MICHIGAN STATE UNIVERSITY

GRAND Forum:
Key Institutional Review Board (IRB) Considerations

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Human Research Protection Program

Obtain all necessary approvals.

- In addition to MSU IRB review and approval, there may be additional approvals required in the international context
  - Engaged entities, including sub recipients
  - Local ethics committees
  - Country specific approvals
- Arrangements may be made to “rely” upon another institution as the IRB of record – contact the MSU HRPP, as they review and process all of these requests

Engaged international sites may require registration with OHRP.

- “OHRP” is the U.S. Office for Human Research Protections; it coordinates the “Federal Wide Assurance” (FWA)
- When an institution is engaged in non-exempt human subjects research that is conducted or supported by certain federal agencies, it must satisfy regulatory requirements related to holding an assurance of compliance (e.g. FWA) and certifying institutional review board (IRB) review and approval

Alternate ways to achieve IRB training are accepted.

- Any individual engaged in human research overseen by Michigan State University (MSU) must complete and maintain current Human Research Protection training
- Alternate arrangements for training can be made when an individual is unable to complete the online modules
- Non-MSU individuals (e.g. individuals affiliated with another institution) may submit a request to accept a completion record for another institution's human subject protection course

The IRB may require additional information about cultural norms and local laws.

- Researchers should describe in their application any cultural norms or laws that impact the research (e.g. risks, benefits, consent)
- The IRB may ask that the investigator and/or research staff provide information about cultural norms and local laws relevant to their research or identify and consult with a local expert or community leader that can identify local cultural norms and laws prior to IRB review of the application
- Additional expertise may be obtained

Researchers should consider how they will communicate . . . with research subjects.

- How cultural norms may impact consent requirements, e.g. signatures, individual consent, languages, site specific consent forms
- Consider how to address this in advance
- Describe a plan to handle different contingencies

Researchers should consider how they will communicate . . . with sites.

- Develop a plan for management of information that is relevant to protection of subjects, e.g. interim results, data safety monitoring

Researchers should consider how they will communicate . . . with the IRB.

- Incidents such as an unanticipated problem involving risks to subjects or others, subject complaints, etc. still need to be reported in accordance with the MSU HRPP Manual
- Develop a mechanism to coordinate information and IRB submissions across sites

Researchers should consider whether they may need to make changes to their IRB approved project and how to do so.

- Any proposed change or revision to an approved non-exempt research study that affects human subjects (with certain limited exceptions discussed below), must be reviewed and approved by the Institutional Review Board (IRB) prior to implementation of the change
- When an immediate change in a research protocol is necessary to eliminate a hazard to subjects, the proposed change need not be reviewed by the IRB prior to its implementation; in such situations, however, investigators must report the change in protocol to the IRB immediately thereafter

Researchers should consider how records relating to the research will be maintained.

- Records relating to research shall be retained for at least 3 years after completion of the research; completion of the research means closed with the IRB
- Documentation of the informed consent of the subjects - either the signed informed consent form or the short form and the written research summary - are records related to conducted research that are typically held by investigators and must be retained for at least three years after completion of the research, unless the IRB waived the requirement for informed consent or the requirement for documentation of informed consent

Additional requirements for international research can take significant time.

- Some countries have in-country requirements that may cause significant delays
- It is recommended to contact the MSU Human Research Protection Program Office

Resources

- MSU Human Research Protection Program Manual
  - 2-1, Ethical Principles
  - 2-4, International Conference on Harmonization – Good Clinical Practices
  - 2-5, Transnational Research
  - 6-9-F, Multiple Research Sites

  https://hrpp.msu.edu/msu-hrpp-manual-table-contents-expanded
- US OHRP International Webpages
  - International compilation of human research standards
  - Ethical codes and research standards

  https://www.hhs.gov/ohrp/international/index.html

Questions?

- Contact the MSU Human Research Protection Program
- Phone: 517-355-2180
- Email: irb@ora.msu.edu
- Website: hrpp.msu.edu
- Reliance questions? IRBReliance@ora.msu.edu
- Set-up a meeting, Monday – Friday, 8:00 A.M. - 5:00 P.M.