



Cornell University
Office of
Research Integrity and Assurance

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Institutional Review Board for Human Participants (IRB) Report to Faculty Senate for 2017-2018

1. IRB Membership (as of May 31, 2018)

Voting Members

- Carol M. Devine (Chair), Professor, Division of Nutritional Sciences
- Adam Anderson, Associate Professor, Human Ecology and Human Development
- Kathleen Bergin, J.D., Non-affiliated member and non-scientist
- Kent Bullis, M.D., Executive Director, Cornell Health (alternate)
- Gary Evans, Professor, Design and Environmental Analysis/Human Development
- Kathleen Friedrich, Prisoner representative and non-scientist
- Kenneth Hill, M.D., Cornell Health Services
- Katherine Kinzler, Associate Professor, Psychology and Human Development
- 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
- Mike Shapiro, Professor, Communication
- Elaine Wethington, Professor, Human Development
- Andrew Willford, Professor, Anthropology

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
- Wyman Miles, Director, IT Security
- Guilaine Senecal, Assistant Director, ORIA
- Josh 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 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, 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 (typically, surveys or interviews)
 - Studies in educational settings using educational practices
 - Certain uses of existing, “on the shelf” data or specimens
 - Taste tests
- 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 common, 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, often because they concern a highly sensitive or risky topic
 - 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 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. At the Cornell 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 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 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, 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 of harm to human participants, are not federal-funded, and meet certain other criteria. Continuation requests for certain expedited protocols can be approved by senior IRB staff.

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

Classification	Active Protocols 5/31/17	Active Protocols 4/30/18*
Exempt from IRB review	2912	1956
Expedited Review	534	490
Full Board Review	39	40
Authorization Agreements	20	19
Administrative Reviews	30	25
Total active projects	3,535	2,530

*In January 2018, IRB Staff closed 1,403 protocols for which research activities had concluded.

4. **IRB Applications reviewed**

Between June 1, 2017 and April 30, 2018, the IRB held 10 duly convened meetings to review research protocols. A total of 1,213 applications were approved during that time. Projects submitted for review during that time that were either approved or determined to be exempt from IRB review are reflected below:

Classification	New	Renewals	Amendments	Total
Exempt	443	N/A	N/A**	443
Expedited	150	160	350	660
Full Board	10	12	3	23
Other*	85	1	1	87
Total	688	173	352	1213

*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 (2017-2018)**

a. **Preparations for Major Revisions to the Common Rule:** A significantly revised version of the Federal Policy for the Protection of Human Subjects (the “Common Rule”), the federal regulations that govern the conduct of research involving human subjects, was to take effect on January 19, 2018. In the months leading up to this major change, the IRB staff was focused on analyzing the complicated new regulations, revising policies and procedures, drafting guidance, designing revised forms, templates, tools and checklists, issuing announcements and planning information sessions to prepare the Cornell research community, and working with staff and consultants to make necessary changes to the technical infrastructure. Two days before the regulations were to take effect, HHS

announced a delay. Although there is no certainty yet about when the new regulations will take effect, the IRB's significant efforts to prepare for this eventuality leave Cornell in a good position to quickly and effectively shift to applying the new regulations when they do become effective.

- b. **New Video Resource:** To supplement our written guidance and policies, and communicate crucial information to new researchers in a more accessible format, IRB staff developed a video explaining the informed consent process. The video, [available on our website](#), provides key information and answers to frequently asked questions about this crucial aspect of research with human participants.

- c. **Initiative to increase presence at Cornell Tech:** In April 2018 the IRB staff traveled to the Cornell Tech campus to deliver a formal presentation to researchers and hold meetings with various faculty and students, to address questions about individual research projects and develop a plan for Ithaca-based IRB staff to achieve a greater and more meaningful presence at the Tech campus. In response to feedback from Cornell Tech researchers, the IRB staff plan to begin holding virtual office hours on the Cornell Tech campus, and to issue guidance documents that will be of particular interest to this community. These efforts are intended to bridge the physical gap between the campuses, and to better address the growing number of IRB applications from Cornell Tech researchers and the unique ethical issues raised by the research projects typically conducted there.

- d. **Classes and workshops:** IRB staff and committee members regularly participate in classes and workshops for undergraduate and graduate students. Groups visited in the past year include:
 - Dietetic Interns Orientation, Mock IRB session, Division of Nutritional Sciences
 - 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)
 - PhD Research Design, City and Regional Planning
 - Office of Academic Diversity Initiatives, McNair Scholars Program, (undergraduates)
 - Qualitative Methods, Developmental Sociology Department, (MPS or Masters/PhD programs)

6. Challenges faced by the committee

- a. **Uncertainty concerning regulations:** As described above, the Revised Common Rule has been delayed, with July 19, 2018 as the current, new effective date. Adding to the uncertainty, on April 19, 2018, HHS released a new Notice of Proposed Rulemaking seeking further delay until January 21, 2019. We are awaiting a final decision on the effective date and compliance date of the new regulations, as well as the issuance of several guidance documents necessary to interpret some of the more arcane new provisions in the Revised Common Rule.

- b. **IRB membership:** Although pending regulatory changes and new internal processes (such as allowing senior staff members to review and approve certain amendments and renewals to minimal risk studies) have lessened the time and effort required by committee members, it nevertheless remains a challenge to recruit active faculty researchers to serve on the IRB. 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 late 2018.
- d. **NIH policy changes:** Researchers and staff have also faced the challenge of deciphering and implementing major policy changes affecting research supported by or seeking NIH funding. These new policies became effective in January 2018:
 - o NIH has imposed a significant new requirement to use a Single IRB (sIRB) for all domestic, multi-site studies where the same protocol is conducted in multiple locations. This burdensome new requirement (and the fact that a plan to address it must be in place at the time a grant proposal is submitted), combined with the inability of the Cornell IRB to serve as the sIRB, has caused frustration for some faculty members as they prepare NIH submissions.
 - o NIH has broadened the definition of the term "clinical trial" to include not just studies treating a medical condition but also some basic biomedical, and social and behavioral research. Under this policy, many more Cornell studies are classified as “clinical trials”, which triggers significant additional responsibilities: (1) to register, submit updates throughout the project, and post results information on ClinicalTrials.gov; (2) to ensure that all researchers involved in a clinical trial are trained in good clinical practices (GCP). In March 2018, as part of an omnibus spending bill, Congress directed the NIH to “delay enforcement” of this new policy for fiscal year 2018, citing “long-term unintended consequences” including unnecessary regulations and the inappropriate inclusion of non-clinical trials in NIH’s clinicaltrials.gov database. Because the NIH has not made any policy statement in response to this directive, the research community is not clear about which rules they should apply, and if or when those rules will be changing again.

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 either in July 2018 or January 2019. While much planning and preparation was completed in the time leading up to the now abandoned January 2018 effective date, more effort will need to be spent educating the Cornell research community, implementing changes to forms, websites, documents and templates, and making technical adjustments, in order to ensure that Cornell research is compliant with the new regulations.
- 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 late 2018, and will require significant IRB staff time.
- d. **New guidance:** 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 summer 2018, the IRB expects to finalize new guidance and a model for using passive (so-called “opt-out”) parental consent in research involving minors.
- e. **New application forms:** To streamline the process of seeking IRB approval or exemption in anticipation of new opportunities for flexibility offered in the Revised Common Rule, the IRB staff is overhauling the application forms that researchers complete when beginning a new project involving human subjects. A new Word form, which will eliminate technical problems of the old pdf form, streamlines questions and better aligns our review process with upcoming revised regulations. User testing of the new form will begin this summer.
- f. **Training**
- **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, streamlined ethics training:** Responding to the need for a shorter, less technical program than the online courses provided by CITI, the staff is developing a streamlined basic training program for student and other new researchers. We anticipate making the program available through CU Learn and the IRB website in the coming year.