



<b>SUBJECT:</b> International Research	<b>Effective Date:</b> October 31, 2018	<b>Policy Number:</b> 10.3.4
	<b>Supersedes:</b> October 9, 2015 October 21, 2011 May 14, 2010	<b>Page 1 of 3</b>
	<b>Responsible Authorities:</b> Vice President, Research Institutional Review Board Associate/Assistant Vice President, Research Integrity	

I. Background

Florida Atlantic University (FAU) faculty and students conduct a diverse array of human subjects research projects, including studies in international settings.

II. Purpose

To clarify the Institutional Review Board’s (IRB) position on international human subjects research and the additional ethical provisions that may apply in the ethical review of such research.

III. General Statement

International human subjects research must adhere to FAU’s policies and procedures as well as those of the host country, institution, or community. The Principal Investigator (PI) should endeavor to design research that is culturally appropriate, and which guarantees, at minimum, protections equivalent to those accepted in the U.S. All such international human subjects research carried out by FAU investigators must be reviewed by the University’s human subjects review board.

FAU investigators conducting research with data from the EU must adhere to their responsibilities established by the European Union’s General Data Protection Regulation (GDPR). The GDPR regulates the use, access, collection, and processing of all personal data from the European Union, regardless of the citizenship or residency status of the individual to whom the data pertains.

Some countries and international institutions have their own institutional review boards and regulations for human subject protections (<http://www.hhs.gov/ohrp/international/>). In those

cases in which an appropriate IRB exists at the foreign research site, their review and approval, in addition to approval by FAU's IRB, must be obtained before research can begin.

#### IV. Policy

Research conducted in international settings by or on behalf of FAU faculty, staff, and students, will adhere to applicable regulations at 45 CFR 46, 21 CFR 50 and 56, the Belmont Report, and other laws as applicable.

FAU's informed consent procedures still apply in international settings. Informed consent documents must be provided in the appropriate language, with a translated version provided to FAU's IRB after approval of the English version. A translator/interpreter may be employed to help with the consent process. In some instances it may be appropriate for the IRB to waive some or all requirements for written consent. Research proposals for which this is requested should include explanations of cultural norms or conditions requiring such a waiver as well as proposed alternative consenting procedures.

#### V. Definitions N/A

#### VI. Accountability

##### **The Principal Investigator (PI) will be responsible for:**

- Ensuring that the proposed research is culturally appropriate, adheres to policies, procedures and laws of the host country, institution, or community, is reviewed by the University's human subjects review board, and contains appropriate informed consent provisions.
- Ensuring that in those cases where a written translated document is not applicable that accurate and appropriate interpretation of the consent process is not only conducted, but documented.

##### **The IRB will be responsible for:**

- Ensuring that any proposed international research submitted for review adheres to this policy.

##### **The Research Integrity office will be responsible for:**

- Ensuring that translations are appropriately verified or that they are provided by a certified translator.

#### VII. Procedures

When submitting an IRB application package for a project conducted in an international setting, the PI should:

- When necessary, include in the IRB application package a letter of cooperation from local experts, a relevant institution, or authority for those international research sites for which there is no formal body comparable to an IRB. Ideally, this should be provided as part of the IRB submission; if for some reason it cannot, it should be submitted to the IRB as soon as possible after IRB approval.
- Provide informed consent documents in the appropriate language, with a translated

version provided to FAU's IRB after approval of the English version. In some instances it may be appropriate to request a waiver for some or all requirements for written consent. The request should be included as part of the IRB application package, and should include explanations of cultural norms or conditions requiring such as waiver.

- In those cases where a verbal consent process is appropriate, incorporate and document the consent process with the inclusion of the interpreter.

VIII. Policy Renewal Date  
NA

IX. References  
45 CFR 46  
21 CFR 50 and 56  
The Belmont Report

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POLICY APPROVAL

*Initiating Authority*

Signature:



Date: 10/29/2018

Name: Daniel C. Flynn, Ph.D., Vice President for Research

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Executed signature pages are available in the Initiating Authority Office(s)