

Supplementary Application for International Research

For research conducted outside of the United States, the LSUHSC-NO investigator must complete and submit this Supplementary Application for International Research along with the appropriate standard research application, demographics form, conflict of interest attestation forms, and all other applicable materials. Review the LSUHSC-NO IRB Guidebook policies regarding international research before submitting this application.

To complete the current application, type responses in the gray text form fields. Check the appropriate boxes in the gray check box form fields.

Section A - Research Context

1. Name of country where research will take place:

2. Describe the country where research will take place (including current social, economic, and political conditions).

3. Name of specific city/region/community where research will take place (if more than one, list all):

4. Describe the specific city/region/community where research will take place (if more than one, describe each; include description of current social, economic, and political conditions).

5. Describe the target subject population.

Why is this subject population being used?

6. Does the research pose any additional risks for subjects due to the local context?

- No
- Yes

If yes, what are the additional risks?

[REDACTED]

If yes, how will these risks be minimized?

[REDACTED]

7. Describe how the recruitment process will take place.

[REDACTED]

8. Describe performance site(s) where research will be conducted.

[REDACTED]

9. Describe the process used by the principal investigator to educate himself or herself on the local setting's standards regarding human subjects research.

[REDACTED]

10. What are the country's key organizations that provide national oversight for human subjects research?

[REDACTED]

See the Office of Human Research Protections (OHRP) International Compilation of Research Standards for a listing of key organizations, laws, regulations, and guidelines governing human subjects research in various countries

(<http://www.hhs.gov/ohrp/international/intlcompilation/intlcomp2013.pdf.pdf>).

NOTE: This listing is not exhaustive.

11. *National standards for conducting human subjects research*: List the relevant legislation, regulations, and guidelines in place for performing human subjects research in the country. Also provide web links to English-language copies of those standards.

[REDACTED]

12. *State or regional standards for conducting human subjects research*: If there are any relevant state or regional standards regarding human subjects research that differ from or expand upon the country's national standards, list and describe those standards here. Also provide web links to English-language copies of those standards.

[REDACTED]

NOTE: the OHRP International Compilation of Human Research Standards does not include standards from state or regional levels.

13. Do any of the relevant national and regional standards for conducting human subjects research differ from or add to the protections afforded subjects by the Common Rule?

- No
 Yes

If yes, explain those differences or additions.

14. What is the age of majority in the country?

15. Will any form of compensation be provided to subjects for participating?

- No
 Yes

If yes, describe the compensation.

Explain the magnitude of the compensation in terms of the relative local context (e.g. the amount equals a typical month's salary for the subject population).

16. Language(s) spoken by potential subjects:

17. Name all members of the research team that are fluent in subjects' language(s). If there is more than one subject language, specify which team members are fluent in each language.

Section B - Local Review and Approvals

1. Who will conduct local review of the study protocol? (check all that apply)

- Local IRB

- Local Ethics Committee (EC)
- Other entity
- No local review will be conducted

2. If you chose "Other entity" for question #1, name and describe the entity that will be conducting the review:

[REDACTED]

Attach copy of the entity's policies/procedures for conducting review.

3. If you chose "No local review will be conducted" for question #1, explain why no local review will take place.

[REDACTED]

If no local review of the study protocol will be conducted, continue to question #6 now.

4. If you chose "Local IRB" or "Local Ethics Committee (EC)" for question #1, answer the following:

Name of IRB/EC:

[REDACTED]

Address of IRB/EC:

[REDACTED]

Name of IRB/EC Chair:

[REDACTED]

Phone number of IRB/EC Chair (if applicable):

[REDACTED]

Email address of IRB/EC Chair (if applicable):

[REDACTED]

Are the policies/procedures for review used by the local IRB/EC equal or equivalent to those used by the LSUHSC-NO IRB?

- No
- Yes

Attach copy of the local IRB/EC policies and procedures.

If the policies/procedures for review used by the local IRB/EC are NOT equivalent to those used by the LSUHSC-NO IRB, explain how the local IRB/EC policies/procedures differ.

[REDACTED]

5. Has local approval of the study protocol been granted already?

- No
 Yes

If no, explain what steps have already been taken and what steps still need to be taken to secure local approval of the study protocol.

If yes, attach copy of documentation of approval.

6. Are there any additional local approvals needed to conduct the research?

- No
 Yes

If yes, answer the following:

Explain what additional approvals are needed.

Have the additional local approvals already been granted?

- No
 Yes

If the additional local approvals have not already been granted, describe the steps that have already been taken and the steps that still need to be taken to secure the additional local approvals.

If the local approvals have already been granted, attach copy of documentation of approvals.

Section C - Institutional Engagement

LSUHSC-NO will consider an off-site institution to be engaged in a non-exempt research project when its employees or agents for the purposes of the research project obtain: 1) data about the subjects of the research through intervention or interaction with them; 2) identifiable private information about the subjects of the research; or 3) the informed consent of human subjects for the research. Refer to the OHRP Guidance on Engagement of Institutions in Human Subjects Research (<http://www.hhs.gov/ohrp/policy/engage08.html>) for more detailed scenarios of institutional engagement and non-engagement.

According to HHS regulations [45 CFR 46 103(a); 45 CFR 46.103(b)], if an institution will be engaged in a non-exempt research project and the research project is conducted or

supported by a U.S. federal department or agency, that institution must: 1) provide written assurance satisfactory to the department or agency head that it will comply with the requirements set forth in the regulations; and 2) certify to the department or agency head that the research has been reviewed and approved by an IRB provided for in the assurance, and will be subject to continuing review by the IRB.

1. Will an institution outside of the United States be involved in the research project? (includes institution's employees or agents)
 No
 Yes. An institution will be involved, but this involvement DOES NOT meet the criteria of engagement.
 Yes. An institution will be involved, and this involvement DOES meet the criteria of engagement.

If no, continue to Section D now.

2. Name of institution that will be involved in research:

3. Describe the nature of the involvement of the institution.

If institution's involvement does not meet the criteria of engagement, continue to Section D now.

4. Does the institution hold an OHRP-approved Federalwide Assurance?

- No
 Yes

If no, describe the steps that have already been taken and the steps that still need to be taken for the institution to acquire the Assurance.

If yes, provide copy of documentation of Assurance.

Section D - Research team

1. Describe the principal investigator's experience with the country, culture, and subject population, and qualifications for conducting research in the local setting.
2. Additional team members that ARE employees/agents of LSUHSC-NO:

For each member of the study team that IS an employee/agent of LSUHSC-NO, list the following:

- a) Team member's name
- b) Role in the study (e.g. sub-investigator, study nurse, etc.)
- c) Experience with the country, culture, and subject population, and qualifications for conducting research in the local setting.

█

3. Additional team members that ARE NOT employees/agents of LSUHSC-NO:
For each member of the study team that IS NOT an employee/agent of LSUHSC-NO, list the following:

- a) team member's name
- b) role in the study (e.g. sub-investigator, study nurse, etc.)
- c) experience with the country, culture, and subject population, and qualifications for conducting research in the local setting

█

As mentioned in the demographic form that must be submitted along with the research application, you will need to attach the following for each non-LSUHSC-NO study team member: 1) copy or description of Human Subject's Protection Education Program and documentation of completion; 2) CV; and 3) copy of approval from IRB of Record when available

4. Name all members of the study team that will be stationed outside of the United States:

█

5. Name all members of the study team that will be stationed domestically:

█

6. How will the off-site team maintain communication with the LSUHSC-NO IRB and any domestically-stationed team members while in the field?

█

7. Name of contact person that will be available locally to address subjects' questions and concerns:

█

What language(s) does this person speak fluently?

█

How will subjects contact this person?

█

Section E - Consent

1. Are there any specific local context issues that must be considered concerning consent (e.g., only husband can consent for a married woman, husband must be present during consent process, subject illiteracy, potential unwillingness of subjects to document consent due to local culture, etc)?

- No
 Yes

If yes, explain what specific local context issues must be considered.

2. Is a waiver of consent being requested?

- No
 Yes

If yes, explain why a waiver of consent is appropriate in the given local context.

Fill out the appropriate waiver section in the standard research application, or complete a separate waiver form and attach with application.

If a waiver of consent is being requested, continue to Section F now.

3. Where will the consenting process take place?

4. Who will be conducting the informed consent discussion?

5. What language is understood by the person consenting?

6. What language will be used by the person obtaining consent?

7. Will translators be needed for the consenting process?

- No

Yes

If yes, explain qualifications of translator(s).

If yes, explain relationship of translator(s) to research subjects.

8. How will comprehension of the consent information be assessed?

9. Will a translated informed consent document be used?

No

Yes

Attach copies of consent documents. If a translated informed consent document is being used, attach both English and translated versions and documentation of verification of translations.

10. Is a waiver of documentation of consent being requested?

No

Yes

If yes, explain why a waiver of documentation of consent is appropriate in the given local context.

If a waiver of documentation of consent is being requested, explain how subjects will be provided with information regarding the research (submit both English and translated copies of any language that will be used).

Fill out the appropriate waiver of documentation section in the standard application, or complete a separate waiver of documentation form and attach to application.

11. Who will be providing consent for the subject? (check all that apply)

Adult subject

Child with assent and parent permission

Immediate family member

Other

12. If you chose "immediate family member" and/or "other" for question #8, explain who the person is and their relation to the subject.

Why is it appropriate for this person to provide consent for the subject in the given local context?

Section F - HIPAA

LSUHSC-NO will consider any individually identifiable information collected in the context of international research and transmitted to LSUHSC-NO (a covered entity) to be protected health information (PHI) as defined by 45 CFR 160.103. Therefore, investigators conducting international research which utilizes such information must abide by the regulations of the HIPAA Privacy Rule (45 CFR Parts 160 and 164) when applicable.

The use of an alteration or waiver of HIPAA Authorization must be appropriate in the local context. Additionally, the following criteria set forth by 45 CFR 164.512 (i)(2)(ii) must be fulfilled in order for a request of alteration or waiver of HIPAA Authorization to be approved:

- The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals;
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information

1. Are there any local laws or customs regarding the protection of health information?

- No
 Yes

If yes, are these local laws or customs comparable to the HIPAA Privacy Rule?

- No
 Yes

Summarize the local laws or customs regarding the protection of health information (include in your response an explanation of how these local laws/customs compare to the protections offered by the HIPAA Privacy Rule). If available, also provide web links to English-language copies.

2. Is a waiver of HIPAA Authorization being requested?

- No
 Yes

If yes, why is the waiver appropriate in the given local context?

[REDACTED]

Complete the appropriate Waiver of HIPAA Authorization section in the standard application, or complete a separate waiver form and attach to application

3. Is an alteration of HIPAA Authorization being requested?

No

Yes

4. Will HIPAA forms (standard or altered) be written in a language other than English?

No

Yes

Attach copy of HIPAA forms.

If translated copies will be used, attach both English and translated versions and documentation of verification of translations.

5. Altered HIPAA

If a request for alteration of HIPAA Authorization is NOT being requested, continue to Section G now.

If a request for alteration of HIPAA Authorization IS being requested, explain why the alteration is needed and why it is appropriate in the given local context.

[REDACTED]

6. If a request for alteration of HIPAA Authorization is being requested, describe how each of the following criteria are being met:

The use or disclosure of protected health information involved no more than a minimal risk to the privacy of individuals:

[REDACTED]

The research could not practicably be conducted without the waiver or alteration:

[REDACTED]

The research could not practicably be conducted without access to and use of the protected health information:

[REDACTED]

Section G - Research Involving Children as Subjects

If the research will NOT involve children as subjects, continue to Section H now.

1. Describe the typical relationship between parents and their children in the country.

2. Describe the acceptable and effective parental permission process in the local context.

3. Describe the acceptable and effective child assent process in the local context.

4. Are there any relevant laws, regulations, and/or guidelines pertaining to research involving children as subjects in the local setting?

 No Yes

If yes, list these local standards and web links to English-language copies of these standards.

Do any of these local standards differ from or add to the protections offered child subjects within the United States (see 45 CFR 46 Subpart D; 21 CFR 50 Subpart D)?

 No Yes

If the local standards do differ from or add to protections offered child subjects within the United States, explain how.

5. Will orphans be used as subjects in the research?

 No Yes

If yes, are there any laws, regulations, and/or guidelines pertaining to research involving orphans as subjects in the local setting?

 No Yes

If there are local standards regarding orphans as subjects, summarize these local standards and list web links to English-language copies of these standards



6. Will children who are wards be used as subjects in the research?

- No
- Yes

If yes, answer the following:

Is the research related to their status as wards?

- No
- Yes

Will the research be conducted in a setting where the majority of children involved as subjects are not wards?

- No
- Yes

Will an advocate for the child be appointed?

- No
- Yes

Are there any laws, regulations, and/or guidelines pertaining to research involving wards as subjects in the local setting?

- No
- Yes

If there are local standards regarding wards as subjects, summarize these local standards and provide web links to English-language copies of these standards.



Section H – Attachments Checklist

The Supplementary Application for International Research (2 copies) must be submitted along with the appropriate standard research application, demographic form, conflict of interest attestation forms, and all additional required materials.

Attach 2 copies of each of the following, when applicable (check the boxes for applicable items that will be attached to application)

- Policies/procedures of local IRB/EC or other entity that will be conducting local review

- Documentation of local approval of study protocol
- Documentation of any additional local approvals needed to conduct the research
- Documentation of local institution's Federalwide Assurance
- Copy or description of Human Subject's Protection Education Program and documentation of completion for each non-LSUHSC-NO study team member
- Curriculum vitae for each non-LSUHSC-NO study team member
- Copy of approval from IRB of Record for each non-LSUHSC-NO study team member
- Informed consent documents (if applicable, include English and translated copies and documentation of verification of translations)
- HIPAA Authorization forms, standard or altered (if applicable, include English and translated copies and documentation of verification of translations)
- Consent/HIPAA waiver forms
- Any other experimental materials to be given to subjects (if applicable, include English and translated copies and documentation of verification of translations)