



Cornell University
Office of
Research Integrity and Assurance

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**Institutional Review Board for Human Participants (IRB)
 Report to Faculty Senate for 2014-2015**

1. IRB Membership

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-affiliated member and non-scientist
- Harry Kaiser, Professor, Applied Economics & Management
- Caitlin Loehr, M.D., Non-affiliated member and non-scientist
- Poppy McLeod, Associate Professor, Communication
- Susan Miller, M.D., Gannett Health Services
- Yasamin Miller, Director, Survey Research Institute
- Hirokazu Miyazaki, Professor, Anthropology
- J. Edward Russo, Professor of Marketing, Johnson Graduate School of Business
- Sarah von Schrader, Senior Research Associate, Employment & Disability Institute, ILR School
- Qi Wang, Professor, Human Development
- Elaine Wethington, Professor, Human Development

Ex-Officio, Voting Members

- Relford (Chip) Patterson, M.D., Director of Occupational Medicine, Gannett Health Services

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
- Cathy Long, Associate Vice President of Research
- Amita Verma, Director, ORIA
- Guilaine Senecal, Assistant Director, ORIA
- Myles Gideon, Senior IRB Administrator
- Denise Payne, 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, in accordance with the federal regulations and based on the level of anticipated risk to participants:

- a. **[Exempt Review](#)** – Certain types of research projects are exempted from IRB review. Such projects are reviewed and approved by the IRB administrative staff and may include:
 - Observation of public behavior
 - Interactions with minimal risk
 - Studies in educational settings using educational practices
 - Use of certain existing, “on the shelf” data Food taste tests

- b. **[Expedited Review](#)** – Research projects that 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 include:
 - Most social/behavioral research interviews and surveys, experiments
 - Some minimally-invasive biomedical procedures (e.g., most blood draws)
 - Use of existing data with identifiers

- c. **[Full Board Review](#)** – Research involving more than minimal risk to human subjects is reviewed by the IRB 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 unknown or 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 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 an IRB staff member.
- f. **Continuing Review** - The IRB reviews all ongoing 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, but may occur more frequently depending upon the perceived risk of the research.
- g. **Active Projects registered with the IRB as of May 31, 2015:**

Classification	Active Protocols
Exempt from IRB review	2,462
Expedited Review	475
Full Board Review	29
Authorization Agreements	13
Administrative Reviews	29
Total Active as of May 31, 2015	3,008

4. IRB Applications reviewed

During the reporting year June 1, 2014 – May 31, 2015, the IRB held 11 duly convened meetings to review research protocols.

a. Applications reviewed by the IRB

- Expedited projects: These projects undergo pre-review by IRB staff, are assigned to an IRB member for review and are approved outside of Full Board meetings.
- Research requiring Full Board review: For these projects IRB staff, in consultation with the IRB Chair, will assign each protocol two primary reviewers. The primary reviewers are IRB members with the applicable expertise in the area of research. These applications are voted on at a convened IRB meeting, and must be approved by a majority of the IRB members present.
- Continuing reviews: Continuing protocols are reviewed using the same level of approval as the original application.
- Amendments: Amendments are typically reviewed using the same level of approval as the original application. Minor amendments may be approved by IRB staff, following guidelines approved by the IRB.

A total of 1,494 applications were reviewed between June 1, 2014 and May 31, 2015. A breakdown of projects submitted for review and approved / determined to be exempt during that time frame is below:

Classification	New	Renewals	Amendments	Total
Exempt (not reviewed by the IRB)	439	N/A	203	642
Expedited	234	152	317	703
Full Board	8	20	44	72
Other*	72	1	4	77
Total	753	173	568	1494

*Other = Authorization Agreements, Course Activities, and other administrative reviews

5. IRB Initiatives during 2014-2015

a. New Guidance for Investigators:

The following new guidance for investigators was developed in 2014-15:

- [Guidance on IRB Review of International Research](#)
- [Guidance on Research Involving Only Existing or Secondary Data, Documents or Records](#)
- [Review of Projects Collecting Oral or Life Histories, Journalism or Case Studies](#)

b. Educational activities for investigators:

- IRB help sessions: IRB staff hold bi-weekly Protocol Help Sessions at various campus locations, providing guidance and hands-on assistance with application forms, and on navigating the IRB process.
- Classes and workshops: IRB staff and committee members regularly participate in classes and workshops for undergraduate and graduate students upon request. Some classes visited in the past year:
 - ALS 6016: Teaching as Research in Higher Education
 - ANTHR 6440: Research Design
 - CRP 7201: Research Design
 - IARD 6990: International Agriculture and Rural Development M.P.S Project Seminar

c. Continued progress on previously complex and time-consuming reviews

- Expedited handling of most MRI renewals and amendments: The IRB approved a proposal to forego Full Board review of most annual continuation applications and amendment requests for protocols using the MRI; these will follow an expedited review procedure. Renewals and amendments of proposals involving the addition of children or individuals with mental or physical health conditions as subjects, or adding or amending procedures in a manner that increases the risk of the project to more than minimal, will continue to be reviewed by the Full Board.
- Research involving biomedical procedures: The IRB administrative staff, in consultation with representatives of Gannett, is in the process of developing more comprehensive and up-to-date guidance for researchers whose studies involve biomedical procedures with human participants, including but not limited to blood draws, use of devices, and functional MRI (fMRI). Although many studies will continue to be reviewed by the Full Board, the document being prepared is intended to make the process of study design and preparing protocol submissions more straight-forward for researchers, and is expected to result in a more efficient review process and turn-around time by the IRB and administrative staff.

d. Initiatives to implement feedback received from the User Satisfaction Survey

The IRB office conducted an Investigator Satisfaction Survey in early 2014 to learn about how the IRB is meeting the needs of investigators, and to identify opportunities to implement necessary improvements in

the services, guidance and resources that the IRB makes available. An action plan was developed in summer 2014, following which the IRB has successfully implemented a number of initiatives, including:

- A new decision tree was issued, assisting researchers in making initial determinations on whether their planned research requires an application to the IRB.
- Auto notification of application receipt has been implemented, informing researchers that their applications have been successfully submitted.

Additional initiatives in response to survey feedback are in process, and the IRB staff anticipates launching the following improvements in the coming year:

- Interactive, web-based tools for PIs: IRB staff has presented to IRB members a new tool that will be available 24/7 on the web, showing PIs key information on active protocols on which they are the PI or faculty advisor, and noting which protocols have recently expired or are in need of renewal. The tool is scheduled to be released for use by the research community in summer, 2015.
- Revision of protocol application forms. Status: In development.
- Interactive form of decision tree to assist researchers in making initial determinations about whether their planned research requires review by the IRB. Status: Nearly complete.
- Additional interactive decision tree, providing guidance to researchers concerning whether their project is eligible for exemption or expedited IRB review. Status: In development.

6. Ongoing education and training for IRB members

IRB staff hosted and facilitated IRB member participation in a number of webinars, including “The Future of Internet Research: What We Can Learn from the Facebook Emotional Contagion Study” and “Anticipate and Communicate for IRBs: Ethical Management of Incidental and Secondary Findings,” both presented by PRIM&R.

7. Challenges faced by the committee

a. Challenges:

- Ensuring that the members of the IRB have the necessary expertise to review the diverse nature of the research that comes before the IRB: recruiting faculty members to serve on the IRB continues to be a significant challenge. As research on this campus continues to grow in complexity and as subject matter specific sensibilities and ethical practices evolve, expertise of IRB members is critical to ensuring that reviews are thorough and appropriate to the research context. 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.
- 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., new interactive decision trees and web-based video trainings) to ensure PIs understand what is required for IRB approval.
- Emerging areas of research and evolving ethical sensitivities: The ethical issues associated with conducting research in the digital world of social media and other

- online channels has led to a robust discussion in the IRB community about the ethical considerations in engaging participants or observing behavior online, and about the potentially perpetual availability of the data collected or available in the online environment. Similarly, as the interest in genetic markers and their effect on human behavior and the human condition has grown, the ethics of using genetic material responsibly is also under discussion. The IRB continues to monitor and stay abreast of the ethical debate in these areas so that these considerations are appropriately addressed in the reviews of such projects on the Ithaca and Cornell Tech campuses.
- Regulatory changes: Nearly four years after submitting an advance notice, the Department of Health and Human Services recently submitted a notice of proposed rule making to the Office of Management and Budget for review, pertaining to a revised Common Rule. The original Common Rule was issued in 1991, and technical amendments were made in 2005. Once the final rule is issued and takes 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.
 - IRB staff turnover: During this past, the IRB office experienced a “Staff renewal” in which several members of the staff retired or moved on to other opportunities. This created a temporary gap in the institutional and subject matter knowledge base as new staff ramped up their learning. During this time, the IRB office saw longer protocol approval times, and often struggled with providing timely guidance to researchers who had complex questions. The staff are well settled in their roles now, and improvements across the board are evident.
 - 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. We are looking forward to the eventual implementation of a comprehensive Research Administration Support System that would 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.

b. Additional Improvement Opportunities

- 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 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. Forthcoming guidance documents in 2015-2016 will cover:
 - Guidance on review of research involving depression or suicidal ideation
 - Guidance on IRB requirements for the use of screenings, including those using SONA
 - Guidance on required procedures in research involving human blood collection
 - Work with relevant college and university leaders to develop guidance for undergraduate student research
 - Guidance and education on human genomics research