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# Westcliff University Policy on International Research

## Application of this Policy

This Policy applies to all faculty, staff, students, and contractors conducting research under Westcliff auspices that involves international locations, collaborators, participants, data, materials, or other foreign-origin research inputs.

This policy covers human participant research conducted outside the United States, recruiting participants located outside the United States, or involving international data transfer, as well as research using data, data sets, biological materials, records, or other research inputs or originating outside the United States, regardless of whether such data or materials are transferred across national borders.

Research involving human participants is subject to approval by the Westcliff IRB (Institutional Review Board). Research not involving human participants is not subject to IRB approval, but does require IRB review and may require institutional review for legal, regulatory, sanctions, export control governance, or publication-related compliance. International researchers may find their work affected by significantly different standards of practice because many research policies and regulatory frameworks have been developed within specific national contexts and governance structure, reflecting local scientific and political cultures and academic traditions.

Factors that can impact international collaborations include:

- International regulations on research with human subjects vary worldwide, as do cultural interpretations of vulnerability and protection (OHRP, 2022).
- There is significant diversity among national policies on research misconduct (Resnick et al. 2015).
- International research may be affected by national export controls sanctions (Bureau of Industry and Security, n.d.) or other restrictions that limit or prohibit certain research activities, data use, technology transfer, services, payments, or collaborations with individuals or entities in particular countries. These considerations may exist even when data remains in-country. National security concerns may be especially prominent in research with advanced computing and encryption, telecommunications, physics, nanotechnologies, and biotechnologies with potential for "dual use" as weapons, as well as for human benefit.
- Language barriers may persist even among English-speaking researchers, technical terms may carry different meanings, and some concepts may not translate well across languages or cultures.

## Guidelines for Conducting International Research

The following guidelines are intended to support faculty, students, and staff in ensuring ethical, lawful, and compliant international research practices.

**1. Compliance with U.S. Regulations and Westcliff IRB Requirements**

- All international research involving human participants requires Westcliff IRB review and approval BEFORE recruitment, consent, enrollment, or data collection begins.
- Westcliff applies ethical principles reflected in *The Belmont Report* (National Commission for the Protection, 1979) and standards consistent with 45 CFR 46 (Common Rule), regardless of funding source.
- Research must comply with U.S. Department of Health and Human Services (HHS) regulations at 45 CFR 46 (Common Rule) (Office for Human Research Protections [OHRP], 2018).
- Research must adhere to Westcliff **IRB policies**, including requirements for informed consent, data protection, and risk/benefit assessments.
- **Conflicts between standards.** When U.S./Westcliff and host-country requirements differ, investigators must meet the standard that provides greater protection to participants..

**2. Host-Country Laws and Ethical Standards**

Research must comply with the **laws, cultural norms, and ethical guidelines** of the country where the study is conducted or where research data or materials originate.

Risk-based local ethics review (in addition to Westcliff IRB approval):

- Local ethics committee/IRB (or equivalent) approval is required when host-country law or site policy requires it.
- Local ethics review is generally required for studies that are greater than minimal risk, involve clinical or health-related interventions, or involve sensitive topics or vulnerable populations.
- Where no local ethics review mechanism exists the Westcliff IRB may require a local context consultation or documentation describing relevant legal and ethical considerations.

**Site Permissions**. When research is conducted at or with an external site (e.g., school, clinic, NGO, archive, data repository), investigators must obtain written site permissions or letters of cooperation unless the IRB determines they are not applicable. Information on various countries may be found in the international regulations OHRP (2022) website.

**3. Informed Consent in Multicultural Contexts**

Consent must be voluntary, informed, and appropriate to the local context, consistent with applicable informed consent requirements (e.g., 45 CFR 46.116) and host-country law.

Documentation of consent (including any waiver of documentation) must satisfy applicable requirements (e.g., 45 CFR 46.117) and host-country law.

Language access and translation:

- Participant-facing materials must be written in locally appropriate language(s) and reviewed for cultural sensitivity.
- Translations must be completed by qualified translators and accompanied by a translation certification or attestation provided with the IRB submission.
- Back-translation and additional comprehension safeguards may be required based on risk level..

Additional protections may apply for vulnerable populations under 45 CFR 46 Subparts B, C, and D (pregnant women/fetuses, neonates, prisoners, and children), and applicable host-country law.

**4. Data Privacy and Security**

- Researchers must comply with applicable U.S. data protection laws (e.g., FERPA,HIPAA) and host-country data protection requirements (e.g., EU General Data Protection Regulation [GDPR] (European Union, 2018) .
- Data handling, storage, access and transfer must be secure, encrypted where required, and legally permissible.

**5. Collaborative Research and Authorship**

- International collaborations must include clear agreements, as applicable, addressing roles, oversight, data ownership, permitted uses, publication and authorship expectations, and appropriate benefit-sharing.
- Collaborative research should respect principles of equity, reciprocity, and appropriate benefit-sharing.

**6. Special Considerations (Non-Human Research, Political Risk; Sanctions; Export Controls)**

- Research that does not involve human participants, but involves foreign-origin, data, materials, locations, or collaborators may be subject to US sanctions, export controls, foreign policy restrictions, or other legal constraints.
- Such research requires institutional review prior to initiation, particularly when conducted in or involving countries or entities subject to US restrictions.
- Researchers must consult the designated institutional contact for sanctions or export control compliance when applicable.
- Investigators must assess and minimize political, social, and cultural risks to collaborators and institutions, including risks, arising from publication or dissemination of research findings.

**References (Non-exhaustive)**


Bureau of Industry and Sanctions: Department of Commerce. (n.d.). *Export Administration Regulations.* https://www.bis.gov/regulations/ear

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European Union. (2018). *General Data Protection Regulation (GDPR).* Official Journal of the European Union, L119. https://www.edpb.europa.eu/sites/default/files/files/file1/edpb_guidelines_202005_consent_en.pdf

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research*. U.S. Department of Health, Education, and Welfare. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

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UNESCO. (2005). *Universal Declaration on Bioethics and Human Rights.* Paris: UNESCO. https://www.unesco.org/en/ethics-science-technology/bioethics-and-human-rights

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