


Office of Research Integrity and Assurance

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Institutional Review Board for Human Participants (IRB) Report to Faculty Senate for 2022-2023

1. IRB Membership (as of June 1, 2023)

Voting Members

- Andrew Willford (Chair), Professor, Anthropology
- Rev. Robin Blair (non-affiliated member, non-scientist)
- Kent Bullis, M.D., Cornell Health Services
- Anthony Burrow, Associate Professor of Psychology and Associate Dean for Outreach and Extension (CHE), Director of the Bronfenbrenner Center for Translational Research
- Bobby Edamala, Chief Information Security Officer (non-scientist)
- Gary Evans, Professor, Human Centered Design & Psychology
- Kenneth Hill, M.D., Cornell Health Services
- Wendy Ju, Professor, Cornell Tech
- Saurabh Mehta, Professor, Nutritional Sciences
- Theresa Pendergrast, Lecturer, Global Development (prisoner representative)
- Sarah von Schrader, Director of Research and Program Evaluation, K. Lisa Yang and Hock E. Tan Institute on Employment and Disability, ILR School
- Michael Shapiro, Professor, Communication
- Meryl Bursic, Senior IT Security Engineer (non-scientist alternate)
- Myles Gideon, IRB Manager (non-scientist alternate)
- Vanessa McCaffery, IRB Administrator (non-scientist alternate)
- Joyel Moeller, IRB Administrator (scientist alternate)
- Robert Scott, Executive Director, Cornell Prison Education Program (prisoner representative alternate)

Ex-Officio, Non-Voting Members

- Krystyn Van Vliet, Vice President for Research and Innovation, Institutional Official
- Joshua Turse, Biosafety Officer, Environmental Health & Safety
- Julie Conyer, Associate Biosafety Specialist (Biosafety alternate)

2. IRB Authorization and Charge

Cornell University has a Human Research Protection Program (HRPP) which is guided by ethical principles, and federal, state, and local regulations regarding research involving humans as subjects. These guiding ethical principles have been set forth in the Nuremberg Code of 1947, the Declaration of Helsinki of 1964, and the Ethical Principles and Guidelines for the Protection of Human Subjects of Research of 1979, called the “Belmont Report.” Cornell University applies the principles of the Belmont Report—respect for persons, beneficence, and justice—to protect the rights and welfare of all human research participants involved in any Cornell study, regardless of funding source.

As part of this HRPP, Cornell's [Institutional Review Board for Human Participants](#) (IRB) is responsible for the ethical review of research with human participants and for maintaining compliance with federal regulations, specifically the "[Common Rule](#)". The IRB is an independent standing committee of the University Faculty. The Vice President for Research and Innovation serves as the Institutional Official for the IRB. Regulatory and administrative support for the IRB is provided by the Office of Research Integrity and Assurance (ORIA). As of June 1, 2023, there are five (5) full-time staff dedicated to supporting the IRB and Cornell's broader Human Research Protection Program.

The Cornell IRB Charge can be accessed [here](#).

3. IRB Review Activities

The IRB and administrative staff review and approve the following categories of human participant research, based on the level of anticipated risk to participants:

- a. **Exempt Review** – Certain types of minimal risk research projects are exempt from federal regulations, and do not require IRB committee review. At Cornell, these projects are reviewed and approved by IRB administrative staff. These commonly involve:
 - Observation of public behavior
 - Interactions with minimal risk, such as surveys or interviews
 - Benign behavioral interventions
 - Studies in educational settings using educational practices
 - Certain secondary analyses of data or specimens

- b. **Expedited Review** – Research projects that cannot receive exempt review under the regulations, but pose no greater risk to participants than what they might experience in their everyday lives, can be reviewed and approved by a single member of the IRB. Such expedited review studies commonly involve:
 - Social/behavioral research interviews and surveys that do not qualify for exemption
 - Some minimally invasive biomedical procedures (e.g., most blood draws)
 - Certain uses of identifiable data or specimens

- c. **Full Board (Convened Committee) Review** – Research that poses more than minimal risk to human subjects is reviewed by the convened IRB. Research that is otherwise considered minimal risk under the federal regulations may also be referred to the full board for review if it involves sensitive topics, or a complex research design that would benefit from a review by the breadth of expertise represented by convened committee. For the Ithaca and AgriTech campuses, studies that most commonly require full board review involve:
 - Invasive biomedical procedures
 - Research on sensitive topics
 - Research in which risk is uncertain but perceived to be high
 - Studies that involve populations especially vulnerable to coercion or undue influence, such as imprisoned individuals

- d. **Reliance (Authorization) Agreements** – In cases where human participant research takes place at or involves investigators at multiple institutions, a reliance agreement—sometimes called an authorization agreement—may be used to formalize an arrangement whereby one institution takes responsibility for IRB review of the entire project, serving as the “IRB of Record” or “Single IRB” (sIRB). These agreements are used to avoid redundancy and streamline the initial review and any subsequent renewal or amendment processes. Changes to federal regulations in recent years *require*

such agreements for most federally funded collaborative projects (depending on the exact circumstances of the project).

- e. **Administrative Reviews** – IRB administrative staff can review and approve submissions for activities that do not, for one reason or another, require IRB committee review. Current examples of submissions eligible for administrative review are program development/prescreening approvals (used for sponsored research, when the human subjects research element of an award has not yet been finalized), as well as projects that do not meet the regulatory definition of “human subjects research”.
- f. **Amendments** – An amendment submission is required for all modifications to non-exempt research protocols. The IRB reviews amendments in the context of the entire protocol and must approve amendments before the researchers can implement the requested changes to their study. Certain types of minor amendments can be approved administratively by IRB staff. Changes made to exempt research protocols must also be communicated to ORIA, but they are only reviewed to confirm that the project is still eligible for exemption.
- g. **Continuing Review** - The IRB conducts an annual review of ongoing research protocols that are deemed to pose more than minimal risk to participants (i.e., those requiring full board review), or those which require a continuing review by a funder or collaborating institution. This continuing review is conducted to ensure that the protection of human participants is consistent throughout the execution of the research project and that the protocol is revised, as appropriate, to include new knowledge generated since the last review.
- h. **Active Projects Registered with the IRB:**

Classification	Active Protocols 5/31/22	Active Protocols 5/31/23
Exempt from IRB review	2,163	2,534
Expedited Review	687	758
Full Board Review	30	29
Reliance Agreements	135	145
Prescreening/Program Development Reviews	36	35
Total active projects	3,051	3,501

4. IRB Applications Reviewed

Between June 1, 2022 and May 31, 2023, the IRB held 11 duly convened meetings to review research protocols. A total of 1238 applications were approved by the IRB (via expedited or full board review), determined to be exempt, or completed an administrative review during that time. These projects are reflected below:

Classification	New	Continuing Reviews	Amendments	Total
Exempt	556	N/A	247	803
Expedited	88	3*	213	304
Full Board	3	19	26	48
Other**	72	N/A	11	83
Total	719	22	497	1,238

*Most Expedited protocols do not require annual continuing review, per the Revised Common Rule.

**The “Other” category includes administrative and other reviews, primarily Reliance Agreements and Prescreening reviews.

5. IRB Initiatives (2022-2023)

- a. **Refining the new IRB Protocol Management System, RASS-IRB:** We launched our new system, an IRB module of RASS (Research Administration Support System), in February 2022, and continued to invite feedback and refine the system in the year that followed. The ORIA IRB staff also coordinated with staff from Research Administration Information Services (RAIS), our system vendor (Novelution), and ORIA Conflict of Interest (COI) staff to ensure that the new RASS-COI module that launched in late 2022 was well-integrated into the IRB protocol review workflow and vice versa. IRB staff will continue to work with RAIS and Novelution on improving the system to meet our users’ needs.
- b. **Change to Training Requirements:** In spring 2022, the IRB voted to extend its existing human subjects research ethics training requirement to apply to study personnel involved in protocols deemed Exempt under the Common Rule (45 CFR 46 Subpart A). Exempt research activities, though minimal risk, still meet the regulatory definition of human subjects research, and Cornell is still responsible for ensuring all its investigators are knowledgeable about and compliant with ethical principles, federal regulations, and state and local laws pertaining to human subjects research. After IRB staff consulted with the training working group of the Research Security & Compliance Committee, worked with Novelution on training reminders and documentation in RASS-IRB, and communicated with the impacted researchers, this training requirement was implemented on October 1, 2022. All study personnel named on an IRB protocol—regardless of review level—are now required to complete the 8-module online CITI Program training once every five years.
- c. **COVID-19 Pandemic Response:** Throughout FY23, the IRB committee and staff continued to respond to the shifts in the University's pandemic response that impacted human participant research conducted on campus, ensuring that Cornell IRB guidance and researcher-facing resources accurately reflected those shifting public health requirements on campus. IRB members and staff also continued to provide support to researchers, facility directors (e.g., from the Human Metabolic Research Unit and Cornell MRI Facility), and college administrators as they refined protocols and procedures to be safe, reasonable, and compliant with university guidelines.
- d. **Collaborative Projects**
 - o **Payments to Research Participants:** IRB staff participated in a working group on developing new policy on payments to human participants in research, which was finalized in February 2023 as a new chapter of the University Buying Manual. The document has helped give much needed clarity to researchers and business center staff on how to document and request reimbursement for compensation/incentives given to research participants in a

way that complies with university and IRS requirements while also respecting participants' privacy and confidentiality.

- **Research Using Student Records:** IRB staff continued to build a close, collaborative relationship with the Office of the University Registrar (OUR), regularly meeting with OUR leadership colleagues to design research-related guidance on FERPA (Family Educational Rights and Privacy Act) and discuss individual cases that impact both OUR and IRB. This past year we co-authored text for new "FERPA FAQs", developed common scenarios where FERPA and IRB compliance overlap, and began drafting a new FERPA-and-Human-Participant-Research decision tree.
- **Academic Integration Initiative:** Cornell's Ithaca-based IRB staff leadership continue to collaborate with their counterparts from Weill Cornell Medicine to help bridge the physical gap between the campuses and to better facilitate collaborative research. IRB staff from both offices have continued regular email correspondence about specific collaborative research projects, and started meeting more regularly via Zoom about process improvement and new areas for collaboration and streamlining.

e. New or Improved Tools and Guidance:

- **Microsoft Bookings:** The IRB team began using Bookings to allow students, staff, and faculty the ability to quickly and easily schedule half-hour consultations with individual IRB and RASS staff to discuss various questions about IRB protocols and processes.
- **RASS Guide Site:** IRB and RASS staff continued to add new how-to documentation to the RASS Guide website, which serves as a resource to help researchers and IRB members use the RASS-IRB system: <https://guide.rass.cornell.edu/>
- **IRB Website:** The IRB team has continued to update the human participant research portions of the [Research Services website](#), revising and adding resources as needed, and providing updated information about COVID-19 restrictions, system changes, and more.

f. Classes and Workshops: IRB staff regularly present to classes and workshops for undergraduate and graduate students, new researchers, and research staff. On occasion, the IRB Chairperson will also co-present. Groups visited in the past year (via Zoom or in person) include:

- ANTHR 6440: Proposal Development Seminar (graduate students)
- CRP 7201: Ph.D. Research Design Seminar, City and Regional Planning (graduate students)
- GDEV 6790: MPS Seminar in Global Development (graduate students)
- GOV 6109: Field Methods, Government Department (graduate students)
- NS 3980: Research in Human Nutrition and Health, Division of Nutritional Sciences (undergraduate students)
- NS 6350: Introduction to Community Nutrition Research for Dietetic Interns, Division of Nutritional Sciences (dietetic interns)
- NS 7040: Grant Writing, Division of Nutritional Sciences (graduate students)
- OSP Roundtable: Where IRB and OSP Meet: Funded Human Participant Research and NFAs (research administrative staff, faculty)
- Research Administration Certification Program, Office of Sponsored Programs and Division of Financial Affairs (research administrative staff)
- SOC 6080: Proseminar in Sociology, CAS (graduate students)

6. Challenges Faced by the Committee

- a. **Acceptance of the New IRB Application Management System:** While the new RASS-IRB protocol management system, implemented in February 2022, has dramatically improved the process of submitting, reviewing, and corresponding about IRB protocol submissions, the transition had a few bumps. While the IRB has primarily received positive feedback, some researchers have found the system confusing or cumbersome to use (primarily those who were used to our old paper-based system). IRB committee members and staff also continue to identify areas for enhancement. Thankfully, the system is very adaptable, and our Product Manager and the vendor are easy to work with, so we expect to continue improving RASS-IRB to meet our various our users' needs.

7. Initiatives and Changes in the Coming Year (and Beyond)

- a. **Single IRB Capacity and Resource Development:** With the aid of a protocol management system that can better support multi-site collaborations and reliance agreement documentation, as well as the addition of new IRB staff hired in 2022, the Cornell IRB is now better able to provide more robust single IRB services. Planned next steps include joining the SMART IRB consortium to enable expeditious development and signing of reliance agreements between IRBs (as well as gain access to myriad sIRB-related resources); developing more resources to support researchers pursuing collaborative human participant research projects; and working with WCM colleagues to synchronize sIRB approaches and continue to streamline the process of Cornell faculty collaborations across campuses.
- b. **New and Revised Guidance, SOPs, and templates:** Due to emerging areas of interest for human participant research, as well as changes in regulations and best practices in this field, the IRB committee and staff aim to regularly review standing policy and guidance materials, SOPs, and templates to identify documents in need of revision, as well as develop new documents as needed. A regular process for reviewing and updating existing documents has not always been feasible due to staffing levels, but with a new FTE added in the past year, and all staff fully trained, this will be a focus of FY24. Some key new and revised guidance/SOPs/templates will include:
 - Implementation of the new NIH policy on data management and sharing as it relates to human participant research
 - International data privacy law and human participant research (revising GDPR guidance, expanding to include UK GDPR, PIPL, PIPA, and more), in collaboration with the Offices of General Counsel and University Compliance
 - Informed consent form templates
 - Implementation of internal worksheets and checklists for IRB staff and members to better document compliance with relevant regulations
 - Adverse event and non-compliance reporting and management
- c. **Post-Approval Monitoring and Quality Assurance for IRB Protocols:** With major IRB staffing changes in late 2019/early 2020 and the disruption of in-person research by the COVID-19 pandemic, our HRPP PAM/QA program was put on hiatus. In FY24, the IRB staff will work with IACUC administrator colleagues to reestablish and refine our program to better ensure compliance with federal regulations, and university and IRB policy.