Institutional Review Board for Human Participants (IRB)
Report to Faculty Senate for 2019-2020

1. IRB Membership (as of June 1, 2020)

Voting Members

- Andrew Willford (Chair), Professor, Anthropology
- Kathleen Bergin, J.D., Adjunct Professor of Law, non-scientist
- Rev. Robin Blair, non-affiliated member and non-scientist
- Anthony Burrow, Professor, Human Development
- John Clarke, M.D., Director of Occupational Medicine, Cornell Health Services
- Bobby Edamala, Chief Information Security Officer, non-scientist
- Gary Evans, Professor, Design and Environmental Analysis/Human Development
- Kenneth Hill, M.D., Cornell Health Services
- Jura Liaukonyte, Professor, Applied Economics & Management
- Saurabh Mehta, Professor, Nutritional Sciences
- Sarah von Schrader, Assistant Director of Research, K. Lisa Yang and Hock E. Tan Institute on Employment and Disability, ILR School
- Robert Scott, Executive Director, Cornell Prison Education Program, Prisoner representative
- Michael Shapiro, Professor, Communication
- Martin Wells, Professor, ILR School
- Kent Bullis, M.D., Cornell Health Services (physician alternate)
- Myles Gideon, Senior IRB and COI Administrator (non-scientist alternate)
- Vanessa McCaffery, IRB Administrator (non-scientist alternate)
- Joyel Moe, IRB Administrator (scientist alternate)

Ex-Officio, Non-Voting Members

- Mara Braddy, IRB Compliance Assistant
- Emmanuel Giannelis, Vice Provost for Research, Institutional Official
- Joshua Turse, Biosafety Officer, Environmental Health & Safety
- Stephanie Mattoon, Biosafety Specialist (biosafety alternate)

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 exempt from federal regulations, and do not require IRB committee review. At Cornell, these projects are reviewed and approved by IRB administrative staff. These commonly involve:
   - Observation of public behavior
   - Interactions with minimal risk, such as surveys or interviews
   - Benign behavioral interventions
   - Studies in educational settings using educational practices
   - Certain uses of previously-collected data or specimens

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 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
   - 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 convened committee. 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 by convened committee. For the 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 especially 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. **Administrative Reviews** – IRB administrative staff can review and approve submissions for activities that do not, for one reason or another, require IRB committee review. Current examples of submissions eligible for administrative review are program development approvals (used for sponsored research, when the human subjects research element of an award has not yet been finalized), as well as projects that do not to meet the regulatory definition of “human subjects research”.

f. **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.

g. **Continuing Review** - The IRB conducts an annual review of ongoing research protocols that are deemed to pose more than minimal risk to participants (i.e., those requiring full board review), or those which require a continuing review by a funder or collaborating institution. This continuing review is conducted 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.

h. **Active Projects Registered with the IRB:**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Active Protocols 5/31/19</th>
<th>Active Protocols 5/31/20</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt from IRB review</td>
<td>2142</td>
<td>2651</td>
</tr>
<tr>
<td>Expedited Review</td>
<td>528</td>
<td>624</td>
</tr>
<tr>
<td>Full Board Review</td>
<td>34</td>
<td>26</td>
</tr>
<tr>
<td>Authorization Agreements</td>
<td>67</td>
<td>80</td>
</tr>
<tr>
<td>Administrative Reviews</td>
<td>477</td>
<td>532</td>
</tr>
<tr>
<td><strong>Total active projects</strong></td>
<td><strong>3,248</strong></td>
<td><strong>3,913</strong></td>
</tr>
</tbody>
</table>

4. **IRB Applications Reviewed**

Between June 1, 2019 and May 31, 2020, the IRB held 11 duly convened meetings to review research protocols. A total of 1,291 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:

<table>
<thead>
<tr>
<th>Classification</th>
<th>New</th>
<th>Renewals</th>
<th>Amendments</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exempt</td>
<td>521</td>
<td>N/A</td>
<td>N/A*</td>
<td>521</td>
</tr>
<tr>
<td>Expedited</td>
<td>87</td>
<td>245**</td>
<td>290</td>
<td>622</td>
</tr>
<tr>
<td>Full Board</td>
<td>5</td>
<td>24</td>
<td>39</td>
<td>68</td>
</tr>
<tr>
<td>Other***</td>
<td>80</td>
<td>0</td>
<td>0</td>
<td>80</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>693</td>
<td>269</td>
<td>329</td>
<td>1,291</td>
</tr>
</tbody>
</table>

*The IRB office continues to review and approve amendments to exempt protocols, but simplified the process for PIs to request such amendments, and stopped tracking these approvals in metrics reports in 2015.
5. IRB Initiatives (2019-2020)

a. Continued Implementation of Major Revisions to the Common Rule: The “Common Rule” is the primary federal regulation that governs the conduct of research involving human subjects. Following a previous delay announced in January 2018, a significantly revised version of the Federal Policy for the Protection of Human Subjects (the “New Common Rule”) became effective on January 21, 2019. While the majority of the implementation work took place prior to this effective date, the Cornell IRB has continued to work on disseminating new resources, revising guidance and policy to reflect the regulatory changes, and implementing the final component of the New Common Rule, which went into effect January 20, 2020. That was the requirement that federally funded cooperative studies taking place in the U.S. and involving more than one institution must use a single IRB (sIRB) for review and approval of the research.

b. Expansion of Role of Experienced IRB Administrators: In May 2020, the IRB approved a proposal to allow experienced IRB administrative staff to serve as voting (alternate) members of the committee, in order to increase efficiency and speed in the IRB review and approval processes. The two main purposes of this role expansion were (1) to enable experienced IRB administrators to finalize the review and approval of minimum risk research that meets the requirement for “ Expedited” review, where they were previously conducting robust pre-reviews but were required to obtain another committee member’s sign-off; and (2) to help avoid the unfortunate but occasional scenario where, during an IRB committee meeting, quorum is lost midway through due to unforeseen circumstances, and a final vote cannot be taken on a protocol approval or another time-sensitive committee matter. The IRB Chair will make the determination about an IRB administrator’s sufficient experience and knowledge to conduct compliant and ethically appropriate IRB reviews, and therefore meet the “experienced” threshold. At present, the IRB office has three staff who are serving the IRB in this expanded capacity.

c. New or Improved Tools for Researchers:

- GDPR guidance: In June 2019, the Cornell IRB issued, in partnership with Cornell’s Privacy Officer, a new guidance document on the impact of the European Union General Data Protection Regulation (GDPR) on research data collected from human participants.

- Redesigned website: In June 2019, the Research Division released a professionally redesigned website with a unified look and feel across all of the research service and compliance offices. As part of this effort, the IRB streamlined, updated and added new, subject-matter specific content to better serve our faculty researchers. Over the year since, IRB staff have regularly added events, new guidance documents, and other updates to the website, including information of relevance to researchers during the COVID-19 pandemic. A new FAQs webpage was created for human participant research-related COVID-19 updates.

- COVID-19 pandemic process changes, resources, and guidance: In early March 2020, the IRB began developing streamlined processes for facilitation of time-sensitive amendments to existing protocols to accommodate remote interaction with participants (i.e., via Zoom or telephone), as well as review of new protocols for COVID-19-related research. A COVID-19 IRB FAQs webpage was published in April, and has been regularly updated with new
developments. Members of the IRB participated in the Committee on Human Subjects Research Reactivation, meeting in May and June to develop a set of guidelines for colleges and other units to use in considering how to review and approve requests from faculty to “reactivate” their human subjects research on campus. In addition, the IRB developed and published in July new Guidance on In-Person Research During the COVID-19 Pandemic, accompanied by sample tools for researchers to use (e.g., study participant COVID-19 information sheet, self-screening attestation, and contact tracing form).

d. Academic Integration Initiative: Cornell’s Ithaca-based IRB staff continue to collaborate with their counterparts from the Weill Cornell Medicine campuses in order to help bridge the physical gap between the campuses and to better facilitate collaborative research. IRB staff from both offices have participated in regular phone calls and email correspondence, participated in another day-long retreat in July of 2019 (hosted by WCM), and published guidance on a formal process for researchers to use to easily obtain IRB review from either Weill or the Ithaca IRB, for a project spanning both campuses.

e. Classes and Workshops: IRB staff and committee members regularly present to classes and workshops for undergraduate and graduate students, new researchers, and research staff. Groups visited in the past year include:

- Undergraduate Honors Research course, Division of Nutritional Sciences (undergraduate students)
- Ethnographic Field Methods seminar, Department of Anthropology, CAS (undergraduate and graduate students)
- International Agriculture and Rural Development seminar, International Programs, CALS (MPS students)
- Graduate Research Seminar, Department of Sociology, CAS (graduate students)
- Research Administration Certification Program, Office of Sponsored Programs and Division of Financial Affairs (research administrative staff)

6. Challenges Faced by the Committee

a. IRB Staff Turnover: During the past year, the IRB office experienced major shifts in staffing, due to two staff members (including the ORIA Assistant Director) leaving the office around the same time in early fall 2019. This created a gap in the institutional knowledge base, as well as a lack of hands on-deck needed to handle the IRB’s heavy fall workload. A few ORIA staff shifted around to accommodate this and other staffing challenges, including a former IRB staff member still working in ORIA who was able to devote time to IRB work, and two additional IRB staff members were hired at the end of the fall semester (along with two other new staff in ORIA). During this transition process, the IRB office saw longer protocol approval times, and often struggled with providing timely guidance to researchers who had complex questions. The new staff are now well-settled in their roles, and are able to respond more swiftly to questions and protocol submissions.

b. COVID-19 Pandemic: As with all Cornell operations, the IRB’s work has been serious impacted by the COVID-19 pandemic. Beginning in early March 2020, the office began fielding urgent requests from researchers to approve new protocols investigating human experiences at the start of the pandemic, as well as time-sensitive requests to modify existing protocols for remote interaction. For several months, the majority of questions and submissions that came to the IRB office were time-sensitive and COVID-related, making it challenging to work on other projects or other non-COVID-related protocols. IRB staff and committee members have spent significant time helping to develop university-level guidelines for reactivating in-person human subjects research on Cornell’s campus, as well as developing IRB-specific guidance and resources for in-person research and use of
teleconference technologies such as Zoom. As in-person human subjects research has been allowed to begin again in a controlled fashion, the IRB has had to develop new processes for reviewing these requests in tandem with colleges’ reviews.

c. **Lack of an IRB Application Management System**: Submission, review, and approval of IRB protocol applications is currently a paper-based process. Lack of a single online system to support these crucial processes leads to inefficiencies for researchers, IRB committee members and the IRB staff. The IRB process would benefit greatly from having an integrated protocol management system. Such a system has been planned for many years, and a vendor was even selected, but the timeline has continued to be pushed back. IRB and IT staff explored other vendor options in early 2020, and the plan is for an IRB system to be chosen by fall 2020, with development work beginning immediately thereafter.

d. **IRB Membership**: Although recent regulatory changes and internal processes shifting work from voting IRB members to IRB administrators have lessened the time and effort required by the committee, it nevertheless remains a challenge to recruit active faculty researchers to serve. 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.

7. **Major Initiatives in the Coming Year**

   a. **IRB application management system**: We look forward to the preparation for and implementation of an IRB application management system. Work on an IRB system has been delayed, but is expected to begin in fall 2020, and will require significant IRB staff time during the year or more it will take to develop the online form and routing procedures, prepare existing data for migration, implement the system, and train researchers and IRB members on use of the new system.

   b. **New and revised guidance**: As the IRB and staff become aware of emerging areas of interest for human participant research—be they related to a global pandemic, new regulations, or 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 2020, the IRB, in collaboration with the IT Security Office, will finalize a draft guidance document on use of video conference technologies (e.g., Zoom) for human participant research. In addition, the majority of the IRB’s existing policies and guidance documents have not been revised in a number of years, so the IRB will be methodically reviewing and revising a number of these over the coming year to ensure they are up-to-date and still useful.