other IRB of its own choosing. The IHS encourages (and will assist) Tribally-managed health programs engaging in research to obtain independent FWAs. (See **References** below for the link to the IHS Research Program.)
- C. Research projects at IHS direct care facilities serving a Tribal Nation that has its own IRB must have the approval of *both* the Tribal IRB *and* the IHS IRB. Projects at facilities managed by the Tribal Nations with their own IRB and FWA require approval of *only* the Tribal IRB.
- D. IHS approved research conducted in facilities serving specific Tribes must first obtain formal, written approval of the appropriate Tribal government(s). This approval must be submitted with the original application to the IHS IRB.

REFERENCES

- A. 21 CFR 56- Institutional Review Boards:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>
- B. 45 CFR 46 Subpart E – Registration of Institutional Review Boards:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subparte>
- C. Division of International Relations at Fogarty International Center:
<http://www.fic.nih.gov/About/Staff/Pages/International-Relations.aspx>
- D. Federalwide Assurances or IRB Registrations:
<http://ohrp.cit.nih.gov/search/search.aspx?styp=bsc>
- E. International FWA: <http://ohrp.cit.nih.gov/efile/FwaStart.aspx>
- F. International Compilation of Human Research Standards:
<http://www.hhs.gov/ohrp/international/intlcompilation/2015internationalcompilation.doc.doc>
- G. Indian Health Service Research Program: <http://www.ihs.gov/Research/>
- H. Council of International Organizations of Medical Sciences (CIOMS):
<http://www.cioms.ch/>
- I. ICH E6- GCP:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm073122.pdf>
- J. EU Directive: <http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf> and http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm
- K. NIAID *ClinRegs* site: <https://clinregs.niaid.nih.gov/index.php>

LIST OF APPENDICES

Appendix A – Points to Consider When Conducting Research in an International Setting
Appendix B – Initial Review Local Context Worksheet

Appendix C – Continuing Review Local Context Worksheet

APPENDIX A: POINTS TO CONSIDER WHEN CONDUCTING RESEARCH IN AN INTERNATIONAL SETTING

The following issues should be considered by Investigators and IRBs when NIH research is to be conducted in a foreign country. This list is not exhaustive and may change. Concerns specific to the research should be addressed in the protocol.

STANDARDS

- A. HHS (45 CFR 46) regulations apply for HHS supported research regardless of where it is conducted.
- B. Is there a local or in-country Ethics Committee (EC) or IRB?
 - Will it review this protocol?
 - Is it experienced?
- C. Does the local institution have an FWA or is a reliance agreement in place?
- D. When an IC requires Clinical Site Monitoring, generally the Monitoring Agreement is based on ICH-GCP to the extent permitted by law and NIH policy.
- E. Voluntary compliance with other international guidance may be expected when the research is conducted in other countries, such as: The International Council on Harmonisation- E6 Good Clinical Practices (ICH-GCP), Declaration of Helsinki or Council of International Organizations of Medical Sciences (CIOMS). See **References** above for links to these documents.
- F. Are there any issues related to differences in regulations between countries? For more information, see *The International Compilation of Human Subject Protections* or the **NIAID ClinRegs** **References** above.

SETTING

Is this type of research appropriate in this setting?

- A. Does the research provide treatment, **and** if so, who will provide Standard of Care after research ends? (E.g. HIV, malaria treatment, etc....)
- B. If this is a resource-poor setting, how will this impact the conduct of the research or the safety of subjects? How will those challenges be addressed?
 - 1. See “Infrastructure” below
 - 2. Will this research build capacity (e.g. bring new resources or provide professional training)?
- C. How much other research is taking place in this setting?
- D. How are differences in cultural norms addressed?

INFRASTRUCTURE

Is infrastructure adequate?

- A. Adequacy of facilities
- B. Qualifications of local research staff
- C. Local/national human subjects protection oversight (EC/IRB)
- D. Clinical resources
 - 1. Realistic expectations: If it is anticipated that 1st- world clinical care be provided in a third-world setting, is this feasible and sustainable after the research ends? Does this impact the risks and benefits of participation of the subjects?
 - 2. Will specimens be processed in-country or sent away (impact on informed consent)?
- E. Is there adequate confidentiality in place for records/data/subjects? For example, could stigma occur if a subject merely walks into the clinic?

STRUCTURAL ISSUES

- A. Order of reviews: The NIH usually requires that the NIH IRB review and approve the protocol before it is submitted to the in-country IRB/EC.
- B. Maintenance of records: Version control for protocols and consents must be consistent in the US and in-country to avoid confusion, particularly when IRB/EC reviews tend to take place sequentially.
- C. If needed, who will provide site monitoring, the Sponsor or the IC?
- D. IRBs and Investigators should be clear about what will happen when lapse of IRB Review occurs either at the NIH or in-country and which activities must cease and which may continue to protect the wellbeing of subjects.
- E. IRBs and Investigators should be clear about what will happen **to protect the wellbeing of subjects** when NIH support ceases or when a protocol is suspended or terminated by the NIH or in-country IRB/EC.
- F. How study closure will be handled: The investigator should have a plan for disposition of records, specimens and/or investigational agents.

SAFETY OF SUBJECTS

- A. Adverse event tracking/reporting/treatment: If there are differences in reporting requirements (e.g. UPs at the NIH and SAEs at the other site), the protocol should specify what is reported and to whom.

- B. Risk/benefit assessment: are risks of research greater than those experienced in daily life? (Risks may be different than those normally encountered in the US, for example, risk of severe malaria.)
- C. Is there a national treatment protocol in place for standard of care treatment? Is it easy for subjects to access standard care, or will the NIH investigator be expected to provide supportive or ancillary care?
- D. How far do subjects have to travel to participate?
- E. Does compensation impact subject safety? (See **Compensation** below.)
- F. Privacy: For example, could partner notification of infectious disease status put a female subject at risk?
- G. Are records and equipment secure?

COMPENSATION

- A. Form of compensation: money (what is the local value? US equivalency?), versus goods (millet, sugar, rice) or services (clinical care, new clinic, etc....)
- B. Is it coercive?
- C. Does it place subjects at risk for robbery?
- D. How is it paid out, (all at once, pro-rated, etc....)?

INFORMED CONSENT

Note that the informed consent must contain all the required elements under 45 CFR Part 46, and, as applicable, 21 CFR Part 50, but there are additional issues related to international research:

- A. What are the local norms for Informed Consent?
 - 1. Community Consent
 - 2. Familial Consent (spouse, head of family, etc.)
 - 3. Individual Consent
 - 4. Perinatal, neonatal consent of parents or pediatric assent
- B. Is autonomy affected by the local norms?
- C. Age of emancipation/majority?
- D. Language barriers: How will the consent process be managed for:
 - 1. Illiteracy
 - 2. Non-written languages
 - 3. A subject whose spoken language is different from that of the investigator
- E. How will specimens and data be handled?
 - 1. How will specimens/data that are being sent out-of-country be handled?

2. What about genetic information and incidental findings or issues of stigma?
 3. Does the consent allow for secondary research use of specimens or data?
(see **Structural Issues** above regarding closure of protocols)
- F. HIV testing/stigma, partner notification
- G. How will subjects be informed about new information and/or results of research?
- H. Conflict of interest issues

APPENDIX B: INITIAL REVIEW LOCAL CONTEXT WORKSHEET

Initial Review Local Context Worksheet

Please complete a copy of this worksheet for each relying institution. This form should be completed by the Site Principal Investigator (PI)/Lead Investigator with the local context representative. The local context representative is typically an individual with knowledge of the institutional human research protection program and its policies as well as state and local law. Answers pertain to the implementation of the protocol named below at your institution.

Date of Submission: _____ (DD/MM/YY)

Site PI/Lead Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution):	
Local Context Representative	
Title of Local Context Representative	
Attestation by Site PI/Lead Investigator	<p>I attest to the accuracy of the responses provided and to having confirmed these with the Local Context Representative listed above.</p> <p>_____</p> <p>Site PI/Lead Investigator signature Date _____</p>

SUBJECT SELECTION

1. Does the selection and recruitment process for this protocol comply with local laws and your institutional policies?

Yes

No (If no, please attach an explanation to this form.)

2. Do you find the selection and recruitment methods in this protocol acceptable in the context of your local area?

Yes

No *(If no, please attach an explanation to this form.)*

3. Is there anything else the NIH IRB should know about the anticipated study population at your institution?

Yes *(If yes, please attach an explanation to this form.)*

No

VULNERABLE POPULATIONS

4. Check all vulnerable populations from which you intend to enroll in this protocol.

Will there be vulnerable groups among the study population?

Children

Pregnant women, human fetuses, and neonates

Prisoner

Adults with impaired decision making capacity

Emancipated minors, mature minors

Wards of the state

Other special populations. An example may include enrolling employees of the relying institution as research subjects.

Please describe: _____

5. Will non-English speakers be enrolled?

Yes

No *(If no, please attach an explanation to this form.)*

INFORMED CONSENT PROCESS

6. Does the consent/assent process for this protocol comply with local laws and your institution's consent policies?

Yes

No *(If no, please attach an explanation to this form.)*

7. Do the consent/assent documents (and/or waiver of consent of documented consent) for this protocol comply with local laws and your institution's policies regarding informed consent?

Yes

No *(If no, please attach an explanation to this form.)*

8. According to the protocol, who will provide consent or parental permission?
(check all that potentially apply)

- Potential study participant
- Parent of potential pediatric study participant
- Legally Authorized Representative (LARs)
- Other: Please describe: _____

9. If non-English speakers will be enrolled, describe how the recruitment and informed consent process will be conducted? *(If applicable, an attachment may be added e.g. copy of the relevant institutional policy.)*

COMPENSATION

10. Will you provide compensation to participants enrolled in this protocol?

- Yes
- No *(If no, please attach an explanation to this form.)*

11. Is the participant compensation described in the protocol consistent with local laws and your institution's policies?

- Yes
- No *(If no, please attach an explanation to this form.)*

PRIVACY AND CONFIDENTIALITY

12. Are the privacy and confidentiality provisions of the protocol consistent with the resources and practices available at your institution?

- Yes
- No *(If no, please attach an explanation to this form.)*

13. Are the privacy and confidentiality provisions of the protocol consistent with local laws, institutional policies, and HIPAA (if applicable)?

- Yes
- No *(If no, please attach an explanation to this form.)*

14. Are there any other sections of the protocol which are inconsistent with local laws or your institution's policies?

- Yes *(If so, please attach an explanation to this form.)*
- No

COMMUNITY DESCRIPTORS

15. Given the nature of this particular research study, are there any additional factors particular to this study site or the community (community attitudes, ethnic diversity, language, etc.) that may contribute to the acceptability of this research in your area?

Yes *(If so, please attach an explanation to this form.)*

No

16. Does the community have a positive attitude toward the conduct of research?

Yes

No *(If no, please attach an explanation to this form.)*

STATE AND LOCAL LAW

17. List the states from which you will be recruiting and provide the age of majority for each state. *(If applicable, an attachment may be added.)*

18. If consent will be provided by LARs, describe your state and local law, and corresponding institutional policy regarding LARs. Describe who may serve as an LAR according to state laws and institutional policies. *(If applicable, an attachment can be added.)*

19. If children or adults who are decisionally impaired will be enrolled, describe your state, local, and corresponding institutional policies regarding assent by children or adults who are unable to provide consent. *(If applicable, an attachment can be added.)*

20. If mature or emancipated minors will be enrolled, please describe the circumstances under which they will be able to provide consent to their own participation and describe any applicable state, local, and institutional policies.

21. If wards of the state or other special populations (child or adult) will be enrolled, describe any applicable state, local, or institutional policies if they have requirements that go beyond what is required in the corresponding subparts of 45 CFR 46. *(If applicable, an attachment can be added.)*

22. What are the other state and local laws that govern the conduct of research at your institution? *(If applicable, an attachment can be added.)*

ADDITIONAL INFORMATION

23. Describe your institution's process to receive and address concerns from study participants and others about the conduct of the research. *If applicable, an attachment may be added.*

24. a. Describe how the relying institution gathers and evaluates the PI and research staff for financial conflicts of interest (COI). *(If applicable, an attachment may be added.)*

b. Confirm that the applicable COI policy has, and will be, followed for the protocol in question, during the entire time period (initial review, continuing review, amendments) that the NIH IRB will be the IRB of record.

Yes

No *(Individuals not in compliance with local COI requirements may not participate in the protocol being reviewed by the NIH)*

25. Please describe your institution's requirements for human subjects protections training for PIs and other staff engaged in research.

a. Confirm that the investigators involved in the research are in compliance with local training requirements.

Yes

No *(If so, please attach an explanation to this form.)*

26. Provide the boilerplate language that is specific to your institution. This is standard language required by your institution that is added to the research-specific text of an informed consent document, such as: birth control language, coverage of research injury, required phone numbers for the PI or study representative, and a person unaffiliated with the study who can answer general study questions, etc. *(If applicable, an attachment may be added.)*

27. Provide the institutional letterhead used for the informed consent document. *(If applicable, an attachment may be added.)*

28. Provide any other institutional requirements for informed consent documents. For example, if the relying institution has identified a conflict of interest, does the relying institution's management plan require a change in the informed consent document? *(If applicable, an attachment may be added.)*

29. Is there anything else the NIH IRB should know about the institution's local context or institutional policies?

- Yes
- No

30. Confirm that the institution has the adequate training, experience, facilities and resources to conduct the proposed research procedures. *(If applicable, an attachment may be added.)*

- Yes
- No

31. Add any additional comments that will help the NIH IRB in its review process: *(If applicable, an attachment may be added.)*

APPENDIX C: CONTINUING REVIEW LOCAL RESEARCH CONTEXT WORKSHEET

Continuing Review Local Research Context Worksheet

Please complete a copy of this worksheet for each relying institution. This form should be completed by the Site Principal Investigator (PI)/Lead Investigator and by the local context representative. The local context representative is typically an individual with knowledge of the institutional human research protection program and its policies as well as state and local law. The topics listed below reflect those asked on the Initial Review Local Context Worksheet that was previously submitted for the protocol named below. Indicate for each topic whether or not there are changes from the information previously provided. If there are changes, please describe. Attachments in support of changes may be added.

Date of Submission: _____ (DD/MM/YY)

Site PI/Lead Investigator	
Protocol Title	
Protocol #	
Institution Relying on NIH for IRB Review (signatory institution);	
Local Context Representative:	
Title of Local Context Representative	
Attestation by Site PI/Lead Investigator	<p>I attest to the accuracy of the responses provided and to having confirmed these with the Local Context Representative listed above.</p> <p>_____</p> <p>Site Principal/Lead Investigator signature Date</p>

SUBJECT SELECTION (Questions 1-3 on the Initial Review Local Context Worksheet)

- No change
- Changed (If changed, please attach an explanation to this form.)

VULNERABLE POPULATIONS (Questions 4-5 on the Initial Review Local Context Worksheet)

- No change

Changed (If changed, please attach an explanation to this form.)

INFORMED CONSENT PROCESS (Questions 6-9 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)

COMPENSATION (Questions 10-11 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)

PRIVACY AND CONFIDENTIALITY (Questions 12-14 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)

COMMUNITY DESCRIPTORS (Questions 15-16 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)

STATE AND LOCAL LAW (Questions 17-22 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)

ADDITIONAL INFORMATION (Questions 23-31 on the Initial Review Local Context Worksheet)

No change

Changed (If changed, please attach an explanation to this form.)