



Cornell University
Office of
Research Integrity and Assurance

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Institutional Review Board for Human Participants (IRB) Report to Faculty Senate for 2018-2019

1. IRB Membership (as of June 1, 2019)

Voting Members

- Andrew Willford (Chair), Professor, Anthropology
- Kathleen Bergin, J.D., non-scientist
- Rev. Robin Blair, non-affiliated member and non-scientist
- Kent Bullis, M.D., Executive Director, Cornell Health
- Anthony Burrow, Associate Professor, Human Development
- Gary Evans, Professor, Design and Environmental Analysis/Human Development
- Kenneth Hill, M.D., Cornell Health Services
- Katherine Kinzler, Associate Professor, Psychology/Human Development
- Saurabh Mehta, Associate Professor, Nutritional Sciences
- Todd Schmit, Associate Professor, Applied Economics & Management
- Sarah von Schrader, Assistant Director of Research, K. Lisa Yang and Hock E. Tan Institute on Employment and Disability, ILR School
- Robert Scott, Executive Director, Cornell Prison Education Program, Prisoner representative
- Michael Shapiro, Professor, Communication

Ex-Officio, Non-Voting Members

- Alexis Brubaker, Biosafety Officer, Environmental Health & Safety
- Emmanuel Giannelis, Vice Provost for Research, Institutional Official
- Janet Jayne, IRB Administrator
- Vanessa McCaffery, Compliance Administrator
- Guilaine Senecal, Assistant Director, ORIA
- Josh Turse, Senior Biosafety Specialist (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 Nuremburg 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 Provost for Research 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, following consultation with the researchers. Under the federal regulations and Cornell policy, the type of review is based on the level of anticipated risk to participants, as described below:

- a. **Exempt Review** – Certain types of research projects that pose no or minimal risk are reviewed and approved only by the IRB administrative staff. Exempt projects 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 uses of previously-collected data or specimens
- b. **Expedited Review** – Research projects that cannot receive exempt review under the regulations, but nevertheless 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 especially vulnerable populations, such as prisoners
- d. **Authorization Agreements** – In cases where research takes place at or involves investigators at multiple institutions, an authorization agreement may be used to formalize an agreement whereby one institution takes responsibility for IRB review of the entire project, in order to avoid redundancy and streamline the initial review, and any subsequent renewal or amendment processes.
- e. **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.
- f. **Continuing Review** - The IRB reviews all ongoing research protocols that are deemed to pose more than minimal risk to participants (those receiving full board review) 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.

g. Active Projects registered with the IRB:

Classification	Active Protocols 4/30/18	Active Protocols 5/31/19
Exempt from IRB review	1956	2142
Expedited Review	490	528
Full Board Review	40	34
Authorization Agreements	19	67
Administrative Reviews	25	477
Total active projects	2,530	3,248

4. IRB Applications Reviewed

Between May 1, 2018 and May 31, 2019, the IRB held 11 duly convened meetings to review research protocols. A total of 1,608 applications were reviewed during that time.

Classification	New	Renewals	Amendments	Total
Exempt	606	NA	NA**	606
Expedited	151	279	383	813
Full Board	9	31	62	102
Other*	86	0	1	87
Total	852	310	446	1,608

*This category includes Authorization Agreements and other administrative reviews.

**The IRB office continues to review and approve amendments to exempt protocols, but simplified the process for PIs to request such amendments, and stopped tracking these approvals in metrics reports in late 2015.

5. IRB Initiatives (2018-2019)

- a. **Implementing Major Revisions to the Common Rule:** The “Common Rule” is the primary federal regulation that governs the conduct of research involving human subjects. Following a previous delay announced in January 2018, a significantly revised version of the Federal Policy for the Protection of Human Subjects (the “New Common Rule”) became effective on January 21, 2019. Taking advantage of [flexibility that HHS has granted](#), which allowed institutions to implement three burden-reducing provisions of the New Common Rule early, the Cornell IRB implemented some aspects of the New Common Rule beginning on July 19, 2018. For over a year leading up to these changes, the IRB devoted considerable resources to analyzing the complicated new regulations, revising policies and procedures, drafting guidance, redesigning forms, templates, tools and checklists, issuing announcements and holding information sessions to prepare the Cornell research community, and working with staff and consultants to make necessary changes to the technical infrastructure.

- b. Academic Integration Initiative:** As part of an initiative by the Vice Provost for Research, in the summer of 2018, Cornell's Ithaca-based IRB staff hosted their counterparts from the Weill Cornell Medicine campuses for a day-long retreat intended to streamline cross-campus collaborations involving human participant research. These efforts are aimed at bridging the physical gap between the campuses, in the hopes of facilitating collaborative research. Building on those preliminary discussions, leadership from both IRBs now hold monthly phone meetings to discuss issues of mutual concern and interest, and hold in-person working sessions at least annually (this year in NYC on July 26). These efforts have culminated in the development of a new process and guidance document, to be formally issued to both campuses in early July, detailing how researchers can quickly and easily obtain IRB review for collaborative projects involving researchers from both Weill and Ithaca.
- c. Improved Tools for Researchers:**
- New application form: To correct for technical issues with the previous tool and take fuller advantage of flexibility offered by the New Common Rule, in the spring of 2019 the IRB released a new, [streamlined protocol application form](#). Among other improvements, this form eliminates the need for PIs to make the confusing initial determination of whether their project qualifies for exemption from full IRB review.
 - Redesigned website: In June 2019, the Research Division released a professionally [redesigned website](#) with a unified look and feel across all of the research service and compliance offices. As part of this effort, the IRB streamlined, updated and added new, subject-matter specific content to better serve our faculty researchers.
- d. Classes and workshops:** IRB staff and committee members regularly participate in classes and workshops for undergraduate and graduate students, at the invitation of faculty and staff. Groups visited in the past year include:
- Undergraduate Honors Research course, Division of Nutritional Sciences (undergraduate students)
 - Field Methods, Government (graduate students)
 - International Agriculture and Rural Development seminar, International Programs, CALS (MPS students)
 - Teaching as Research in Higher Education course, Center for Teaching Excellence (graduate students)
 - Global Service Learning, ILR (students)
 - Anthropology Proposal Development course, CAS (PhD students)
 - Fiber Science and Apparel Design graduate seminar, HD, CHE (faculty and graduate students)
 - Consumer Behavior course, Applied Economics and Management, CALS (undergraduate and graduate students)
 - Research Methods in Psychology course, CAS (undergraduate and graduate students)
 - PhD Research Design, City and Regional Planning (graduate students)
 - Office of Academic Diversity Initiatives, McNair Scholars Program, (undergraduate students)
 - Qualitative Methods, Developmental Sociology Department, (MPS or Masters/PhD programs)
 - Research Administration Certification Program, Office of Sponsored Programs and Division of Financial Affairs (staff)

6. Challenges faced by the committee

- a. **Lack of an IRB Application Management System:** IRB application submission, review and approval is currently a paper-based process. Lack of an online system to support these crucial processes leads to inefficiencies for researchers, faculty committee members and the IRB staff. The IRB process would benefit greatly from having an integrated protocol management system. Such a system is now planned and a vendor has been selected, with work on the IRB module set to begin in early 2020.
- b. **IRB membership:** Although recent regulatory changes and internal processes shifting work from voting IRB members to IRB administrators have lessened the time and effort required by the committee, it nevertheless remains a challenge to recruit active faculty researchers to serve. 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. Major Initiatives in the coming year

- a. **Preparation for and implementation of the Research Administration Support System (RASS):** We look forward to the implementation of a comprehensive Research Administration Support System that will bring together the sponsored programs, conflict of interest and IRB systems so that relevant information can be made available to researchers, staff and reviewers easily and in a timely manner. Work on the IRB module of the system is scheduled to begin in early 2020, and will require significant IRB staff time during the year or more it will take to design and implement the system.
- b. **New guidance:** As the IRB and staff become aware of emerging areas of interest for human participant research, including new regulations, techniques and methodologies that pose new concerns about or different perspective on ethics pertaining to research with human participants, the committee members and staff collaborate to revamp standing policies and guidance materials, as well as develop new ones. In summer 2019 the IRB will issue, in partnership with Cornell's Privacy Officer, a new guidance document on the impact of the [European Union General Data Protection Regulation \(GDPR\)](#) on research data collected from human participants.