Pandemic Related IRB Adjustments to Research Protocols Involving Human Subjects

Wesleyan Statement on Research Involving Human Subjects During the Covid-19 Pandemic:

All in-person research must follow the general University guidelines and policies for Covid-19 precautions for safety currently in force at the time the research is conducted, and will further adhere to Wesleyan's Covid-19 Guidelines for Research with Human Participants, as approved by the Wesleyan Pandemic Response Physician (Dr. Thomas McLarney), currently in force at the time that the research is being conducted. It is the study team's responsibility to review these guidelines regularly, as they may change as circumstances change.

New Research Submissions:

All new research proposing in-person data collection should include a statement of why in-person data collection is necessary, and a description of the protocol that will be used to ensure the health and safety of participants and research staff. This protocol should adhere to Wesleyan's Covid-19 Guidelines for Research with Human Participants. In addition, the IRB application should include an explanation of the methods by which informed consent will be obtained and participant confidentiality protected.

Making changes to exempt/approved research:
Federal regulations allow study teams to make immediate changes in research to protect the health and safety of research participants and staff. Many studies are undergoing changes to limit exposure to COVID-19. Changes to limit exposure to COVID-19 should be immediately implemented to help ensure safety for participants and study team members. In-person data collection changes must adhere to Wesleyan's Covid-19 Guidelines for Research with Human Participants.

Some changes do not require IRB approval, unless there are changes in study conduct (see below). However, all ongoing research that undergoes, or has undergone, COVID-19 related changes that do, requires submission of a *Project Update Form* outlining the changes.

Note: Researchers who previously received approval from a departmental ethics committee, should consult first with the ethics committee to determine whether changes should be reviewed by the ethics committee.

COVID-19 changes that require IRB approval (these apply to all research, not just research involving in-person data collection):

A *Change of Protocol Form* must be submitted for IRB review if you alter study conduct. Examples of changes that require IRB approval include, but are not limited to:

- Elimination of study procedures
- Changes to study procedures
- Change in the frequency of procedures
- Changes to the type of research data being collected
- Changes to data collection/analysis location (i.e., off-campus data collection or analysis that was originally proposed to be conducted on-campus)
- Using a remote process to consent or re-consent, in some circumstances (see **Obtaining consent through remote means** section below)

The IRB recognizes that study teams must always prioritize safety for participants and these changes may need to be implemented prior to IRB submission. However, study teams are asked to submit these changes for IRB review/documentation within at least 60 days after implementation. Changes that do not require IRB approval should be submitted to the IRB via a Project Update Form. In describing changes,

- Please specify whether the protocol changes are temporary, during response to the pandemic, or permanent changes to study conduct.

Below is sample text that could be used to update/revise your protocol:

For transition from in-person to remote data collection:
During the COVID-19 pandemic, we will modify this protocol to conduct virtual study visits. We will employ [***cite the technology and methods you plan to use, as well as steps to ensure participant confidentiality.***]

As applicable:
Study visits will be altered as follows: [***provide description***]

The following data points will not be collected during this time: [***provide description***]

In order to ensure subject safety and welfare we will [***provide description***]

In order to address data integrity issues, we will: [***provide description***]

Obtaining consent through remote means:
In response to the pandemic, many study teams are switching their consent process from an in-person interaction to obtaining consent through remote means. For consent forms that require a signature, investigators must follow the IRB's remote consent protocol below.

A Change of Protocol Form must be submitted for IRB review and approval is required with implementation of a new consent process in the following circumstances:

- If the protocol or consent form explicitly describes an in-person consenting process, such as noting that informed consent will be obtained during a research lab visit, then a Change of Protocol Form must be submitted to update those documents.
- If a study sponsor distributes a memo instructing study teams to obtain informed consent remotely, then a Change of Protocol Form must be submitted including the memo and other revised documents.

It is the research team's responsibility to review study documents to determine whether an IRB modification is needed. The modification for remote consent may be combined with other changes.

If the protocol and consent form do not specify that informed consent will be obtained in person, then study teams can follow the protocol outlined below for remote data collection in a Project Update Form. If the protocol for obtaining consent remotely below must be altered, the alterations and rationale for the alterations must be described.

Remote consent protocol: Zoom or any remote video data collection should require a password to minimize the risk that the meetings can be hacked. Researchers should inform the participants of the potential risk for a breach of confidentiality. For example, “There is the potential that the video meeting might be hacked, but we believe that the steps we have taken protect you makes this risk small”.

If the study is minimal risk (i.e., Exempt or Approved via Expedited Review), oral consent may be obtained by the researcher after explaining the consent form, allowing the participant to ask questions, and confirming that the participant understands what they are being asked to do and their rights as participants. The consent process should be recorded, regardless of whether the study data collection is recorded, and stored in a secure location. participants should be informed that consent will be recorded prior to beginning the consent process. If the video session is to be recorded, the participant must be informed of this, and must provide explicit consent. All recordings should be stored in a secure, password protected location. The investigator must explain how consent will be obtained, and how confidentiality will be protected.

For studies that have received (or will receive) Full IRB review and approval and for other forms of remote data collection (for example, phone interviews), researchers may email the consent form in advance of the session, then review it live during the session and ask the interviewee to return it via email with a message confirming consent. Researchers may also submit a Change of Protocol form requesting an exemption from this consent process, if it is believed that the process will have a negative impact on their research. The IRB will review these requests and make a determination as to whether an exemption will be granted.