Wayne State University
Institutional Review Board (IRB)

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The Coronavirus/COVID-19 Pandemic:
IRB Submission Guidance

The IRB Administration has provided this guidance to consolidate the IRB's changing requirements and other outside guidance available to help researchers make revisions or complete new research applications to address the Stay Home Stay Safe mandate

IRB Updates:

It is important for investigators to stay informed during this time as the status of the outbreak in Michigan and Detroit continues to evolve. Our leadership meets regularly to share the latest guidance available, and make sure we are prepared to respond to needs of our researchers as the state and federal recommendations change.

The IRB is communicating updates to our research community through our Coronavirus website, listserv and through weekly webinars.

- Check out our Coronavirus website and Coronavirus FAQ's
- To sign up for the listserv to receive email updates, send an email request to wsuirbinfo@wayne.edu
- Weekly Webinars take place every Tuesday at 10:30am through Go-To-Meeting. To register, send an email to wsuirbinfo@wayne.edu

IRB Requirements for Protocols Pertaining to COVID-19 Research

The IRB is prioritizing the reviews of protocols pertaining to COVID-19 research.

There are many challenges to researching a public health crisis like COVID-19. It is important for investigators to remember that while the demand for knowledge is extremely high and urgent, we must not take shortcuts that could put participants at risk, or compromise the quality of the research. As the IRB prioritizes the review of COVID-19 research, we will continue to hold investigators to the same high standards for safe, equitable and compliant research that we always have.

We have been quickly responding to challenges that are coming up as investigators prepare COVID-19 research protocols. The following guidance is provided to help the researcher know what aspects of their study they should consider revising and recommendations for new submissions.

Submitting an Amendment

Completed Amendment Form

- The amendment form should be completed in entirety answering the applicable questing regarding modifying study procedures, recruiting, and consenting practices. Indicate for the amendment form that the submission is a COVID-19 modification per the form's instructions.

Study Procedures new/updated:

- Description of your consenting and/or recruiting procedures
- Description of your study procedures
- These descriptions should be updated for your study proposal/protocol document
- Make remote activities as an addition to your previously approved research activities to address the social distancing and remote work mandate. It should not be a total replacement of previous study procedures unless the study will completely transition to become remote.

Consenting/Assenting updated:

- Research Informed Consent (if applicable)
- Research Information Sheet (if applicable)
- Oral Consent Script (if applicable)
- Assenting documents (if applicable)
- Requesting a waiver of written documentation of consent if not previously requested for use of an Information sheet or oral consent.

Data Collection new/updated:

- Surveys/Questionnaires (if applicable)
- Telephone Scripts

Addendums/Appendices

If Recruiting, Consenting, or Obtaining data using the internet submit:

- Internet Use in Research Addendum for eProtocol
- Appendix B Internet Use in Research (for non eProtocol submissions)

CITI Training

- If using the internet for recruitment or data collection the Internet CITI training modules should be completed by key personnel

New Submissions What to Consider

- Required CITI Training completed by all key personnel
- Remote Recruitment Procedures
- Remote Consenting Practices
- Burden on the population
- Burden on the Healthcare System
- Confidentiality
- Researchers access if there are restrictions to reduce exposure to contagion

Investigators conducting clinical therapeutic research pertaining to COVID-19 should review the

FDA guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic

Electronic Consent:

- Informed consent can be obtained electronically when a waiver of documentation of informed consent is not an option. Electronic informed consent must be documented in a way that is legally valid. Electronic signatures must verify the signer's identity in order to be accepted.

- The submission must include a description of the process for electronically documenting consent and verifying the signer's identity.
    - Some common electronic authentication methods to verify the signer's identity include:
        - Email
        - Corporate ID
        - Password Protection
        - Pin sent to mobile phone
- All other requirements of informed consent apply

How to submit

New/Initial: non-VA submissions, submit using eProtocol. In eProtocol for the "**Protocol Checklist"** select "COVID-19 focused"

VA Full Board Protocols:

Please email all the protocol documents (see Protocol Summary Form for detailed list) to the assigned VA reviewing IRB

M1board@wayne.edu	B3board@wayne.edu

Non eProtocol Full Board Amendments, Expedited Amendments, Continuations, & Unanticipated Problem (UP)reports: Please email all to: eIRBManager@wayne.edu

*Please note: **All** UP reports including eProtocol must be emailed to*: eIRBManager@wayne.edu

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