



Cornell University
Office of
Research Integrity and Assurance

395 Pine Tree Road Suite
 320
 Ithaca, NY 14850
 Phone: 607-255-6182
 Fax: 607-255-0758
www.oria.cornell.edu

Institutional Review Board for Human Participants (IRB) **Report to Faculty Senate for 2016-2017**

1. IRB Membership (as of May 31, 2017)

Voting Members

- Carol M. Devine (Chair), Professor, Division of Nutritional Sciences
- Kathleen Bergin, J.D., Non-affiliated member and non-scientist
- Gary Evans, Professor, Design and Environmental Analysis/Human Development
- Kathleen Friedrich, Prisoner representative, non-scientist
- Kenneth Hill, M.D., Cornell Health Services
- Katherine Kinzler, Associate Professor, Psychology and Human Development
- Poppy McLeod, Professor, Communication
- Todd Schmit, Associate Professor, Applied Economics & Management
- Sarah von Schrader, Assistant Director of Research, Yang-Tan Institute on Employment and Disability, ILR School
- Qi Wang, Professor, Human Development
- Elaine Wethington, Professor, Human Development
- Andrew Willford, Professor, Anthropology

Ex-Officio, Non-Voting Members

- Alexis Brubaker, Biological Safety Officer
- Robert A. Buhrman, Senior Vice Provost for Research, Institutional Official
- Myles Gideon, Senior IRB Administrator
- Janet Jayne, IRB Administrator
- Vanessa McCaffery, Compliance Administrator
- Wyman Miles, Director, CIT Security
- Guilaine Senecal, Assistant Director, ORIA
- Joshua Turse, Senior Biosafety Specialist (Alternate)
- Amita Verma, Director, ORIA

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 the federal regulations, specifically the "[Common Rule](#)". The IRB is an independent standing committee of the University Faculty. The Senior 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 at:

http://theuniversityfaculty.cornell.edu/governance/committees/institutional_review_board/IRBCharge.pdf

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 research projects are reviewed and approved only by the IRB administrative staff and commonly involve:
 - Observation of public behavior
 - Interactions with minimal risk
 - Studies in educational settings using educational practices
 - Certain uses of existing, “on the shelf” data
 - Food taste tests

- b. **[Expedited Review](#)** – Research projects that are not exemptible but pose no greater than minimal risk to participants compared to what they might experience in common, everyday lives can be reviewed and approved by a single member or a small sub-committee of the IRB. These studies commonly involve:
 - Social/behavioral research interviews and surveys, experiments that do not qualify for exemption
 - Some minimally-invasive biomedical procedures (e.g., most blood draws)
 - Certain types of uses of existing, identifiable data

- c. **[Full Board Review](#)** – Research involving more than minimal risk to human subjects is reviewed by the Full Board. 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 at the Full Board, or if the study is referred to the Full Board by an expediting reviewer, particularly when the reviewing member is unable to assess the risk of the proposed procedures. At the Cornell Ithaca campus, studies that most commonly require Full Board review include:
 - Most biomedical procedures
 - Research on sensitive topics
 - Where risk is uncertain but perceived to be high
 - Studies that involve certain vulnerable populations, such as prisoners

- d. **Authorization Agreements** – In cases where research takes place at or involves investigators at multiple institutions, an authorization agreement is sometimes used to formalize an agreement whereby one institution takes responsibility for IRB review of the project, and is designated as the IRB of Record, reducing redundancy and streamlining 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 some additional changes to lower risk expedited protocols can be approved by senior staff, as well.

- f. **Continuing Review** - The IRB reviews all ongoing non-exempt research protocols 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. Continuing Review for federally-funded research occurs at least annually. Triennial (three-year) IRB approval is available for studies that pose no more than minimal risk or harms to human participants, are not federal-funded, and meet certain other criteria. Continuation requests for certain types of lower risk expedited protocols can be approved by senior IRB staff.

- g. **Active Projects registered with the IRB:**

Classification	Active Protocols 5/31/16	Active Protocols 5/31/17
Exempt from IRB review	2,396	2,912
Expedited Review	552	534
Full Board Review	31	39
Authorization Agreements	12	20
Administrative Reviews	23	30
Total active projects as of May 31, 2017	3,014	3,535

4. IRB Applications reviewed

During the reporting year June 1, 2016 – May 31, 2017, the IRB held 10 duly convened meetings to review research protocols. A total of 1,381 applications were approved during that time. Projects submitted for review and either approved or determined to be exempt are reflected below:

Classification	New	Renewals	Amendments	Total
Exempt	528	N/A	N/A**	528
Expedited	151	168	337	656
Full Board	11	33	55	99
Other*	97	1	0	98
Total	787	202	392	1381

*This category includes Authorization Agreements and other administrative reviews.

**The IRB office continues to review and approve amendments to exempt protocols, but discontinued tracking such amendments in late 2015.

5. IRB Initiatives (2016-2017)

- a. **New Live Chat Feature:** To increase visibility and improve outreach, a live online chat feature has been added to the existing routes by which researchers can seek help from staff. While the feature has only been in use for a few months, it has been popular, especially with student researchers and others seeking to request help quickly, and without needing to pick up a phone or meet in person.

- b. **Classes and workshops:** IRB staff and committee members regularly participate in classes and workshops for undergraduate and graduate students. Groups that were visited in the past year include:
- Dietetic Interns, Mock IRB session, Division of Nutritional Sciences (interns)
 - Undergraduate Honors Research course, Division of Nutritional Sciences (undergraduate students)
 - Grant Writing Course for Nutrition Graduate Students, Mock IRB session, Division of Nutritional Sciences (graduate students)
 - Research Administration Certification Program, Office of Sponsored Programs and Division of Financial Affairs (staff)
 - International Agriculture and Rural Development seminar, International Programs, CALS (MPS students)
 - Teaching as Research in Higher Education course, Center for Teaching Excellence (graduate 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)
 - Food and Brand Lab, Applied Economics and Management, CALS (graduate students)
 - Research Methods in Psychology course, CAS (undergraduate and graduate students)
- c. **Continued and expanded senior staff approval process for routine amendments and renewals of expedited protocols:** Starting in December of 2015, the IRB piloted new procedures designed to provide an easier, quicker review process for eligible studies by allowing senior members of the IRB office staff (as opposed to committee members) to review and approve amendment and continuation requests for certain lower risk expedited protocols. Over the past year, 15% of expedited amendments were approved via the senior staff process (with the average review time cut by over two-thirds), and 70% of expedited continuation requests (with the average review time cut by nearly half). The IRB reexamined this program in May 2017, and voted to continue its use and expand the parameters under which applications are eligible for this review process.
- d. **New and revised templates for human participant research materials**
- **Data Sharing Language:** In response to an increasing number of requests from sponsors and journals for investigators to share individual-level, de-identified data with colleagues and the public, at large, the Cornell IRB developed template language in the fall of 2016 for inclusion in consent forms, in order to address this topic and ensure research participants understand what will be done with their data.
 - **Biomedical Resource Repository:** In early 2016, the IRB office began work on an initiative to develop accessible, standardized guidance and templates that researchers can use to develop their protocols for research involving biomedical procedures. We are developing these materials in consultation with representatives of Cornell Health, the Human Metabolic Research Unit, the Cornell MRI Facility, and other labs, as well as faculty who use biomedical procedures. Over the past year, we have developed—and the IRB has reviewed and approved—guidance documents, template SOPs, and template consent forms for venipuncture, capillary blood draws, and functional MRI (fMRI). These documents—which streamline and simplify the protocol development and submission process for researchers conducting these common biomedical procedures, and the review process for the IRB—are available on the IRB website:

<https://www.irb.cornell.edu/biomedicalresources/index.htm>. This initiative will continue over the coming year for the remaining common biomedical procedures.

- e. **New guidance for research involving risk of harm to self or others:** As the IRB and administrative staff become aware of emerging areas of research—including new 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 consultation with staff from Cornell Health, the IRB recently finalized new [guidance for research involving the identification of risk of harm to self or others](#).

6. Challenges faced by the committee

- a. **Pending regulatory changes:** On January 19, 2017, the Department of Health and Human Services published a final revised version of the Federal Policy for the Protection of Human Subjects (the “Common Rule”), the set of federal regulations that governs the conduct of research involving human subjects. The effective date for most provisions in the rule is January 19, 2018. IRB leadership and staff have begun the process of reviewing and interpreting the significant changes that will result from the new rule, ensuring that Cornell’s policies and procedures accurately reflect the revised regulations, and educating the research community about these changes.
- b. **IRB membership:** It remains a challenge to recruit active faculty researchers to serve on the IRB, as faculty time continues to be scarce. 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. It has proven especially difficult to recruit members from certain colleges and departments whose researchers are submitting an increasing number of requests to the IRB, including Information Science.
- c. **Lack of an IRB Application Management System:** The IRB application, review and approval process is currently a paper-based process. Lack of an online system for application completion submission and tracking leads to inefficiencies for the campus, IRB members and the IRB staff. The IRB process would benefit greatly from having an integrated protocol management system. Such a system is now in process of being developed, with work on the IRB module set to begin in January 2018.

7. Initiatives and changes in the coming year, and beyond

- a. **Implementation of changes to the Common Rule:** As noted above, revised federal regulations that govern the conduct of research involving human participants are expected to go into effect in January 2018, although the regulation is on hold for review by the new administration and we have not received confirmation of its final form or promulgation date. IRB leadership and staff will be spending significant time implementing major changes to many aspects of the IRB’s processes, policies and procedures, as well as planning and delivering communications on the relevant changes to the Cornell research community.
- b. **Continued development of accessible, standardized guidance and templates for research involving biomedical procedures:** In consultation with representatives of Cornell Health, Environmental Health and Safety, the Human Metabolic Research Unit, and the Human Development EEG and Psychophysiology Lab (including but not limited to urine and stool sample collection, EEG/ECG, and eye tracking).

- c. **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 January 2018, and it will require significant IRB staff time.
- d. **Outreach Video Project:** To supplement our written guidance and policies, and communicate crucial information to new researchers in a more accessible format, IRB staff is developing a video explaining the critical process of obtaining informed consent from potential human research participants. We will complete our first video, “Informed Consent 101,” and make the content available on our website in the summer of 2017.

Depending on the feedback received about delivering guidance in this format, the IRB staff may go on to develop additional video guidance on other topics relating to human participant research and IRB processes.

e. **Training**

- **New CU Learn implementation:** As part of a larger institutional project to consolidate and enhance the tracking of training across the university, the IRB will be employing the new CU Learn system to track online training required for all investigators conducting human participant research subject to IRB review.
- **New exempt training:** In connection with implementation of the new CU Learn system and pending regulatory changes, and responding to a perceived need to provide an alternative, shorter, less technical education program than the courses provided online by CITI, the staff is developing a streamlined basic training program. We anticipate making the program available to faculty and students through CU Learn and the IRB website in the coming year.