MU IRB Submission and Review Process

Janelle Greening, MBA – Associate Director, HRPP/IRB

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MU Human Research Protection Program (HRPP) and Institutional Review Board (IRB)

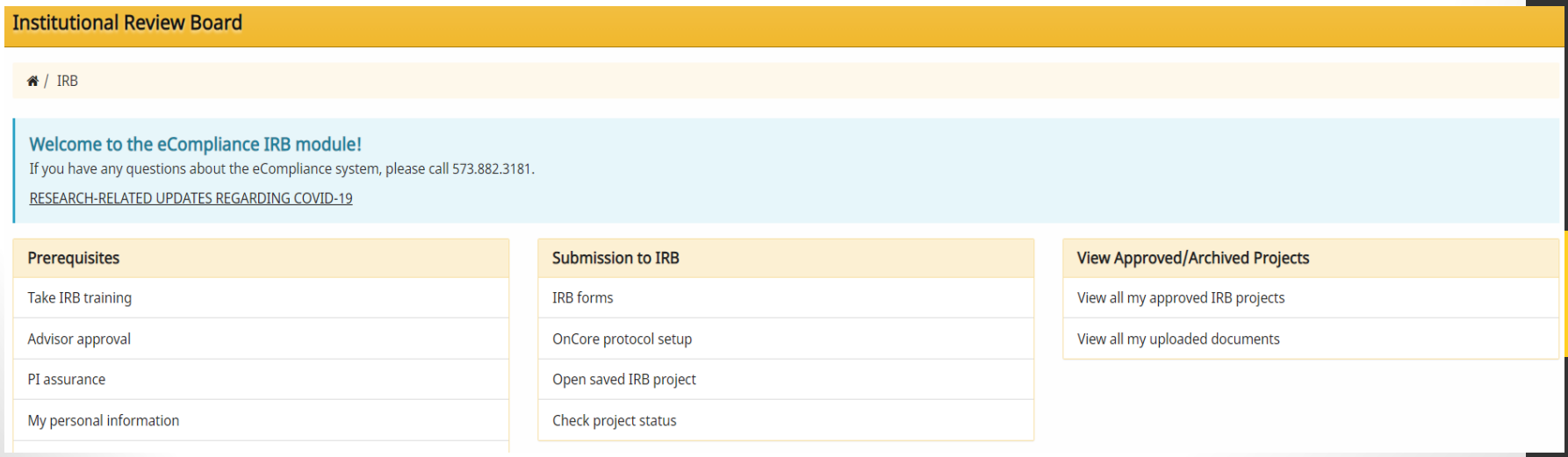
- Under the Office of Research & Economic Development
  - https://research.missouri.edu/
- Full AAHRPP Accreditation
  - https://www.aahrpp.org/
- HRPP Home Page
  - https://research.missouri.edu/hrpp/
- Researcher Resources
  - https://research.missouri.edu/irb/researcher_resources

MU IRB/HRPP

- Protection of human subjects involved in MO S&T research
- Review all human subject research activities conducted by MO S&T faculty, staff, and students to ensure regulatory and ethical compliance.
  - Biomedical
  - Social/Behavioral/Educational
- Includes human subject research:
  - on-site and off-site
  - international
  - collaborations with external universities, organizations, and hospitals
  - funded and unfunded

eCompliance

- Login Site: https://mst.ecompliance.umsystem.edu/login
- Internal Users – Login with MST username and Password
- Institutional Review Board Module:
  - CITI Training (must be completed before IRB submission) – good for 3 years, then refresher course is required
    - Basic Human Subjects Research (Required for all studies)
    - Good Clinical Practices (Required for all clinical trials)
  - Submission of IRB Forms
  - Access to approved studies and studies currently being submitted



Prerequisites

- Principal Investigator on IRB Application
  - PI Assurance
- Advisor – overseeing conduct of the study
  - Advisor Approval - Assurance
- Two-Step Application Submission Process: Assurances (received via email) must be completed before the application will submit

Levels of Review

- Exempt (6 categories)
  - Minimal risk
  - Administrative Review (some limited IRB review by board member)
- Expedited (7 categories)
  - Minimal risk
  - Review by at least one board member
- Full Board
  - Minimal risk or greater than minimal risk
  - Does not fit exempt or expedited categories
  - Review by the convened board

- Minimal Risk: Probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt Examples

- Surveys (identified and de-identified)
- Interviews
- Observational studies
- Secondary data analysis of identifiable data
- Research in the educational setting
- Benign, behavioral interventions
- Children can only be included in limited circumstances, same with prisoners
- https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1104

Expedited Examples

- Blood collection under a certain amount by certain non-invasive methods
- Non-invasive collection of biological specimens – hair clipping, buccal swab, skin swab
- Non-invasive procedures – Ultrasounds, non-radiation emitting devices, physical sensors, minimal exercise
- Surveys, interviews, observations that are deemed not exempt

- https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html

Full Board Examples

- Investigational drugs and/or medical devices
- Alcohol or other substance consumption
- Collection of identifiable data including illegal activities, abuse, or other sensitive information
- Invasive testing/interventions
- Radiation-emitting devices

Turn Around Times for Complete Submissions

- Exempt
  - ~3-5 days
- Expedited
  - ~10-14 days
- Full Board
  - ~30 days
  - Deadline: 25th of the month (presented at the next month's meeting falling on the 2nd Wednesday of the month)

Other Reviews/Determinations:

- Case Reports (Medical record review of 3 or less cases)
- Quality Improvement Activities
- Determining Human Subject Research
- Emergency use of a Test Article
- Humanitarian Use Devices
- Approval of using another IRB – see next slide

Collaborations – Multi-Site Research

- When more than one site is engaged in the research (i.e. institution, hospital, clinic, organization), it must be determined which site will serve as the IRB of Record
- If interested in MU serving as the IRB of Record for S&T and another site(s):
  - Submit the **Initial Request for MU to be the IRB of Record**
  - Required for most federally sponsored studies (Single IRB Process)
  - Documentation may be required by OSPA and sponsor
- If interested in using another IRB (not MU):
  - Submit the **Initial Reliance Request Form**
- MU IRB must be part of this decision (involve us early in the process)
- Instructions: https://research.missouri.edu/irb/reliance_procedures

QI and Non-Human Subject Research Determinations

- Although a study may not fall into “human subject” or “research”, publishers often require a determination from the IRB
- Submission of the Human Subject Research (HSR) Determination form will allow us to review and provide a letter
- If all secondary data/biospecimens/information is de-identified and no re-identification or interaction with subjects will occur = not human subject
  - Other examples of non-HSR included on determination form.
- If purpose of the study is to measure performance or process change; data gathered for admin purposes; individuals could potentially benefit; sample of organization’s population; risks is no greater than daily lives; registry/database for clinical care = Quality Improvement, not Research
- Submission of HSR determination form will let IRB confirm QI

Post-Approval Reporting

- Proposed study changes **(prior to implementing changes)**
- Personnel changes
- Continuing Review – Annual Updates
  - Typically - one-year approvals (do not let study expire)
- Deviations – noncompliance
- Unresolved complaints
- Unanticipated problems
  - Unexpected
  - Related or possibly related to study
  - Places subjects at greater risk of harm than previously recognized
- Study completion

Questions?

https://research.missouri.edu/hrpp/contacts

Laura Ward – S&T IRB contact – 573-882-8957
wardla@missouri.edu

General Contact:
573.882.3181
muresearchirb@missouri.edu