



Cornell University
Office of
Research Integrity and Assurance

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Institutional Review Board for Human Participants (IRB) Report to Faculty Senate for 2015-2016

1. IRB Membership (as of May 31, 2016)

Voting Members

- Carol M. Devine (Chair), Professor, Division of Nutritional Sciences
- Gary Evans, Professor, Design and Environmental Analysis/Human Development
- Melissa Ferguson, Professor, Psychology
- Kathleen Friedrich, Prisoner representative, non-scientist
- Kenneth Hill, M.D., Gannett Health Services
- Caitlin Loehr, M.D., Non-affiliated member and non-scientist
- Poppy McLeod, Associate Professor, Communication
- Susan Miller, M.D., Gannett Health Services
- J. Edward Russo, Professor of Marketing, Johnson Graduate School of Business
- 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, Associate Professor, Anthropology

Ex-Officio, Non-Voting Members

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

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.

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.

g. Active Projects registered with the IRB:

| Classification | Active Protocols 5/31/15 | Active Protocols 5/31/16 |
|---|-----------------------------|-----------------------------|
| Exempt from IRB review | 2,462 | 2,396* |
| Expedited Review | 475 | 552 |
| Full Board Review | 29 | 31 |
| Authorization Agreements | 13 | 12 |
| Administrative Reviews | 29 | 23 |
| Total active projects as of May 31, 2016 | 3,008 | 3,014 |

* While nearly 600 exempt protocols were approved during the reporting year, more than that were closed during the same time period. As a result, the total number of active exempt protocols as of the end of May 2016 is lower than at the end of the previous season.

4. IRB Applications reviewed

During the reporting year June 1, 2015 – May 31, 2016, the IRB held 8 duly convened meetings to review research protocols. A total of 1,374 applications were approved between June 1, 2015 and May 31, 2016. Projects submitted for review and either approved or determined to be exempt during that time frame is below:

| Classification | New | Renewals | Amendments | Total |
|----------------|------------|------------|------------|--------------|
| Exempt | 453 | N/A | 125** | 578 |
| Expedited | 157 | 146 | 356 | 659 |
| Full Board | 5 | 27 | 31 | 63 |
| Other* | 68 | 5 | 1 | 74 |
| Total | 683 | 178 | 513 | 1,374 |

*This category includes Authorization Agreements and other administrative reviews.

**The IRB office discontinued tracking exempt amendments in late 2015, so this number does not fully represent the amount of amendments to exempt protocols that we processed.

5. Educational Initiatives

- **Open Office Hours:** To be more accessible to researchers, the staff increased the frequency of Open Office Hours in the fall of 2015, to twice every week, up from bi-monthly. The IRB staff has provided one-on-one assistance to about 130 researchers during these designated times.
- **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:
 - Human Dimensions Research Unit, Natural Resources, CALS (faculty, staff, post-docs, grad students)
 - Dietetic Interns, Mock IRB session, Division of Nutritional Sciences
 - NS 3980, Undergraduate Honors Research course, Division of Nutritional Sciences
 - NS 7040, Grant Writing Course for Nutrition Graduate Students, Mock IRB session, Division of Nutritional Sciences
 - 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)
 - McNair Scholars Program, Office of Academic Diversity Initiatives (undergraduate students)
 - Teaching as Research in Higher Education course, Center for Teaching Excellence (graduate students)
 - Institute for the Social Sciences Fellows Program (junior faculty)
 - City and Regional Planning Research Design course, AAP (PhD students)
 - Anthropology Research Design course, CAS (PhD students)
 - OADI Research Scholars Program, Office of Academic Diversity Initiatives (undergraduate students)
 - Adolescent Transitions Lab, Human Development, CHE (undergraduate students)
 - Program in International Nutrition Seminar, Division of Nutritional Sciences (PhD students, faculty)

6. Ongoing efforts to increase efficiency in the IRB application and review processes, and improve the researcher experience

- Instituting senior staff review of 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 to review and approve amendment and continuation requests for expedited protocols, that do not involve new procedures or instruments that may pose unknown or increased risk to participants.
- Implementation of web-based self-help tools
 - Two interactive decision-making tools to guide researchers in determining: 1) whether a project requires an application to the IRB (https://cornell.qualtrics.com/jfe1/form/SV_3QSf0FsaVDWsRdX) and, if so, 2) whether the project is eligible for exemption, or requires expedited or full board review by the IRB (https://cornell.qualtrics.com/jfe/form/SV_8qVCPVrJ2sUKyq1). Where an application is necessary, the tool points the researcher to the correct form.
 - Online protocol status report: A tool that shows PIs key information on the status of protocols on which they are the PI or faculty advisor, and notes which protocols have recently expired or are in need of renewal (<https://www.irb.cornell.edu/resources/index.cfm>)

7. New guidance to meet the changing needs of researchers

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 perspectives 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. During the past year, the IRB issued [guidance on sanitation](#) for devices and other objects that come into contact with research participants (including pedometers, phones, or other wearable devices, eye trackers).

8. Challenges faced by the committee

- **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 and the College of Business.
- **Educating new researchers:** As new students and faculty join the Cornell University research community each year, extensive outreach and education are essential for ensuring researchers are aware of the IRB and its role, and understand what is needed to ensure a swift review and approval process. Given the quantity of protocol submissions each year—as well as other work involved in the maintenance and enhancement of the Human Research Protection Program—this can present quite a challenge. Therefore, the IRB office will continue to expand its resources and communication tools (e.g., web-based video training) and to pursue opportunities for personal outreach, to ensure that student PIs understand what is required for IRB approval.
- **Pending regulatory changes:** On September 8, 2015, the Department of Health and Human Services proposed sweeping revisions to 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 notice of proposed rulemaking (“NPRM”) is the first systematic attempt to overhaul the 1991 Common Rule, and sets forth proposals to modify informed consent for biospecimen research, improve consent forms, mandate single IRB oversight of multi-site research, and recalibrate the level of IRB oversight so that it is more consistent with the seriousness of the harm to participants to be avoided, among other changes (some studies that currently require IRB approval would now become exempt, and others that are currently exempt would specifically become excluded). In partnership with the other Cornell campuses, the Ithaca-based IRB office officially expressed its views on the NPRM to the OHRP by letter in December 2015.
- **IRB staffing:** During the past year, the resources of the IRB office were strained by having one member out on extended leave, and another member resigning to pursue another opportunity. These two situations created temporary but meaningful gaps in the institutional and subject matter knowledge base as well as capacity, and contributed to delays in application review and approval time. The IRB office is now fully staffed and staff are trained and are able to provide the quality and speed of service expected by the campus community.
- **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.

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

- Launching additional improvements designed to improve efficiency in IRB operations and enhance the researcher experience, including revising protocol application forms to simplify the application process and address technical issues that made it unduly complicated for many users to easily download the necessary documents
- Development of accessible, standardized guidance and templates for research involving biomedical procedures, in consultation with representatives of Gannett, the Human Metabolic Research Unit, and the Cornell MRI Facility (including but not limited to blood draws, use of devices, and functional MRI (fMRI)).
- Once the final changes to the Common Rule are issued and take effect, Cornell IRB leadership and staff will need to spend significant time reviewing and interpreting the revised rule, and determining what changes must be made to policies and procedures in order for Cornell to comply.
- We look forward to the implementation of a comprehensive Research Administration Support System in 2017 or 2018 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.