Conducting research in international settings has become increasingly popular among students and faculty in the University of Rochester research community. Carefully planning this type of research well in advance is critical as regulatory and cultural differences can vary drastically from one international site to the next.

One of the principal hurdles study teams will face in conducting international research is navigating regulatory requirements. Per Office for Human Subject Protection (OHSP) Policy 301, when faculty, staff or students engage in human subject research on behalf of the University, regardless of where the research is conducted, review and approval by the Research Subjects Review Board (RSRB) is required. Based on the institution’s FederalWide Assurance, this further requires study teams to comply with the Common Rule (45 CFR 46), regardless of study of sponsorship.

To meet U.S. federal requirements as well as the University’s institutional requirements, study teams must:

- Include information pertaining to the setting in which the research will be conducted in their RSRB submission (e.g., description of the population, information pertaining to local languages, laws and cultural issues), as described in the Guideline for Conducting International Research.
- Obtain a local letter of support or local IRB/Ethics Committee approval, as appropriate.
- Obtain RSRB approval prior to implementation of the research.
- Obtain documentation of the local site’s FederalWide Assurance, if federally funded.
- Comply with Food & Drug Administration (FDA) regulations, if the research involves the use of an FDA-regulated product.

Study teams must also comply with the regulatory requirements of the setting in which the research will be conducted. This can range from detailed national/regional human subject research requirements much like the US (e.g., Europe, India, and Japan) to no clearly defined human subject protections. When there are no clearly defined protections, the ethical principles that guide human subject research (e.g., Nuremberg Code, Declaration of Helsinki, Belmont Report) still hold true. This includes obtaining ethics committee approvals (or letters of support by community leaders or other local experts in the absence of an ethics committee), allowing subjects to participate in the research voluntary and with informed consent, minimizing risks to subjects, appropriately selecting study subjects, etc. To further aid study teams in identifying applicable international regulations and guidelines, the Office for Human Research Protections within the Department of Health and Human Services publishes the International Compilation of Human Research Standards annually (though study teams are also encouraged to collaborate closely with local experts to ensure local requirements are adequately addressed).

Once the research has met both RSRB and local approval requirements, study teams must continue to comply with both sets of expectations during (continued on page 2)
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(continued from page 1) the implementation and close out phases of the research (meaning, OHSP Policy 901 Investigator Responsibilities [inclusive of U.S. federal regulations and state law] and the requirements of the setting in which the research is conducted). Generally, this includes:

- Obtaining informed consent;
- Complying with the study protocol;
- Ensuring subject questions and concerns are properly addressed;
- Submitting recruitment/consent/protocol revisions to both ethics committees (per their requirements) for review and approval prior to implementation; and
- Submitting research events to both ethics committees (per their requirements).

Additional Considerations

Cultural Competence – Having a thorough understanding of a site’s social habits, language, political and religious views, attitudes, values, and infrastructure is key to the success of the research. Demonstrating awareness of these cultural components should begin early in the planning phase, as the research is being designed, and continue throughout the life of the project. Failing to do so will negatively impact a study team’s ability to foster a relationship with the community, communicate and enroll subjects, carry out study procedures and protect the rights, safety and welfare of subjects.

Communication Barriers – Consistent with the Belmont Report, communications with potential and enrolled study subjects should be informative (providing adequate information) and understood (providing information in a manner that is comprehensible to the study population). Subject communications should initially be thought through with input from individuals with local knowledge, during the planning phase of the research in the development of recruitment methods/materials, informed consent processes and any subject-completed measures. During this time, study teams must be mindful of a site’s literacy rates and cultural practices, incorporating the use of illustrations, videos, demonstrations and/or community advisors, as appropriate. All written materials provided to study subjects must be translated to the site’s native language by a fluent individual (translation software is not sufficient) and submitted to the RSRB for review and approval with a corresponding Translator Declaration. In some cases, for example when a professional translation service is not used, additional confirmatory translations may be required by the RSRB.

Once a study has been approved and the team is ready to initiate the research, verbal communications including day-to-day recruiting, enrollment and study activities should be facilitated via an interpreter. Utilizing interpreters not only allows study teams to communicate clearly with subjects but also likely improves the likelihood of enrollment, retention and subject compliance. Generally, interpreters should be fluent in the community’s native language and unaffiliated with the research (i.e., not part of the research team), though it is also best practice to ensure the interpreter has a general understanding of the purpose and design of the research, privacy and confidentiality, and medical terminology (as appropriate).

Privacy & Confidentiality – Generally, the requirements pertaining to adequately (continued on page 3)
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(continued from page 2) protecting the privacy of subjects and maintaining the confidentiality of data still apply (as defined by 45 CFR 46.111 and OHSP Policy 404). A common misconception is that requirements set forth by the Health Insurance Portability and Accountability Act (HIPAA) do not apply to research that involves collecting protected health information (PHI), given that research is being conducted outside of the U.S. While this is true while outside the U.S., HIPAA applies (and therefore must be complied with) once study teams return with PHI to the U.S. Furthermore, it is not uncommon for other countries to have their own standards for protecting privacy and confidentiality and, similar to regulations governing the conduct of human subject research, these must also be complied with (see the aforementioned International Compilation of Human Research Standards for privacy and data collection standards).

Respecting Subjects & Community Engagement – Respecting study subjects requires more than the necessary steps of obtaining ethics committee approvals and informed consent; it includes valuing their opinions and choices. Conducting international research often involves fostering community partnerships secondary to the purposes of the research and respecting that relationship throughout the life of the project (and potentially beyond the project) is vital. Similar to understanding a community’s culture, a study team must understand what the community’s expectations are concerning the research and then honor those expectations, or provide feedback to the community on exactly what they can deliver from the research. This could include sharing the results of the research or providing training, resources or equipment.

Timing – Needless to say, not all of the requirements and considerations described above can happen overnight. Planning plenty of time to develop your study protocol, research the necessary review requirements, collaborate with local experts, digest applicable cultural elements, and obtain ethics committee approvals (including the RSRB) is essential. The more forethought and effort that goes into planning international research, the more likely you will be able to conduct compliant research, collect quality data and meet your objectives.

Have questions? Contact your RSRB Specialist. An additional listing of external resources is available here.

Note: The recent Common Rule and National Institutes of Health policy/regulatory revisions pertaining to the use of a single Institutional Review Board for multi-site research do not apply to research conducted internationally.

Research QI ‘Gold Star’ Award

The QI division is recognizing Joyce Duckles, PhD, George Moses, Sandhya Seshadri, Rita Acosta, Chang Cao, Ashley Ortiz, and Peng Wang for their quality work on the ‘Growing a Healthy Community: Families Building Sustainable Gardens and Community Spaces’ study. This vibrant multidisciplinary study team is based out of the Department of Counseling and Human Development at the Warner School in collaboration with the North East Area Development, Inc.

The study site received the OHSP-QI ‘Gold Star’ award for their commendable work in demonstrating communication and a focus on teamwork, being open to educational opportunities and using available resources, displaying respect for the subjects and their families, and high quality, organized study-related documentation.

Congratulations!
Study Start-Up (SSU) Consultation Q&A

After receiving IRB approval and prior to enrolling subjects, the OHSP’s Division of Quality Improvement (OHSP-QI) staff is available upon request to provide guidance on best practices and to evaluate study documentation. The primary goal of an SSU consultation is to assist study teams in their ability to achieve compliance applicable to their specific study and to further protect subjects participating in research.

Over the past 18 months, OHSP-QI has conducted 63 study start up consultations. Three recipients of a SSU, BriAnna Diluigi (Mt. Hope Family Center), Lynne Massaro (School of Nursing), and Noya Rackovsky (Pediatrics), have graciously shared their experiences and advice. Many thanks to BriAnna, Lynne, and Noya!

Why did you want to have a SSU consultation?

- BriAnna: I am new to the Project Coordinator Role, and wanted to be sure I was following all protocols.
- Lynne: I had some experience with research but it had been many years since I was actually involved in an active study. I needed to reacquaint myself with basic terms, requirements, and actual University policies in order to be compliant, efficient, and effective in how I managed the study.
- Noya: We wanted to do things correctly, right from the start. We thought we could use some help and direction and fix early whatever needs fixing.

Would you recommend the SSU service to other sites? If so, why?

- Lynne: I would recommend the service to others. I found it informative and a good way to start a new study, especially for someone who was not actively involved in research every day. Thinking you know what to do based on written information is one thing – being able to discuss, ask questions, and verify working knowledge with an individual expert in the field was so much better and increased my confidence to be successful.
- Noya: I would highly recommend SSU services. It was very beneficial, we learned a lot, we got a lot of support and we found a very professional, knowledgeable, and friendly face.

What surprised you about the SSU service?

- BriAnna: That the consultant was very familiar with our project already, so we were able to communicate effectively.
- Noya: I was pleasantly surprised by the depth and the detail of the review.

The final question asked each interviewee if they felt better prepared to conduct their new study; each agreed they...

- ‘felt better prepared’;
- ‘understood proper study documentation’; and
- ‘were able to reach out for assistance and receive guidance’.

Contact OHSP-QI to schedule your team for a study start-up consultation. Additional information concerning SSU consultations is also available in the 2015 Q2 OHSP Newsletter.
Utilizing ResearchMatch.org for Subject Recruitment

ResearchMatch is a national recruitment registry meant to bring researchers and individuals interested in participating in research together (currently with well over 100,000 subject volunteers). Prior to utilizing this free resource as one of your recruitment methods, study teams must obtain IRB approval for each protocol employing ResearchMatch. As part of the IRB submission, the University’s ResearchMatch Request Form must be completed (in its entirety). This includes identifying the IRB number, Investigator contact information, as well as providing the recruitment message that will be sent to matched volunteers. Note that this form is occasionally updated; use the form provided through the Clinical & Translational Science Institute’s (CTSI) website with each request, rather than updating previously versions of the form that may have been saved to a desktop or shared network drive.

Once IRB approval has been obtained, study details (including a PDF file of either the IRB approval letter or ResearchMatch Request Form, which indicates IRB approval) can be entered into the registry from the researcher’s account. Local ResearchMatch Administrators will then review the request and verify IRB approval, after which study teams will be allowed to recruit potential subjects using the registry.

Further instructions for utilizing this recruitment tool are available through the CTSI. Questions can also be addressed via the CTSI’s Research Help Desk.
What is a ‘covered entity’ and how does it affect my research?

Per the Health Insurance Portability and Accountability Act (HIPAA) rules, a ‘covered entity’ is a term used to collectively identify health plans, health care clearinghouses, and health care providers that transmit electronic health information in connection to a transaction (e.g., billing, payments). At the University of Rochester (UR), this includes (but is not limited to): Strong Memorial Hospital; Highland Hospital; FF Thompson Hospital; Eastman Dental Center; UR Faculty and Dental Groups; UR School of Medicine and Dentistry; UR School of Nursing and Community Nursing Center; University Health Service and Mt. Hope Family Center (for a complete list, click here).

Researchers are considered a covered entity when they are health care providers that transmit electronic health information as described above and, in turn, they must comply with HIPAA in using and/or disclosing health information for research purposes. When all study team members are within a covered entity, complying with HIPAA is clearly required. These requirements become less clear however, when a study team includes members of the covered entity (e.g., URMC) and members who are not part of the covered entity (e.g., River Campus faculty or staff). Anytime a study team includes at least one member of the covered entity, the entire study team must comply with HIPAA. Generally, this means that specific conditions must be met in order to use or disclose subject health information (e.g., a HIPAA authorization needs to be included in subject consent forms) and appropriate security measures need to be in place to protect subject information once collected (e.g., data can only be stored on appropriately encrypted devices).

Additional information pertaining to HIPAA compliance as it relates to the conduct of research is available through OHSP Policy 702, the University’s Privacy and Security webpage, and the National Institutes of Health’s Protecting Personal Health Information in Research webpage.

Can I use money raised through ‘Go Fund Me’ to fund my research?

No. While crowdfunding through online and social media platforms like Go-FundMe and Kickstarter have become increasingly popular, utilizing them to raise funds for conducting research is not permitted. Unlike routine sponsored research (i.e., federal funding, industry-sponsors, and non-for-profit organization funding), there is no mechanism to account for funds utilized in this manner and ensure compliance with federal and institutional standards.
Upcoming Educational Opportunities

Achieving High Quality Clinical Research Seminar Series

The Achieving High Quality Clinical Research Seminar Series will resume in September. Miss a seminar? Presentation materials and videos of previously recorded seminars are available on the OHSP and CTSI websites.

OHSP Education & Training Framework Opportunities

Course objectives, a content outline and recommendations regarding course completion, as well as instructions for self-enrolling in the course are available here.

- **Orientation to Conducting Human Subject Research:** This course is available through MyPath. Instructions for self-enrolling in the course are available here.
- **Research Boot Camp:** This course is available through MyPath. Instructions for self-enrolling in the course are available here.
- **Core Training:** Registration for these courses is required through MyPath. Registration hyperlinks for the courses listed below are available on the OHSP Education & Training homepage.

  Module 7 Investigational Products: June 26th, 12-1:30pm, HWH 1W-501
  Module 8 Subject Safety: July 25th, 2-4pm, Med Ctr 2-7536
  Module 9 Essential Documentation: August 10th, 2-4pm, HWH 1W-501

**Note that Core Training Modules are in the process of being ‘converted’ to online training modules available via MyPath (similar to the Orientation and Research Boot Camp courses referenced above). As modules become available, they will be announced via the OHSP listserv.**

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