**Institutional Review Board**

 **Meeting Agenda**

September 23, 2020 at 2:15 PM

Virtual Meeting on Teams

IRB Committee Members

Diane Fenster, Myunghee Jun, J P Leary, James Kabrhel, Mark Kiehn (Chair), Christine Smith, Katie Turkiewicz, Christopher Paquet (ex-officio, voting), Pieter deHart (ex-officio, non-voting)

Additional Participants

Roger Wareham (Director of Grants and Research), Liz Brinks (Program Associate)

Agenda

1. **Introductions**
2. **Approval of May 2020 IRB meeting minutes** (please see attachment at end of Agenda)

Comments or amendments to the May minutes? Consent to pass minutes by acclamation

1. **IRB Meeting Schedule for the 2020-2021 Academic Year** (see attachment at end of Agenda)
2. **Review - IRB Committee Charge** (attachment at end of Agenda)
3. **Summer IRB Chair Report**

Requests for IRB assistance (N=18). Exempt/Expedited proposals submitted for review (N=8): [proposals approved (n=4), proposals currently under initial review (n=3) other (n=1)]

Chair shares the IRB timeline in terms of response times, Chair’s function, and transparency with proposal applications submitted to the IRB

1. **Discussion - Review the updated IRB COVID – 19 Statement** (attachment at end of Agenda)

What is our stance on human subjects research when social distancing research is not possible?

1. **Discussion- Review the Requests for Outside Access** (attachment at end of Agenda)
2. **Discussion** – What is the relationship - What happens when a University employee leaves the institution? [Consider the following circumstances with regard to IRB review of a proposal:

(a) retirement from the institution, (b) resigned from another institution, (c) contract is not renewed/or fired from the institution, and (d) other circumstance scenarios]

What relationship is needed to gain IRB approval for a research protocol proposal?

1. **Other information items, announcements**

CITI – IRB Members course training requirement (see attachment at end of this document)

We ask everyone to complete the *CITI IRB Members* course containing the training modules

1. **Adjournment**

 **Attachments**

May 2020 minutes

IRB Fall 2020 Meeting Schedule

**Wednesdays, 2:15 - 3:45 p.m.**

Let’s plan to meet in the virtual meeting format on Microsoft Teams this semester:

23 September 2020 18 November 2020
21 October 2020 09 December 2020
**(Note**: There is a 45 minute overlap with the Faculty Senate meeting time on December 9 – please make arrangements to ask your unit Alternate to attend the Faculty Senate meeting on Dec. 9)

IRB Committee Charge

 UW-Green Bay Institutional Review Board (IRB) Committee Charge

 SOFAS, September 2020

1. The Institutional Review Board (IRB) shall be composed of eight (8) persons: six (6) members of the faculty appointed by the Provost, one (1) community member, and the Risk Manager and Contracting Officer (who will serve as an ex officio, voting member). At least two of the faculty members will be non-scientists, i.e., the major field of study of their highest degree held is not in the natural or social sciences and at least one will be a scientist. All members, with the exception of the Risk Manager and Contracting Officer, will serve three-year, staggered terms to assure continuity.
2. The Provost and Vice Chancellor for Academic Affairs, or designee, is the designated Institutional Official responsible for matters pertaining to research involving the use of human subjects.
3. The IRB Chair shall collaborate with the Committee on Committees and Nominations when nominating the slate of faculty candidates to serve on the IRB or when nominating faculty candidates when replacements are necessary. The IRB Chair shall be responsible for the nomination of the community candidate when a replacement is necessary. Final appointments are made by the Provost and Vice Chancellor of Academic Affairs, or designee.
4. IRB activities are coordinated by a chairperson appointed by the Provost and Vice Chancellor of Academic Affairs, or designee, for a three-year, renewable term. The term of the chair begins on July 1 and concludes on June 30.
5. The IRB serves the following functions:
	* Is the UW-Green Bay Institutional Review Board as defined in the Federal Government Regulations 45 CFR Part 46 (Federal Register 11/01, PP83668392).
	* Develops and makes recommendations to the Institutional Official regarding guidelines and procedures for the review of research proposals, submitted by UW-Green Bay faculty, staff and students, involving more than trivial risks to human subjects participating in the research.
	* Reviews and approves or denies the conduct of all proposed research, to be conducted by UW-Green Bay faculty, staff and students, involving more than trivial risks human subjects participating in the research.
	* Investigates allegations of research misconduct of UW-Green Bay faculty, staff or students when the misconduct is associated with research proposals previously approved by the Committee. The Committee may suspend approval of previously approved research if allegations are substantiated.
6. The Chair of the Board has the following responsibilities:
	* Maintain official records of submitted research proposals reviewed by the Committee, indicating approval or denial of all proposals.
	* Report the results of investigations of research misconduct, when the misconduct is associated with research proposals previously approved by the Committee, to the Institutional Official (or designee).
	* Notify the Institutional Official when the Board suspends approval of previously approved research and make recommendations for actions to be taken as a result of the suspension.
	* Submit a report of all Board activities at the end of each academic year to the Provost and Vice Chancellor for Academic Affairs, or designee.

IRB COVID-19 statement

UW-Green Bay Institutional Review Board

 Institutional Research During the COVID-19 Crisis

The IRB of UW-Green Bay dedicates itself to facilitating faculty, staff and student research within the safe parameters established by the COVID-19 shelter-in-place statewide policies. The following guidelines provide information about how campus researchers may continue their research programs.

1. Research procedures that do not involve any direct, in-person contact with participants or co-researchers may continue. This includes data analysis, online surveys, telephone interviews.

2. Collaborative research involving an external institution may continue, as long as the researchers and participants adhere to the exclusion of direct, in-person contact with anyone involved in the study.

3. The Institutional Review Board will continue to perform reviews.

4. Changes to protocols because of the at-home requirements may be submitted via the Protocol Modification form. Indicate that the change is related to COVID-19. Modifications of protocols that do not compromise the safety of participants or researchers will be approved.

5. In proposing changes, researchers must consider whether or not they present any new risk to participants, such as compromising anonymity, or requesting that something be done that places participants in situations that increases exposure to COVID-19.

6. Changes require a revised informed consent that may be electronically signed by the research participants. A request for “waiver of consent” may be made to the IRB. See the website for further information.

7. Researchers need to consider how research location (and any restrictions on the sites) may be impacted by COVID-19.

8. New studies are still being reviewed. Studies that involve in-person contact will either need to be conducted remotely or postponed until the COVID-19 restrictions at UW-Green Bay are lifted.\*\* As restrictions are relaxed it is the expectation that the researcher must clearly address in their protocol current best practices as advices by the CDC and the university being taken to protect researchers and participants. These measures must be noted in the protocol and the informed consent for participants to sign.

9. The IRB will continue to accept and review Modifications and Extension requests. Research that is postponed due to COVID-19 will still have to file an extension request prior to the protocol expiration date.

10. IRB meetings and reviews are proceeding as scheduled.

11.The following changes do not need to be reported to the IRB. Researchers should document their changes for their research records.

* 1. a. Pausing recruitment or testing.
	2. b. Adding links to reputable websites for information about COVID-19.
	3. c. Postponing or cancelling in-person visits.
	4. d. Communications to participants in changes in research procedures due to the COVID-19 crisis.
	5. e. Messages to participants do not require IRB approval. In addition, messages about changes to study visits, like administering questionnaires over the phone or video conferencing, do not require IRB approval. Make a note to your study files to document these communications.

12. Research funded by federal agencies (e.g., NIH, NSF) must also adhere to their policies regarding conducting research during the COVID-19 crisis. Please consult the Office of Grants and Research for further guidance.

The above guidelines will remain in place until resumption of fully functioning university activities as dictated by University policy. The IRB will continue to monitor research impacted by COVID-19 and will work with constituents to ensure that research is not negatively

Approved by the UW-Green Bay Institutional Review Board in May, 2020

Requests for Outside Access - IRB Current Policy

This is the current IRB Policy on Outside Institutional Access to UW-Green Bay Participants:

Institutional Review Board of the University of Wisconsin-Green Bay

 Policy on Outside Institutional Access to UW-Green Bay Participants

This policy pertains to requests from institutions other than the University of Wisconsin-Green Bay (including other UW System Institutions).

All requests for access to student emails will be made via the Research Sample Request Form which is located on the IRB website. Requests shall include a complete copy of an approved IRB document from the home institution.

The IRB Chair, in consultation with the full IRB Board, shall review the approved IRB document.

If approval is granted, the Chair of the UW-Green Bay IRB Board shall request that the UW-Green Bay Dean of Students randomly select up to 1000 student email addresses to forward to the requestor. Upon completion of the project the researcher of the outside institution shall submit a copy of the completed report to the current IRB Chair.

Approved by the UW-Green Bay Institutional Review Board, December 14, 2015.

CITI Course Training

Our collaborative work through the Institutional Review Board is vital to UW-Green Bay, since all research involving human subjects needs IRB approval. It’s important to begin on the same page, so we are asking that you complete the *CITI IRB Members* course on the UW-Green Bay IRB website. Ideally, it would be great if everyone could have the training done by our first meeting on September 23rd if possible.

Please use the following link and click the green **Registration Instructions** button:

<https://www.uwgb.edu/institutional-review-board/citi-training/>

CITI provides a certificate upon completion, and this training endorsement is good for 4 years. If you have any questions, please contact Mark Kiehn or Roger Wareham anytime.  Here are the 14 required modules in the course training for IRB members:

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| Belmont Report and Its Principles |
| History and Ethics of Human Subjects Research |
| The IRB Member Module - 'What Every New IRB Member Needs to Know' |
| Defining Research with Human Subjects – SBE |
| Basic Institutional Review Board (IRB) Regulations and Review Process |
| Privacy and Confidentiality – SBE |
| Informed Consent |
| Populations in Research Requiring Additional Considerations and/or Protections |
| Conflicts of Interest in Human Subjects Research |
| Hot Topics |
| Unanticipated Problems and Reporting Requirements in Social and Behavioral Research |
| Assessing Risk – SBE |
| Students in Research |
| FERPA for Institutional Review Boards (IRBs) |