Bureau of International Osteopathic Medicine: IRB Requirements for International Health Research

The Bureau of International Osteopathic Medicine requires all research abstracts submitted to the research abstract competition to submit proof of Internal Review Board (IRB) approval. Internal review boards are responsible for protecting the rights and welfare of the human participants in research. IRBs are assembled by universities, healthcare facilities, and research institutions to ensure that all research projects comply with federal laws and institutional rules governing research ethics, including the US Federal Policy for the Protection of Human Subjects (also known as the Common Rule), the US Department of Health and Human Services' human subject protection regulations (45 CFR part 46), and additional institutional standards.

The review process exists to ensure that all humans who participate in research conducted at or sponsored by a given institution enter into and withdraw from research activities of their own free will, receive adequate information on the benefits and risks of research activities, are safe from undue risk while engaging in the activities, and have their privacy, confidentiality, and anonymity maintained throughout. The review also serves to protect researchers from possible safety and ethical issues in the field and any negative ramifications that might result from publishing data collected in unethical circumstances.

This document is intended to help students conduct international research projects that will be most adherent to ethical standards and therefore eligible for academic publication as well as submission to the BIOM research competition. Research conducted by COM faculty and students will fall under the COM's purview and guidelines even when conducted elsewhere, including internationally. Therefore students should be aware of the following general advice.

IRB before Everything
Researchers considering participating in the BIOM research competition are encouraged to pursue IRB approval among the very first steps of their research. In almost all cases, IRBs must review research protocols before any data collection occurs. We advise all researchers not to collect or analyze any data before securing official approval.

Timeliness
The review process often takes a considerable amount of time, and can sometimes inform the exact procedures the research project uses. All participants are advised to pursue IRB review early and to secure all necessary institutional approvals in advance of any travel.

Resources at Your Institution
An initial step should be to review the IRB website or documentation at your institution. This typically provides a step-by-step guideline for creating and submitting a research protocol for review. In addition, check in with faculty advisors, senior researchers, and the Office of Human Research Protection at your COM or residency program. Their advice can be useful for ensuring that your protocol meets standards, and might prove highly time-efficient.

Human Subject Research Ethics Training
Institutions that conduct research often ask new researchers, including students, to participate in training in federal law and ethical guidelines in advance of conducting any research. As part of your review of the institutional IRB documentation, check to ensure you have the correct certifications, and sign up for trainings as necessary.

Developing a Protocol

Every internal review requires a protocol. This is a document that details what your research is about, how it will be conducted, and how it will meet specific safety requirements. To draft a protocol, refer to IRB documentation and talk to your advisor(s). The component parts are typically determined by the specific type of review your research requires.

Types of IRB Review
For the purposes of IRB approval, there are typically three classifications of research protocols:

- *Exempt protocols*, for research that does not directly involve human subjects;
- *Expedited protocols*, for projects that involve human subjects engaged in activities of minimal risk; and
- *Fully reviewed protocols*, which involve human subjects at greater than minimal risk, as well as special demographics such as children and economically vulnerable people.

Each of these has specific qualifying attributes (that each institution will describe fully in their submission materials). Many international projects will require full board review due to complexities inherent to international research.

Internal Review with International Partners
Before submitting your protocol to the US IRB, you should communicate with your international partners. International research projects typically take place in universities, healthcare facilities, organizations, or communities. These institutions and groups are stakeholders in the research process, and often they are the parties who assume the most risk as a result of research activities. For these reasons, **it is crucial that any international research project incorporate reviews from their international partner(s) into their planning.**

In some cases, this might involve an IRB similar to the one found in the American researcher's COM or institution. In that case, **the protocol submitted in America should go through a review with the international partner *first*, and evidence of approval should be part of the package submitted to the researcher's US IRB.** Please note that this review process can take a significant amount of time, and may require changes to the protocol that reflect local laws, standards, or best practices. Approval should be made in writing, and should include clear explanation of the extent of support the institution can provide.

In the case that the research relies on an organization or a community that does not have and cannot reasonably access an IRB, an informal process can be substituted. This should involve a close review of the protocol, a discussion between researchers and partners, any necessary changes to the protocol, and an approval given by at least one organizational or community authority figure. Approvals should be made in writing wherever possible, and should be submitted to the local IRB along with other protocol materials.

International Guidelines
Because IRB processes can differ substantially between countries, effort has been put into harmonizing approaches. The following guidelines offer further guidance:

- International Conference on Harmonization (ICH) guidelines,
- World Medical Association Declaration of Helsinki, and
- Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects (PDF).

Special Issues in International Research
Travel Safety

All travelers, including researchers, are advised to see if their destination is on the Department of State's travel warning list. Faculty and staff who are leading osteopathic medical students to countries on the U.S. Department of State's travel warning list will need to gain approval from their institutions. In addition, as with any research protocol, all researchers should be able to explain why international travel is required for the implementation of their research plan.

Privacy

In the US, HIPAA law specifies patient information that must be kept private. (For a list of protected health information [PHI], please click here.) Privacy laws differ substantially from country to country, and researchers are encouraged to research specifics of what participants abroad are legally entitled to and what they will expect. This is particularly relevant for research on topics that might be stigmatized or taboo in the areas where the research is occurring, and in places where a lack of confidentiality might create a barrier.

Please note that while the researchers do not need to obey HIPAA law while working abroad, they *do* need to obey HIPAA in the United States, including for data analysis, storage, and sharing and for research publication and participation in competitions such as BIOM. Research protocols should include a plan for HIPAA compliance, such as de-identification of data at the point of collection or prior to returning to the United States.

Consent

Like privacy, laws and cultural expectations around consent differ from country to country. In addition, working with a population abroad might pose challenges that are uncommon in America, such as including participants who cannot read or write. Other issues with consent can involve clarity around the age of majority (the point at which a young person can consent for him- or herself), the rights of women to consent for themselves, and the right of junior members of community to withdraw if a senior or more powerful community member has already granted general consent for research to proceed. Because these issues and workable solutions are often specific to given communities, researchers are encouraged to review existing academic literature on the same demographics, inquire closely of the partner organizations, and make plans with the greatest caution and inclusivity in mind. Ideal consent procedures will meet the standards of US law *and* the laws and cultural standards of the area where research is done.

Many IRBs impose a standardized consent procedure, which involves issuing a written description of risks, benefits, alternatives, and relevant legal rights and duties to each participant. Substitutions (for example, a verbal consent process for a population in which many people are illiterate) must be justified in the protocol and approved by both international and local IRBs. If the research team would like to request a waiver of written consent, they must provide justification for the request and describe how consent will be documented.

The research team might also wish to consider the need for supplemental consent from local leaders, parents, or male family members. Protocols should describe how researchers will include these additional procedures, if needed.

Language and Translation

As with consent, this is an area where particular attention is helpful to ensure ethics are upheld. If the researcher cannot speak the language and/or dialect that the participant population speaks, it is necessary to explain the project will proceed. This can include translation of written documents, bilingual research assistants or translators, etc. Often, language is particularly important to consent and should be integrated fully into the planning of consent procedures.

Informed consent forms and all other study documents that will be shared with participants and their communities (e.g., recruitment material, instructional materials, hand-outs, presentations, etc.) must be prepared in languages understandable to the participants, including the appropriate dialect and reading level. These should be included in all IRB submissions to both international partners and the researchers' COM or residency. Certified translations into English may be required.

Other Cultural Issues
Protocols should include information on any other cultural issues that require specialized procedures to protect subjects or respect local standards. Information about local requirements or customs for obtaining appropriate access to the population should also be included. If minors will be enrolled in research, provide the legal age of majority in the country where the research is conducted, and describe an appropriate assent process for the local context.

Sharing Data and Results
Although few IRBs specifically require it, many international institutions, communities and organizations where research is conducted are interested in receiving data sets, publications, or other presentations of the results of the research. Researchers are encouraged to consider the manner in which their information will be shared with their partner sites, and to give special consideration to those groups for whom research is less common and regularized (such as rural communities) as opposed to those whose research experience is greater (such as universities).

Questions to Answer in Developing a Protocol

1. In what country will the research be conducted?
2. Describe the rationale for selection of this site.
3. Is this research being conducted by a student, or by faculty or staff leading students?
4. If the researcher is a student, describe how the faculty advisor and student will communicate to ensure there is adequate oversight of the project.
5. Is this site listed on the Department of State's travel warning list? If yes, explain how the researchers will remain safe while conducting research.
6. What is the primary language of the potential research subjects? Is the researcher fluent in the primary language? If no, explain how the researcher will communicate with the subject population during recruitment, consent and completion of the study.
7. Describe the researcher's qualifications to conduct research at the host site. Include past experience, relevant training, and/or coursework to corroborate his/her ability to do so.
8. Describe how the researcher will obtain culturally appropriate access to this community.
9. Describe the ways in which cultural norms and/or local laws differ between the host site and the US. Consider differences in literacy, age of majority, individual autonomy, group consent, and/or parental consent. Additional guidance is available here.
10. Describe any aspects of the cultural, political, or economic climate at this research site which might increase risks to participants.
11. In most instances, an ethics committee or other regulatory entity in the host country must approve proposed research. Provide contact information for the committee/entity reviewing this project.
12. Are there any foreseeable issues that will impede the researcher's ability to communicate with the IRB if the project requires changes or if there are reportable events? If yes, explain below and address how the researcher will mitigate these.