Cornell University
Office of
Research Integrity and Assurance

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Institutional Review Board for Human Participants (IRB)
Report to Faculty Senate for 2013-2014

1. IRB Membership

Voting Members

- Carol M. Devine (Chair), Professor, Division of Nutritional Sciences
- Gary Evans, Professor, Design and Environmental Analysis/Human Development (on leave 2013-14)
- Melissa Ferguson, Associate Professor, Psychology
- Kathleen Friedrich, Prisoner representative, non-affiliated member, and non-scientist
- David Just, Associate Professor, Applied Economics & Management
- Caitlin Loehr, 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, Associate Professor, Anthropology
- J. Edward Russo, Professor, Marketing
- Sarah von Schrader, Research Associate, Employment & Disability Institute, ILR School
- Qi Wang, Professor, Human Development
- Elaine Wethington, Professor, Human Development (on leave 2013-14; Prof. Sharon Sassler, PAM, covering fall 2013)

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
- Frank A. Cantone, Biological Safety Officer
- Robert A. Buhrman, Senior Vice Provost for Research, Institutional Official
- Cathy Long, Associate Vice President of Research
- Amita Verma, Director ORIA
- Matthew Aldridge, CIP. Sr. IRB Administrator
- Denise Payne, IRB Administrator

2. IRB Authorization and Responsibilities

a. Authorization

Cornell University's Human Research Protection Program (HRPP) is guided by ethical principles, Federal, State and local regulations regarding research involving humans as subjects. These guiding ethical principles

have been set forth by 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".

The University maintains a Federal Wide Assurance ((FWA # IRB00000340) with the U.S. Department of Health and Human Services, Office for Human Research Protections. This Assurance is updated periodically and commits the University to abiding by all federal regulations and guidelines with respect to its research activities involving human subjects funded by the agencies that subscribe to the "Common Rule". The 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.

In its FWA, Cornell University commits to having an Institutional Review Board for Human Participants (IRB) that is responsible for the ethical review of research with human participants and for maintaining compliance with the Federal regulations regarding the review. 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).

b. Responsibilities

All research projects involving human subjects conducted by University faculty, staff and students or done under the sponsorship or auspices of the institution must be reviewed and approved by the Cornell HRPP. This includes research involving subjects from outside the university and research which is not funded.

The primary responsibility for protecting the rights and welfare of human subjects rests with each individual who initiates, directs, or engages in research. The IRB is responsible for helping ensure that the rights and welfare of human research participants recruited to participate in research activities conducted under Cornell University auspices are protected; for providing guidance and oversight for Cornell's Human Research Protection Program, and for helping to maintain compliance with applicable laws, regulations, and policies.

3. IRB Review Activities

The IRB committee and administrative staff review and approve the following categories of human participant research, in accordance with the federal regulations and based on 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
   - Educational tests
   - Use of existing data "on the shelf" (public or de-identified)
   - 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 include:
   - Most social/behavioral research interviews and surveys, experiments

- Some minimally-invasive biomedical procedures (e.g., blood draws)
- Use of existing data with identifiers

c. **Full Board Review –** Research studies involving more than minimal risk to human subjects are reviewed by the IRB full board. Research that is otherwise considered minimal risk in 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
- Studies that involve certain vulnerable populations, such as prisoners

d. **Authorization Agreements** – research that may take place at or involve investigators at multiple institutions, where one institution is designated as the IRB of Record to reduce redundancy in review.

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 the 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. As of Nov. 25, 2013, the IRB began granting triennial approval to minimal risk, non-federally funded human participant research projects that do not qualify for exemption from IRB review (see section 8).

Active Projects registered with the IRB as of April 30, 2014:

Classification	Active Protocols
Exempt from IRB review	1979
Expedited Review	328
Full Board Review	23
Authorization Agreements	15
Administrative Approvals	269
Total Active as of April 30, 2014	**2,614**

4. IRB Applications reviewed

During the reporting year May 1, 2013-April 30 2014, the IRB held 10 duly convened meetings to review research protocols.

a. Applications reviewed

- Exempt projects: IRB staff review and may approve exempt projects under guidelines approved by the IRB. These approvals are reported to the IRB at a subsequent meeting.
- 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 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 1,140 applications were reviewed during May 1, 2013- April 30, 2014. A breakdown of projects submitted for review during the same time frames in 2012-2013 and 2013-2014 is below:

Classification	Number reviewed during 2012-13	Number reviewed during 2013-14
Exempt (new and amendments)	728	570
Expedited (new, continuing reviews and amendments)	518	480
Full Board (new, continuing reviews and amendments)	44	44
Authorization Agreements and other Administrative Protocols	70	46
Total reviewed	1,360	1,140

5. IRB Initiatives during 2013-2014

a. New Guidance for Investigators: New guidance for investigators was developed in 2013-14 on:

- Use of Social Networking Sites or Mobile Devices
  http://www.irb.cornell.edu/documents/IRB%20Policy%2020.pdf

Forthcoming guidance documents for investigators in the summer of 2014 will cover:

- Secondary Data Analysis
- Oral History
- Research in International Settings

b. Educational activities for investigators:

- **IRB help sessions:** IRB staff holds bi-weekly Protocol Workshops at various campus locations, to provide guidance and hands on assistance with application forms, and on navigating the IRB process.
- **Classes and workshops:** IRB staff and members regularly participate in classes and workshops for undergraduate and graduate students upon request.

c. Initiatives to reduce investigator burden

- **Triennial review**: As of November 25, 2013, the Cornell IRB began granting triennial approval to minimal risk, non-federally funded human subject research projects that do not qualify for exemption from IRB review. Those projects that would normally have required an annual review by the IRB can now be considered for a three year approval.

d. User Satisfaction Survey

The IRB office conducted and recently concluded an Investigator Satisfaction Survey to learn about how the IRB is meeting the needs of investigators in advancing research while protecting the interests of the participants who engage in it, and to identify opportunities to implement necessary improvements in the services, guidance and resources that the IRB makes available to the researchers in support of their research involving human participants. Survey results are being compiled; and an action plan will be developed over the summer to identify opportunities and implement needed changes.

e. Protocol Outcome Analysis: In an effort to identity the primary causes and sources of the most common problems and issues encountered in successful IRB reviews of protocols, the IRB office conducted an analysis of a random sample of over 100 submitted applications, and identified several recurring issues with submitted materials, that if addressed by PIs as part of their submissions, can greatly improve approval times and overall ease of review. Results from the analysis will be compiled and shared in summary format with the research community, as well as used in educational and information sessions for students and faculty.

6. Ongoing Education and Training for IRB members:

- Using Measures of Depression – Greg Eells, PhD, Associate Director of Gannett, and Director of Counseling and Psychological Services
- Computing and Information Sciences: research on social networking sites or mobile devices - Jeff Hancock & Jon Kleinberg, Co-Chairs, Information Science
- Using Amazon Mechanical Turk to recruit study participants – Manoj Thomas, JGSM
- Occupational Medicine role in Human Participant research – Relford (Chip) Patterson, MD, Director of Occupational Medicine, Gannett Health Services
- Research with human subjects utilizing the new fMRI equipment in MVR, and the administrative and physical controls and procedures set up to protect users and human participants engaged in the research activities: Professor Valerie Reyna and Dr. Wenming Luh.
- Updates from PRIM&R – International Research in Resource-Poor Settings; Consent, Privacy, and Date Sharing in the Age of the Genome; Conducting Internet Research: Challenges and Strategies for IRBs

Appendix A: Time to Approval for Protocols submitted to the IRB office (May 1, 2013- April 30, 2014)