**Office of Research Integrity and Assurance**
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# Institutional Review Board for Human Participants (IRB)
# Report to Faculty Senate for 2020-2021

1. **IRB Membership (as of June 1, 2021)**

   <u>**Voting Members**</u>

   - Andrew Willford (Chair), Professor, Anthropology
   - 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, IRB Manager (non-scientist alternate)
   - Vanessa McCaffery, IRB Administrator (non-scientist alternate)
   - Joyel Moeller, IRB Administrator (scientist alternate)

   <u>**Ex-Officio, Non-Voting Members**</u>

   - Mara Braddy, IRB Compliance Assistant
   - Emmanuel Giannelis, Vice President for Research and Innovation, 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 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." 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 President for Research and Innovation 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 minimal risk 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 secondary analyses of 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—sometimes called a reliance agreement—may be used to formalize an arrangement whereby one institution takes responsibility for IRB review of the entire project, serving as the "IRB of Record" or "Single IRB" (sIRB). These agreements are used in order to avoid redundancy and streamline the initial review and any subsequent renewal or amendment processes. Recent changes to federal regulations now *require* such agreements for many federally funded collaborative projects (depending on the exact circumstances of the project).

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. Changes made to exempt research protocols must also be communicated to ORIA, but they are only reviewed to confirm that the project is still eligible for exemption.

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:**

| Classification | Active Protocols 5/31/19 | Active Protocols 5/31/20 | Active Protocols 5/31/21 |
|---|---|---|---|
| Exempt from IRB review | 2142 | 2651 | 3100 |
| Expedited Review | 528 | 624 | 719 |
| Full Board Review | 34 | 26 | 23 |
| Authorization Agreements | 67 | 80 | 124 |
| Administrative Reviews | 477 | 532 | 498 |
| **Total active projects** | **3,248** | **3,913** | **4,464** |

4. **IRB Applications Reviewed**

**Past Year Reviews:** Between June 1, 2020 and May 31, 2021, the IRB held 11 duly convened meetings to review research protocols. A total of 931 applications were approved by the IRB, determined to be exempt, or completed an administrative review during that time. These projects are reflected below:

| Classification | New | Renewals | Amendments | Total |
|---|---|---|---|---|
| Exempt | 443 | N/A | N/A* | 443 |
| Expedited | 95 | 21** | 203 | 319 |
| Full Board | 6 | 19 | 28 | 53 |
| Other*** | 115 | 0 | 1 | 116 |
| **Total** | **659** | **40** | **232** | **931** |

*The IRB office reviews amendments to exempt protocols, but simplified the process for PIs to request such amendments, and stopped tracking these approvals in metrics reports in 2015.

\*\*Most Expedited protocols no longer require continuing review ("renewal") under the 2018 revised HHS regulations, but IRB staff continued to process the last of the necessary renewals administratively over the past year, in order to ensure all PIs had accurate protocol documentation.
\*\*\*The "Other" category includes Authorization Agreements and other administrative reviews.

**IRB Staff vs. IRB Member Reviews:**

IRB staff have historically reviewed protocols determined to be exempt, as well as other types of submissions that can receive administrative review (e.g., authorization/reliance requests, program development, studies deemed "not human participant research"). Over the past several years, more experienced IRB administrators ("senior staff") have been given gradually expanded authority by the IRB to review and approve other minimal-risk research protocols. This has lessened the burden on the faculty and community members of the IRB—allowing their efforts to be aimed at the more complex and risky protocol submissions—as well as increased efficiency in the IRB review and approval processes.  The chart below compares IRB administrative reviews with senior staff reviews and non-staff IRB member reviews over the past three years:
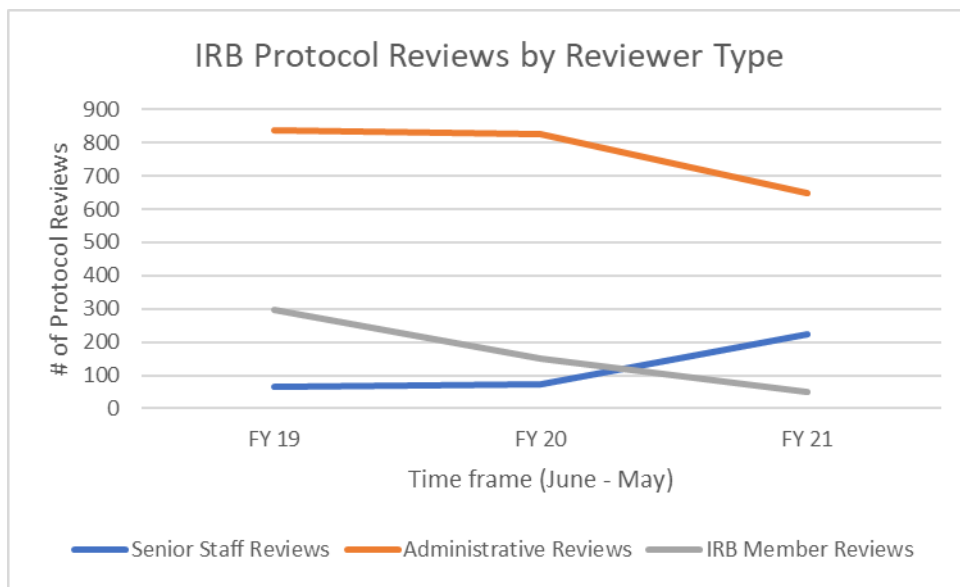


5.  **IRB Initiatives (2020-2021)**

    a.  **COVID-19 Pandemic Process Changes:** Several members of the IRB committee and staff participated in a Committee on Human Subjects Research Reactivation in late spring/early summer 2020, developing 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 participant research on campus. Using these guidelines and additional IRB guidance (see item 5.e below), the IRB proceeded to review and approve 30 in-person, on-campus human participant research projects from mid-July 2020 through May 2021, when the campus public health restrictions began to lessen. The IRB members and staff provided support to researchers, facility directors (e.g., from the Human Metabolic Research Unit and Cornell MRI Facility), and college administrators in developing protocols and procedures that would be both safe (from a public health perspective) and compliant.

    b.  **Research Use of COVID-19 Surveillance Samples and Data**
        IRB staff and committee members spent significant time over the past year working with other members of the university community to think through how to appropriately allow use of COVID-19 surveillance samples and data for research purposes by Cornell investigators, while still protecting the privacy and rights of the Cornell community members from whom the samples were obtained.

This work happened via ad-hoc conversations, at first, and then through involvement in a committee co-chaired by the Associate Vice Provosts for Social and Life Sciences. This committee developed a robust set of instructions for requesting letters of interest from faculty interested in utilizing surveillance samples or data for research purposes, and now that the first set of letters has been submitted, the committee will review and determine which projects will be allowed to move forward. These projects will need to go through the regular compliance committee processes (i.e., IRB, IBC).

c. **IRB Application Management System:** The Cornell IRB and Human Research Protection Program have been using outdated systems for protocol documentation and workflow management for a number of years. Finally, work on an IRB module of the Research Administration Support System—an online grant and research protocol application management system built by vendor Novelution—began in earnest in November 2020. IRB staff and leadership contributed to a gap-fit analysis process which was completed in February 2021, and development of system features began at that time. IRB staff have continued to meet weekly with IT project support staff and the vendor to discuss system specifications, data migration plans, and findings from internal testing. Data clean-up projects are underway, and a set of "users" will soon be identified to assist with more significant user testing. The system is slated to be ready for investigator use by early 2022.

d. **Review of Multi-site, Collaborative Research (sIRB):** In recent years, two new federal policies have mandated single IRB ("sIRB") review of certain types of collaborative human participant research projects. This means that one IRB (the sIRB) must be the IRB of Record, providing the ethical review for all sites participating in a multi-site and/or collaborative human participant study, involving researchers from multiple institutions. Serving as the sIRB can require a great deal of time and resources on the part of the IRB and administrative staff, so the Cornell IRB had been reticent to agree to serving in this capacity for complex projects involving more than one or two other sites. In order to determine the actual need for Cornell's IRB to increase its capacity to serve as an sIRB, in early 2021 ORIA conducted a survey of federal funded Cornell faculty members about their collaborative human participant research projects. The survey response indicated that at least 40 Cornell faculty researchers have current or planned projects that require sIRB review, so the Cornell IRB's ability to serve in that capacity would be quite useful (and, perhaps, necessary for ensuring Cornell's ability to compete for certain prestigious federal grants).

e. **New or Improved Tools for Researchers**:
   o **Website**:  The IRB team has continued to streamline and update the human participant research portions of the [Research Services website](), revising guidance and resources as needed, and periodically providing updated information about research restrictions and recommendations pertaining to the COVID-19 pandemic.
   o **COVID-19 Human Participant Research Guidance:** In July 2020, the IRB developed and published 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). The guidance and appendices were tweaked periodically over the past year, and are now under review for major updates.

f. **Academic Integration Initiative:** Cornell's Ithaca-based IRB staff continue to collaborate with their counterparts from Weill Cornell Medicine 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 periodic phone and Zoom calls, and regular email correspondence, both about specific collaborative research projects and about process improvement. WCM IRB leadership were invited to participate in several ad-hoc Ithaca-based committees over the course of the past year (e.g., regarding use of SARS-CoV-2 surveillance samples for research).

g. **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 (all via Zoom) include:
- ANTHR 2482: Anthropology of Climate Change, CAS (undergraduate students)
- City & Regional Planning 7201 Research Design, AAP (graduate students)
- City & Regional Planning 5250: Introductory Methods of Planning Analysis (graduate students)
- Fiber Science and Apparel Design Futures seminar, FSAD 4444, CHE (undergraduate and graduate students)
- Information Science 4900 seminar, CIS (undergraduate and graduate students)
- LAW 6238: Advanced Admin Law: Food and Agricultural Regulation (law students)
- NS 3980: Research in Human Nutrition and Health, Division of Nutritional Sciences (undergraduate students)
- NS 7040: Grant Writing, Division of Nutritional Sciences (graduate students)
- PRO Team Training, Office of Sponsored Programs (research administrative staff)
- Research Administration Certification Program, Office of Sponsored Programs and Division of Financial Affairs (research administrative staff)
- SOC 6080: Proseminar in Sociology, CAS (graduate students)

6. **Challenges Faced by the Committee**

   a. **COVID-19 Pandemic**: As with all Cornell operations, the IRB's work was serious impacted by the COVID-19 pandemic. The IRB fielded 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, followed by time-sensitive projects exploring experiences and impacts of vaccination. For a number of 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 spent significant time helping to develop university-level requirements and guidance related to research during the pandemic and research with surveillance samples and data. As public health requirements have changed, the IRB has had to adjust its guidance and resources, accordingly.

   b. **Lack of an IRB Application Management System**: Submission, review, and approval of IRB protocol applications is currently a paper- and email-based process. Lack of a single online system to support these crucial processes has led to inefficiencies for researchers, IRB committee members and the IRB staff. The need for an integrated protocol management system has been discussed for many years, but such a system for Cornell only just began development in late 2020. The system will not go live until early 2022, so in the meantime, the old, inefficient process must be used.

   c. **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:** The work on the new online IRB application management system will continue to require significant IRB staff and member time through the coming year,

involving data clean-up, data migration, system testing, and training of researchers and IRB members on use of the new system, once launched.

b. **Single IRB:** The IRB and a sub-committee on sIRB needs will continue to identify next steps for Cornell to serve responsibly as an sIRB for multi-institution collaborative research projects. This will likely include joining the SMART IRB consortium, developing clear guidelines for when Cornell can and cannot serve as the sIRB, and identifying additional resources needed—including, potentially, staffing—to provide more robust sIRB services.

c. **University Policy on Human Participant Research:** There are over 40 ORIA policy and guidance documents related to IRB procedures and human participant research at Cornell, but no university-level policy. ORIA has started to work on developing such a policy.

d. **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. The IRB, in collaboration with the IT Security Office, has been working on a guidance document on use of video conference technologies (e.g., Zoom) for human participant research. The IRB staff have also been collaborating with the Office of the Registrar on development of FERPA-related guidance as it pertains to human participant educational research. Revised guidance about exempt research is also being drafted, and a number of other existing IRB policies and guidance documents are also in need of review and revision to ensure they are up-to-date and still useful.

In addition to guidance for investigators, the IRB is implementing a new program of continuing education for committee members to keep them up to date on new policies and regulations, emerging areas of interest, and shifts in ethical thinking within the landscape of human participant research.