



Office of Research Integrity and Assurance
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Institutional Review Board for Human Participants (IRB) Report to Faculty Senate for 2021-2022

1. IRB Membership (as of June 1, 2022)

Voting Members

- Andrew Willford (Chair), Professor, Anthropology
- Rev. Robin Blair (non-affiliated member, non-scientist)
- Anthony Burrow, Associate Professor of Psychology and Associate Dean for Outreach and Extension (CHE), Director of the Bronfenbrenner Center for Translational Research
- John Clarke, M.D., Director of Occupational Medicine, Cornell Health Services
- Bobby Edamala, Chief Information Security Officer (non-scientist)
- Kenneth Hill, M.D., Cornell Health Services
- Jura Liaukonyte, Professor, Applied Economics & Management
- 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
- Martin Wells, Professor, ILR Statistics and Data Science and Computational Biology
- Nancy Wells, Professor of Human Centered Design, Senior Associate Dean for Research & Graduate Education (CHE)
- Kent Bullis, M.D., Cornell Health Services (physician 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

- Emmanuel Giannelis, Vice President for Research and Innovation, Institutional Official
- Joshua Turse, Biosafety Officer, Environmental Health & Safety
- Stephanie Mattoon, 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).

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 Review](#) – Research that poses more than minimal risk to human subjects is reviewed by the convened committee. 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 campus, 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. [Authorization/Reliance Agreements](#) – In cases where research takes place at or involves investigators at multiple institutions, an authorization agreement—sometimes called a reliance 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 in order 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 many 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 to meet the regulatory definition of “human subjects research”.
- f. **Amendments** - An amendment is necessary 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, and certain changes to expedited protocols can be approved by senior 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 in order 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 5/31/21	Active Protocols 5/31/22
Exempt from IRB review	3100	2163
Expedited Review	719	687
Full Board Review	23	30
Reliance Agreements	124	135
Administrative Reviews	498	484
Total active projects	4,464	3,572

Note: The drastic decrease in total numbers of active IRB protocols is due to the tremendous effort IRB staff put into contacting PIs and closing inactive Exempt and Expedited protocols prior to migrating protocol data to the new RASS-IRB system.

4. IRB Applications Reviewed

Past Year Reviews: Between June 1, 2021 and May 31, 2022, the IRB held 11 duly convened meetings to review research protocols. A total of 1,166 applications were approved by the IRB, determined to be exempt, or completed an administrative review during that time. These projects are reflected below:

Classification	New	Continuing Reviews	Amendments	Total
Exempt	541	N/A	84*	625
Expedited	127	21**	219	367
Full Board	4	18	44	66
Other***	102	0	6	108
Total	774	39	353	1,166

*The IRB office reviews amendments to exempt protocols, but prior to February 1, 2022, did not track them in the IRB system of record. Amendments to new exempt protocols are now being documented in RASS-IRB, and that number is reflected here.

**Most Expedited protocols no longer require continuing review (“renewal”) under the 2018 revised HHS regulations, but IRB staff processed the last of the necessary renewals administratively over the past year, in order to ensure all PIs had accurate protocol documentation.

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

5. IRB Initiatives (2021-2022)

- a. **IRB Protocol Management System, RASS-IRB:** After years of using outdated paper- and email-based systems for protocol documentation and workflow management, the Cornell IRB and Human Research Protection Program dedicated over a year of intensive work with Research Administration Information Services (RAIS) and vendor Novelution to identify system specifications, develop data migration plans, clean up existing data, conduct internal and user testing, and create training and “how-to” documentation on the new system for researchers, staff, and IRB members. RASS-IRB was slated to go live by the end of Q1 2022, and was able to launch early, on February 1, 2022. IRB and RAIS project staff provided trainings over Zoom and one-on-one help sessions, and continue to work with Novelution to identify and implement changes needed to improve the system.
- b. **COVID-19 Pandemic Response:** Throughout FY22, the IRB committee and staff continued to respond quickly to 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 guidance on in-person, on-campus human participant research and its appendices (sample COVID-19 information sheet for study participants, self-screening attestation, and contact tracing form) were revised six times during FY22. 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 in developing protocols and procedures that would be both safe (from a public health perspective) and compliant.
- c. **Collaborative Projects**
 - o **Research Use of COVID-19 Surveillance Samples and Data:** IRB staff and committee member leadership continued to work with other members of the university community to think through how to appropriately allow use of COVID-19 surveillance samples and data for research purposes by Cornell investigators, while still protecting the privacy and rights of the Cornell community members from whom the samples were obtained. This work happened via ad-hoc conversations and through involvement in a committee co-chaired by the Associate Vice Provosts for Social and Life Sciences.

- **Research Using Student Records:** IRB staff have developed a close, collaborative relationship with the Office of the University Registrar (OUR), regularly meeting with OUR leadership to design FERPA-related research guidance as well as discuss one-off cases that impact both OUR and IRB.
 - **Payments to Research Participants:** IRB staff participated in a working group on developing a new policy on payments to human participants in research. Once finalized, this document will help 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.
 - **Academic Integration Initiative:** Cornell's Ithaca-based IRB staff continue to collaborate with their counterparts from Weill Cornell Medicine in order to help bridge the physical gap between the campuses and to better facilitate collaborative research. IRB staff leaders from both offices have participated in periodic phone and Zoom calls, and regular email correspondence, both about specific collaborative research projects and about process improvement.
- d. Management of Multi-site, Collaborative Research Projects (sIRB):** In recent years, two new federal policies have mandated single IRB ("sIRB") review of collaborative, multi-institution human participant research projects. This means that one IRB (the sIRB) must be the IRB of Record, providing the ethical review for all sites participating in a multi-site and/or collaborative human participant study involving researchers from multiple institutions. Serving as the sIRB can require a great deal of time and resources on the part of the IRB and administrative staff, so the Cornell IRB had been reticent to agree to serving in this capacity for complex projects involving more than one or two other sites. In order to determine the actual need for Cornell's IRB to increase its capacity to serve as an sIRB, in 2021 ORIA surveyed federally funded Cornell faculty members about their collaborative human participant research projects. The results of that survey were analyzed, and IRB staff developed a set of recommendations for how Cornell's sIRB infrastructure can be strengthened given current resources. See *Initiatives and Changes in the Coming Year* later in this document for more information about planned next steps.
- e. New or Improved Tools and Guidance:**
- **RASS Guide Site:** New resources to help researchers and IRB members use the new RASS-IRB system were created and posted to the RASS Guide Site: <https://guide.rass.cornell.edu/>.
 - **IRB Website:** The IRB team has continued to streamline and update the human participant research portions of the [Research Services website](#), revising guidance and resources as needed, and providing updated information about COVID-19 restrictions, system changes, and more.
 - **IRB Member Continuing Education:** The IRB implemented a new program in FY21 of continuing education for committee members to keep them up to date on relevant policies and regulations, emerging areas of interest, and shifts in ethical thinking within the landscape of human participant research. At most IRB committee meetings, a continuing education session was presented by a member of the IRB, IRB staff, or another member of the Cornell community with expertise in a given area (e.g., the University Registrar spoke on FERPA considerations for research, and the Director of the Cornell MRI Facility shared an update on the work taking place at that facility).

f. Classes and Workshops: IRB staff and committee members regularly present to classes and workshops for undergraduate and graduate students, new researchers, and research staff. Groups visited in the past year (via Zoom or in person) include:

- AAP Faculty Presentation
- AEM 4415 & 5415: Pre-Engagement with Social Enterprises in Emerging Markets (undergraduate students)
- ANTHR 7930: Independent Study (graduate students)
- Faculty Senate: Overview of new RASS-IRB System
- New York Sea Grant Employee presentation: IRB Overview
- NS 3980: Research in Human Nutrition and Health, Division of Nutritional Sciences (undergraduate students)
- NS 7040: Grant Writing, Division of Nutritional Sciences (graduate students)
- OSP Roundtable: Sponsored Projects Involving Human Participant Research & RASS (research administrative staff, faculty)
- PAM 3120: Research Design, Practice, and Policy (undergraduate students)
- 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. Implementation of a New IRB Application Management System:** While the new RASS-IRB protocol management system has dramatically improved the process of receiving, reviewing, and responding to IRB protocol submissions, the transition has not been without its bumps. While the IRB has primarily received positive feedback, some researchers have found the system confusing or cumbersome to use. Committee members and staff continue to get to know the nuances of the new system, as well, after spending years using systems and processes that were far less sophisticated and less efficient, but nonetheless familiar. IRB staff will continue to work with RAIS to improve RASS-IRB and develop more useful “how-to” documentation for researchers and other system users.
- b. IRB Membership:** Although regulatory changes and internal processes shifting work from voting IRB members to IRB administrators have lessened the time and effort required by the committee in recent years, it nevertheless remains a challenge to recruit active faculty researchers to serve. The COVID-19 pandemic seemed to increase this challenge, in fact, as it was even more difficult than usual to recruit a replacement for a psychologist member of the committee in spring/summer 2021 (though we ultimately succeeded). The IRB’s ability to continue to serve as an effective and balanced committee is inextricably linked to its ability to recruit faculty who have the expertise in the relevant subject matter areas and are willing to volunteer their time to conduct the reviews and participate in policy and guidance development.

7. Initiatives and Changes in the Coming Year

- a. Single IRB Capacity:** With the aid of a new protocol management system that can better support multi-site collaborations and reliance agreement documentation, as well as additional IRB staff hired in recent months, the Cornell IRB anticipates being able to provide more robust sIRB services in FY23. Next steps will 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 resources (e.g., trainings, templates, guidance documents) to better support researchers pursuing collaborative human participant research project; and work with WCM research compliance colleagues to synchronize sIRB approaches and continue to streamline

the process of Cornell faculty collaborations across campuses.

- b. Expanded Training Requirements:** The Cornell IRB and ORIA have decided to extend the human subjects research ethics training requirement (met by an online CITI Program course) to Cornell researchers conducting studies determined to be exempt from IRB review and approval. The training requirement already applies to all investigators conducting research receiving Expedited or Full Board IRB review. There were a number of reasons for this decision, not least of which that this type of differentiation between human subjects research review levels for training requirements is not common in our peer institutions, nor does NIH differentiate for its funded projects. The training requirement for exempt research will be officially announced shortly, and implemented for the Fall 2022 Semester.
- c. University Policy on Human Participant Research:** There are over 40 ORIA policy and guidance documents related to IRB procedures and human participant research at Cornell, but no university-level policy. ORIA created an impact statement for such a policy in FY22, and intends to move forward with policy development in the coming year.
- d. New and Revised Guidance:** Due to emerging areas of interest for human participant research, as well as changes in regulation and community best practices, the IRB committee and staff intend to regularly review standing policy and guidance materials in order to identify documents in need of revision, as well as new guidance needed. Given the level of staffing in recent years, along with the added challenges of the COVID-19 pandemic, not much movement has been possible in this area (besides guidance specifically related to COVID); however, the IRB staff has added a new FTE for FY23, and we intend to reprioritize creating new and enhancing existing IRB policy and guidance in the coming year.