

 <b>Office of Research Integrity - Human Subjects</b>			<b>SOP #:</b> ORI(HS) – 3.11
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Approved By: ORI Executive Director	*Signature on file	Date:	<b>Date First Effective:</b> 03/13/2019
Approved by: Biomedical Chair	*Signature on file	Date:	
Approved by: Social Behavioral Chair	*Signature on file	Date:	<b>Revision Date:</b>

## SOP 3.11 – Transnational Research

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### 1. Objective

The purpose of this SOP is to describe the procedures for review of transnational research.

### 2. General Description

This SOP describes how the HRPP ensures that transnational research is consistent with the ethical principles set forth in the Belmont Report, and meets equivalent levels of protections afforded to subjects in the United States where applicable while also complying with local laws and the local cultural context.

This is done to ensure protections for research conducted by UNLV investigators in other countries are equivalent to those for research conducted in the United States. UNLV applies the ethical principles of the Belmont Report, the Department of Health and Human Services (DHHS) regulations at Title 45 Code of Federal Regulations (CFR) Part 46, and other applicable federal requirements, and relevant UNLV policy conducted outside of the United States.

#### Definitions

*Transnational research* - Research that will be conducted outside of the United States of America.

### 3. Roles & Responsibilities

Execution of SOP: Principal Investigator (PI)/Study Personnel (SP), Office of Research Integrity – Human Subjects (ORI-HS) Director/Staff, IRB Chairs/Co-Chairs, IRB members

#### Investigator Responsibilities:

Investigators who conduct research outside of the United States must be qualified through training and experience to conduct research in those locations. Investigators must conduct the study through scientifically sound procedures and with culturally appropriate consideration toward the needs and conditions of the study population.

The investigator conducting transnational research is responsible for:

1. Ensuring that the resources and facilities are appropriate for the nature of the research;
2. Verifying the qualifications of the investigators and research staff for conducting research in the country(ies);
3. Obtaining all appropriate host country permissions to conduct research (e.g., institutional, governmental or ministerial, IRB, local, or tribal);

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4. Ensuring that the consent process and consent document are appropriate for the language(s) of the subjects and the subject population, and that arrangements are made to be able to communicate with subjects throughout the study (e.g., to ask and answer questions);
5. Ensuring that the following activities will occur:
6. Initial review, continuing review, and review of modifications;
7. Post-approval monitoring of the conduct of the research in accordance with the plan approved by the IRB; and
8. Handling of complaints, noncompliance and unanticipated problems involving risk to subjects or others;
9. Not relying upon an IRB or EC that does not have policies and procedures for the activities listed above;
10. Ensuring that reportable information such as complaints, noncompliance, protocol deviations and unanticipated problems involving risks to participants or other are communicated to the IRB;
11. Notifying the IRB promptly if a change in research activities alters the performance site's engagement in the research (e.g., performance site "not engaged" begins to obtain consent of research participants, etc.); and
12. Ensuring that there are mechanisms for communicating with the IRB when they are conducting the research in other countries.

**IRB Responsibilities:**

The IRB reviews transnational research involving human subjects to ensure that adequate provisions are in place to protect the rights and welfare of the subjects. All policies and procedures that are applied to research conducted domestically are applied to research in international settings where appropriate.

In addition to review considerations discussed in other SOPs, the IRB will consider the following when reviewing transnational research:

1. The qualifications of the investigator and research staff to conduct research in that country including knowledge of relevant laws, regulations, guidance and customs;
2. Whether the consent process and consent documents are appropriate for the language(s) of the subjects and the subject population, and that arrangements are made to be able to communicate with subjects throughout the study (e.g., to ask and answer questions);
3. How modifications to the research will be handled;
4. How complaints, noncompliance, protocol deviations and unanticipated problems involving risks to subjects or others are handled;
5. How post-approval monitoring will be managed;
6. Whether the investigator has obtained the appropriate host country permissions to conduct research (e.g., institutional, governmental or ministerial, IRB, local, or tribal). When appropriate, the IRB communicates and coordinates with the local institutions or ethics committees; and
7. Mechanisms for communicating with the investigators and research staff when they are conducting the research in other countries.

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## 4. Procedures

For federally conducted or supported research, approval of the research by a UNLV IRB for foreign institutions or site(s) “engaged in” the research is permitted if the foreign institution or site holds a FWA with OHRP and an IRB Authorization Agreement is executed. Local IRB approval from a foreign institution or site holding an OHRP validated FWA can be considered for replacing a UNLV IRB review provided that an IRB Authorization Agreement is executed between UNLV and the foreign institution or site. Considerations for executing an IRB Authorization Agreement of this nature will depend on the conditions of the applicable study. Approval of research by a UNLV IRB for foreign institutions or site(s) “not “engaged in” the research is only permitted if one or more of the following circumstances exist:

- When the foreign institution or site has an established IRB/EC, the investigator must obtain approval to conduct the research at the "not engaged" site from the site’s IRB/IEC or provide documentation that the site’s IRB/EC has determined that approval is not necessary for the investigator to conduct the proposed research at the site.
- When the foreign institution or site does not have an established IRB/IEC, a letter of cooperation must be obtained demonstrating that the appropriate institutional or oversight officials permit the research to be conducted at the performance site.
- IRB approval to conduct research at the foreign institution or site is contingent upon receiving documentation of the performance site’s IRB/EC determination, or letter of cooperation, as applicable.

The IRB seeks sufficient knowledge of the local research context by requesting approval for the project from local IRBs or ethics committees (which may or may not be OHRP-registered) and/or local letters of support. The source of this information will depend on the nature of the study, on the country, and on the resources available to the investigator. Where there is a local IRB/EC, UNLV IRB must receive and review the foreign institution or site’s IRB/EC review and approval of each study prior to beginning the research at the foreign institution or site.

In settings where there are no IRBs/ECs, the UNLV IRB may require additional verification and information from people outside the particular research project who are familiar with the customs, practices, or standards of care where the research will be taking place, including other IRBs or committees with experience reviewing research in the region, other UNLV investigators with knowledge of the region, or a consultant who is an expert on the region, prior to approval. These individuals may either provide a written review of the research protocol or attend an IRB meeting to provide the UNLV IRB with recommendations based on his or her expertise.

### **Informed Consent Documents**

The informed consent documents must be appropriate for and in a language understandable to the proposed subjects. The IRB will review the proposed document and a back translation of the exact content contained in the foreign language informed consent document, with the credentials of the translator detailed in the IRB application or Modification Request form. All documents, including verification of the back translation, are maintained in the IRB file.

When some or all of the prospective participants do not speak English, documentation must take the form of a written consent document drafted in language understandable to the participant that embodies all the elements necessary for legally effective informed consent.

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When the researchers anticipate that many individuals in the sample population will not speak English, the best approach would be to have the IRB approved informed consent form translated into the languages they anticipate to encounter. If the researchers anticipate the sample population may include a few potential participants who do not speak English (as opposed to a majority), researchers may obtain consent using short form consent procedures that include oral presentation of informed consent information and a short form written document that is in a language readily understandable to the participant.

For the oral presentation, investigators may use an IRB approved summary or the approved English language informed consent document.

To preclude the need for revisions to the translated versions of consent forms, for the initial IRB review investigators may submit only the English versions of consent documents. The researchers may revise the English version as requested by the IRB and submit the revised versions for confirmation that the revisions are satisfactory. After hearing from the IRB office that the revisions are sufficient, the researchers may then have the documents translated. Upon completion of the translations, the investigators must submit all foreign language versions of the informed consent form, short form document and any other translated documents presented to the participants.

Translations must be certified or back-translations must be provided. ‘Certification’ should be a statement provided by the translator noting their ability and experience to provide translation. A certification statement template is available for download and use in IRBNet if one is not initially provided.

#### **Informed Consent Approval**

The consent process and associated document(s) approved for use will be documented in the ORI-HS study file. A stamped informed consent/permission/assent document(s) with the IRB approved protocol number and study expiration date will be issued to the Principal Investigator upon approval. Online informed consent materials approved by the IRB may or may not contain a stamp issued by the IRB.

#### **Monitoring of Approved Transnational Research**

The IRB is responsible for the ongoing review of international research conducted under its jurisdiction through the continuing review process in accordance with all applicable federal regulations. When the IRB and a local ethics committee are both involved in the review of research, there is coordination and communication with the local IRB/ECs for conducting any necessary continuing reviews will be made. The IRB requires documentation of regular correspondence between the University of Nevada, Las Vegas investigator and the foreign institution or site, and may require verification from sources other than the University of Nevada, Las Vegas investigator that there have been no changes made to the research since its last review.

## **5. References**

The Belmont Report  
45 CFR 46