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

Presented by:
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• 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 $\rightarrow$ 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
• Proposal detailed budget
• “Own” feature for task management
• Proposal approver language changes
• Updates to current & pending
• Sponsored project searching improvements
Questions?
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
• RASS resources:
  o [http://guide.rass.cornell.edu/](http://guide.rass.cornell.edu/)
    o System logins
    o “How-To” guidance
    o Contact RASS for support: [rass@research.cornell.edu](mailto:rass@research.cornell.edu)
    o Attend office hours
    o Learn about new features: [https://guide.rass.cornell.edu/timeline/](https://guide.rass.cornell.edu/timeline/)
  o Share your feedback on RASS