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| **NEW WSU LOGO** | **IRB Policy and Procedure** |

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| **Wayne State University**  **Institutional Review Board** | |
| **SUBJECT** | 4-19 Public Health Crisis Emergency Response |
| **Approvals** | Administrative, Office of General Counsel & IRB Committee Approval: 04/2020 |

**Background**

Research operations may be impacted in many different ways when a Public Health Crisis affects the local community. When the IRB learns of a public health crisis that may impact standard operating procedures, leadership teams will come together to draft various contingency plans to prepare for any potential disruptions in standard operating procedures.

**Considerations for Ongoing Research**:

1. Whether the research involves in-person contact with participants.

2. The locations and facilities where research activities take place.

3. The prevalence of the contagion and the risk of exposure both due to geographical location and the facility types (e.g., hospitals, clinics, schools, etc.).

4. Any requirements or restrictions that have been or may be put into place at a national, regional, organizational or facility level and how these impact the research (e.g., travel restrictions, school closings, remote work mandates, etc.).

5. The study population and their risk profile.

6. The risk profiles of investigators and staff, and their likely availability.

7. The possibility and likelihood of investigators, staff, and supplies or equipment being diverted to meet a critical need.

8. Whether there are opportunities to conduct certain research activities remotely (e.g., telemedicine, videoconference, phone, electronic surveys) or in alternative settings (e.g., at an outpatient phlebotomy center vs. a hospital-based center).

9. Whether investigational product and any subject materials may be delivered directly to participants rather than having them come on-site.

10. Whether and how any interruptions in standard care will impact the research.

11. Whether there are opportunities to coordinate research activities (e.g., safety assessments) with other essential patient care visits.

10. Whether all or a subset of research activities may be safely paused.

11. The necessity or importance of continuing the research during the public health crisis (e.g., is the research essential or non-essential)

12. The risks of exposure (for all) compared to the potential for benefit.

13. The availability of emergency medical services.

**U.S. Regulatory Considerations**:

1. Modifications to research may not be implemented until the proposed changes have been reviewed and approved by the IRB, unless the change is necessary to eliminate apparent immediate hazards to the participant(s).

2. Reporting of modifications made to research to eliminate apparent immediate hazards to the participant(s).

3. Whether and how the public health risk itself and any proposed modifications to research impact the criteria for approval, for example:

a. Whether risks to participants remain minimized by using procedures that are consistent with sound research design and that do not unnecessarily expose participants to risk; and, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.

b. Whether risks to participants remain reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.

c. Whether the research plan continues to make adequate provisions for monitoring data to ensure the safety of participants.

d. Whether the research plan continues to provide adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.

3. Informing participants of information that may impact their willingness to continue participation (such as any changes to their risk and any changes to research procedures).

4. Prompt reporting and management of health crisis unanticipated problems involving risks to participants or others.

**IRB Procedure**

In the event of a public health crisis, the IRB’s policies and standard operating procedures may be modified as appropriate for the situation. Such modifications may include alternative meeting procedures, alternative procedures for the submission and review of modifications, alternative procedures for prompt reporting, and any other changes necessary to ensure appropriate ongoing oversight and conduct of research.

Because procedural modifications may vary based on the nature of the event, these cannot be anticipated and described in the IRB policies. Instead, such procedural modifications will be documented and communicated to the research community. This documentation will be maintained in accordance with applicable record retention requirements.

For documents which normally require wet signatures, the IRB Administration Office will accept and allow for digital signatures and/or other communication (email from signatory) to affirm a submitter and/or reviewers' identity.

**Pandemic Response:**

When the federal, state, or local government issues recommendations and restrictions to reduce the spread of the contagion, the IRB, in line with the University directive, will implement an appropriate contingency plan to reduce the risk of infection to research participants, researchers, IRB administrative staff, and IRB members.

Research activities that involve face-to-face interactions without any direct therapeutic benefit to research participants will be restricted. These restrictions will be communicated to investigators and research community via the IRB webpage and through listserv email notifications.

**Research Activity Modification Reporting Requirements:**

When the mandated restrictions apply to research activities that involve face-to-face interactions without a direct therapeutic benefit to research participants, investigators should consider the impact on all active ongoing research.

Any modification made to an IRB approved research protocol as a result of mandated restrictions will need to be reported to the IRB as an amendment. Modifications to research may not be initiated until the proposed changes have been reviewed and approved by the IRB, unless the change is necessary to eliminate an apparent immediate hazard to the participants.

If a modification must be initiated before the IRB approval to eliminate an apparent immediate hazard to the participant, the modification must be reported as an Unanticipated Problem to the IRB.

If study accrual/enrollment is put on hold due to a public health crisis/pandemic (but not due to research-related risks or safety concerns) by the Principal Investigator or Sponsor, then notification to the IRB may be submitted to the IRB at the next routine amendment submission and also indicated at the next continuation.

If study accrual/enrollment is put on hold due to research-related risks or safety concerns by the Principal Investigator or Sponsor, the notification should be reported to the IRB as an amendment in a timely manner. An Unanticipated Report and Event form may be required, if applicable.

If investigators suspect that a participant or the investigators or staff were exposed to the contagion during a research visit, an Unanticipated Problem Report must be submitted to the IRB as soon as possible. The corrective action plan should include the plan for notifying all participants and individuals who were potentially exposed.

**Reviewing Research Protocols Investigating a Public Health Crisis:**

During an active public health crisis, the IRB will prioritize the reviews of all research pertaining to the health crisis.

IRB members reviewing such protocols should consider the following:

* Consent considerations
  + In cases where a Legally Authorized Representative is required, and cannot sign in person, exceptions can be made to allowing Legally Authorized Representative to consent over the phone when potential participant is quarantined, or visitation restrictions will not allow an LAR to be physically present to obtain consent.
  + When a waiver of documentation of consent is not permissible, alternative mechanisms (instead of exchanging a paper consent form) can be considered. Applicable regulations will need to be considered. For example, it may be acceptable for consent forms to be faxed, scanned, or photographed. The requirements for a valid consent process still apply (e.g., the opportunity to consider participation and to ask and have questions responded to).
* Burden on the population
  + Responding to a public health crisis requires research to quickly develop new tests, treatments and vaccines to control the spread of the contagion. Potential participants may become overwhelmed by research opportunities. This may place an added burden on the population which should be considered. The number of incoming protocols related to the public health crisis and the number of ill participants should be understood when assessing a potential burden to the population.
* Confidentiality
  + Regulating agencies may issue enforcement discretion or temporary waivers of certain requirements to ensure that providers may exchange information appropriately during a public health emergency. Investigators and staff must at all times take appropriate steps to ensure the confidentiality of research information but may need the flexibility to share information that they otherwise would not during a public health emergency within the parameters of the guidelines issued by agencies, any involved healthcare facilities, and the University.
  + Consideration must be given to the privacy and confidentiality during the consent process
  + Consideration must be given to the confidentiality of the participant’s own infectious diagnosis within the data collection documents.
* Burden on the healthcare system-
  + When the healthcare system is faced with the increased demands of a public health crisis, the burden of the additional interventions that may be required by a research protocol should be considered including the consumption of resources, supplies, and equipment.
* Researchers access to the participant if there are restrictions to reduce exposure to contagion.
  + When essential research is being done on a population infected with a highly infectious contagion, the researchers interacting with participants must have access to the area where the participant is being cared for outside of the context of the research. Researchers should also be a part of the participant’s care team, so as to not add unnecessary exposure to the infectious contagion and must observe all precautions to avoid exposure.

**Informed Consent During a Public Health Crisis:**

**Participant**

During a public health crisis, a “remote” informed consent process such as a telephone/tele-video conferencing discussion in conjunction withan informed consent document (that is sent to the participant, signed, and transmitted back to the site investigator by mail, fax, secure email or secure messaging app) and signed by the consenting investigator/research staff before any research procedures begin, may be used.

**Legally Authorized Representative (LAR)**

When potential participants are in isolation and require a Legally Authorized Representative (LAR) to consent on their behalf, there may be challenges in obtaining the LAR’s physical signature due to the facility’s visitation restrictions or the LAR themselves being quarantined.

When investigators are faced with these challenges, the IRB will allow the LAR to consent by telephone/tele-video conference in conjunction withan informed consent document.

Remote LAR Consent Process:

* The confirmation the LAR’s identity and relationship to the participant must be documented in the research record.
* The LAR is provided an informed consent document that has been transmitted to the LAR by mail, fax, secure email or secure messaging app.
* The investigator/research staff will read and review the consent with the LAR by telephone/tele-video conference.
* Two individuals, who are able to physically sign the consent document, must act as witnesses to the telephone/tele-video conference with to the LAR. Each witness must sign the informed consent form. Witnesses must have access to the participant under the contact isolation restrictions.
* The LAR should sign the consent form and return an image of the signed page (e.g. by fax, secure email or secure messaging app).
* The use and the reason for an alternative consent procedure is documented in the research record.

All other requirements of informed consent apply.

See WSU IRB Policy:

* 9-1: Requirements of Informed Consent.
  + - 3.1 – Written Informed Consent
      * 3.1.1 – Written Informed Consent via Fax
      * 3.1.2 – Obtaining Informed Consent via Mail
      * 3.1.3 – Electronic Consent
* 9-2: Informed Consent Involving Non-English Speaking Participants
* 9-3: Informed Consent Process
  + - Electronic Consent