CornellResearch

Sponsored Projects Involving Human Participant Research
Research Administration Support System (RASS)

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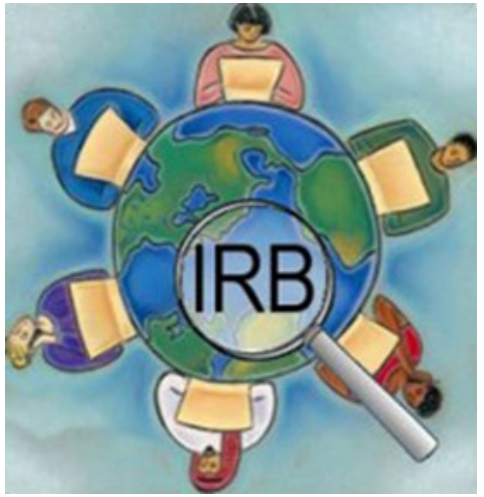
Agenda

- Human participant research & sponsored projects
- RASS-IRB demonstration
- RASS updates

Human Research Protection Program (HRPP)

- Federal Regulations and Cornell University Charge
  - Govern the use of human participants in research and require the establishment of an HRPP and IRB
- IRB: Institutional Review Board for Human Participants
  - Conducts ethical review of research that involves human participants
  - Assesses risk / benefit ratio of research projects
  - Scientists, non-scientists, unaffiliated member(s), experts
- ORIA: Office of Research Integrity and Assurance
  - Subject matter expertise related to compliance
  - Determines which activities constitute human participant research
  - Supports and administers the IRB



What is covered by Cornell's Human Research Protection Program?

Activities or projects that…

- involve human participants

AND

- are defined as research

AND

- Cornell is "engaged"

Common activities that need IRB review/exemption

- Surveys, interviews, focus groups
- Observational research (e.g., shadowing individuals or observing classrooms)
- Collection or secondary use of biological samples
- Secondary analysis of identifiable data
- Testing new devices

Categories of Review

- IRB Review
  - Convened Committee (a.k.a., Full Board)
  - Expedited
    - Minimal risk research (but not eligible for exemption)
    - One IRB member reviewer

- Exemption from IRB Review
  - Specific types of minimal risk human participant research
  - Administrative review required → exemption determination

Externally funded research with human participants

Human participant research must be reviewed and approved by the Cornell IRB (or determined to be exempt) before funding is released and before research begins.

- **Proposal stage**: in the Compliance section of RASS-SR, check the box for human participant research. If able, link to your Cornell IRB protocol.
- **Award stage** (or JIT): must have IRB approval or exemption. Must link to your Cornell IRB protocol within RASS-SR.

Externally funded research, cont.

- Award Stage, Cont.
  - If the project is not yet ready for IRB review, can request a preliminary/program development approval ("prescreening" in RASS-IRB) to satisfy funder requirements. A complete IRB review will still be needed at a future point in time (via an amendment)

Externally funded research, cont.

- Other federal regulatory requirements:
  - Clinical Trial requirements (i.e., additional training, posting on ClinicalTrials.gov)
  - Collaborative studies: multiple IRBs vs. Single IRB (sIRB)
    - For non-exempt research, if another IRB has or will review the project, a reliance agreement is needed, and a Cornell protocol record is still required. *(If Cornell researchers are engaged in non-exempt human participant research, our IRB must review or agree to rely on another IRB.)*

Collaborative/Multi-site research

- Researchers from multiple institutions engaged in the same human participant research project
- NIH, other federal agencies: “Single IRB” (sIRB) requirement for non-exempt studies (one IRB of Record responsible for all sites)
- Multiple factors for determining the sIRB (complexity, procedures, involvement, location, etc.)
- If an sIRB is needed, an Authorization/Reliance Agreement will be needed. This can be requested through RASS-IRB.
- Contact the IRB office early in the process

Introducing RASS-IRB

- RASS-IRB launched February 1, 2022
- Replacing the .doc and .pdf IRB protocol forms and email-based review and approval process with a single online smart form and workflow
- All details and documents in one place, easy access for PIs as well as IRB staff and committee members.
- Connection between IRB protocols and sponsored proposals/awards
- For more details about RASS-IRB launch: https://researchservices.cornell.edu/news/rass-irb-launch-plan

RASS Updates

- Proposal detailed budget
- “Own” feature for task management
- Proposal approver language changes
- Updates to current & pending
- Sponsored project searching improvements

Questions?


Ethics
IRB
Human
Subjects
Monitoring
Compliance
Justice
Beneficence
Respect
Education
Research

HRPP/IRB Resources & Guidance

- Questions?

  Contact the IRB office: irbhp@cornell.edu

  - Myles Gideon, IRB Manager (mbg223, 607-255-6182)
  - Vanessa McCaffery, IRB Administrator
  - Joyel Moeller, IRB Administrator
  - Mara Braddy, IRB Compliance Assistant

- IRB Office Hours: 2nd and 4th Tuesday of each month, 1-4pm
  - Contact irbhp@cornell.edu to schedule a conversation

- IRB Website: https://researchservices.cornell.edu/compliance/human-research
  - IRB Guidance, policy, and resources
  - RASS Guide Site

Thank you

- RASS resources:
  - http://guide.rass.cornell.edu/
    - System logins
    - “How-To” guidance
    - Contact RASS for support: rass@research.cornell.edu
    - Attend office hours
    - Learn about new features: https://guide.rass.cornell.edu/timeline/
    - Share your feedback on RASS