Spartan RAN

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Office of Regulatory Affairs
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Office of Regulatory Affairs

- Human Research Protection Program
- Animal Care Program
- Environmental Health and Safety
- Conflict of Interest
Human Research Protection Program

- Institutional Review Board Office
- Human Research Liaison Office
- Clinical Research Billing Compliance
- Institutional Review Boards
Submit
- Researcher Submits Application

Pre-Review
- IRB staff reviews submission for completeness.

Review
- Exempt: IRB staff, chair, or reviewer
- Expedited: IRB chair or experienced reviewer(s)
- Full Board: Primary IRB reviewers, convened IRB

Q&A
- Questions are provided to researcher(s) to respond and if needed, submit modified documents (e.g. informed consent)
- Process repeats as needed

Decision
- Dependent on review type
  - Exempt: Determined exempt, not exempt
  - Expedited: Approved
  - Full Board: Approved, Denied, Tabled, Conditional Approval
Exempt

- If involvement of human subjects will only be in one or more of the exempt categories, research activities are exempt from the regulations.
- Reviewed and determination made by IRB staff and/or IRB chair.

Expedited

- If research study meets one or more of the expedited categories and is no more than minimal risk, the project can undergo expedited review.
- ** Regulations for the protection of human subjects apply.
- Project does not need to be reviewed and approved by a convened IRB.
- Reviewed and approved by IRB chair or by one or more experienced reviewers designated by the IRB chair.

Full Board

- More than minimal risk or research that does not fit into an expedited category.
- ** Regulations for the protection of human subjects apply.
- Reviewed and approved by convened IRB.
Exempt Life Cycle (Overview)

Initial Review

- Review and determination before human research activities begin

Report changes that may impact exempt status

- When there are proposed modifications that change exempt category or review level or more than minimal risk

Report urgent events

- E.g., unanticipated problems that may involve risks, subject complaints

Retain Records

- At least three years upon completion of human research

Determination Letter Issued
Expedited or Full Board Life Cycle (Overview)

- **Initial Review**: Review and approval before human research activities begin.
- **Revisions**: When there are proposed modifications.
- **Renewal**: Prior to expiration.
- **Report urgent events**: E.g., unanticipated problems that may involve risks, subject complaints.
- **Closure**: When human subject research is complete.
- **Retain Records**: At least three years upon closure with IRB.

Approval Letters Issued
New Investigator Resources

• Contact the IRB early
• Transfer of IRB projects
• Access to HRPP online system
• HRPP training
• HRPP website resources
  • “Getting Started”
  • Informed consent templates
  • Contacts
Research Participant Payments

- Disbursement Vouchers
- Cash Advances (MSU Manual of Business Procedures, Section 61: Cash Advances: Travel and Research Participants)
Questions?

HRPP Office Location
- Olds Hall, 408 West Circle Drive, Room 207, East Lansing, MI 48824
- Monday - Friday, 8:00 A.M. - 5:00 P.M. (office hours)

Phone
- 517-355-2180

Fax
- 517-432-4503

Email
- irb@ora.msu.edu (IRB project specific questions, website or training suggestions, FAQs, presentations)
- irbdocs@ora.msu.edu (IRB application and attachment submissions)
- hrl@ora.msu.edu (email contact for HRL office)
- crbc@ora.msu.edu (email contact for Clinical Research Billing Compliance)

Website
- hrpp.msu.edu