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

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| **Wayne State University****Institutional Review Board** |
| **SUBJECT** | 4-19 HRPP Emergency Preparedness Response: Continuing protection of research participants during emergencies (Previously titled Public Health Crisis Emergency Policy) |
| **Approvals** | Administrative, Office of General Counsel & IRB Committee Approval: 04/2020, IRB Approval 11/2024 |

**Background**

Although relatively infrequent, emergencies and disasters of all types can occur and have a devastating effect on institutional operations that in turn also affect research operations. Every institution and individual department is responsible for responding appropriately to any emergency and to ensure a timely and efficient resumption of research activities after the emergency or disaster.

To ensure that research participants are protected from research-related harms during an emergency or disaster, it is essential that the HRPP be able to function in its protective capacity throughout any disruptions caused by an emergency or disaster. Examples of the research activities that must be protected and/or modified to ensure the safety and welfare of research participants include but are not limited to:

* Participants in clinical trials may need to continue their investigational interventions (drug, device, behavioral) or receive an alternative intervention to assure their safety and well-being,
* Research plans may require a pause in enrollment activities
* Research activities may need to be modified to be conducted remotely.

The Wayne State University Human Research Protection Program (HRPP) is committed to the protection of the rights and welfare of research participants during both normal and emergency operations. The procedures described in this policy are intended to assist in:

* maximizing the effectiveness of the HRPP’s response to emergencies and disasters;
* ensuring HRPP operational continuity to the extent possible throughout the emergency or disaster; and
* protecting research subjects and efficiently recovering from disruptions from emergency situations.

**Related Policies**

* 4-5 Expedited Review Procedures
* 4-7 Continuation/Renewal of Protocol
* 4-6 Amendments to the Research Protocols and Informed Consent
* 5-1 Expectations of IRB Membership
* 5-2 Selection and Review of IRB Members and Staff
* 11-1 Research and Expanded Access involving Investigational Drugs
* 11-3 Emergency Single Time Use of a Test Article (Drug, Biologic, Device)
* 13-1 Unanticipated Problems and Other Reportable Events
* 13-2 IRB Reporting Unanticipated Problems, Suspensions and Terminations, Serious & Continuing Non-Compliance

**Definitions:**

*Essential Services:* Activities that:

1. Are necessary to preserve lives;
2. Maintain the physical infrastructure, or
3. Continue essential business services until an emergency has abated.

*Critical Services:* Activities that:

1. Define the institution such as teaching and research; and
2. support services that make teaching and research possible.
3. **HRPP Emergency Preparedness Plan:**

The HRPP Director and the Associate Vice President of Research (AVPR)/Institutional Official (IO) are responsible for developing and maintaining the HRPP emergency preparedness, continuity, and recovery plan. The overall plan is intended to cover a worse-case scenario, however, only the components of the plan that are required for the specific emergency will be implemented. The HRPP emergency preparedness plan will coincide and coordinate with [the Wayne State University Division of Research Office of Environmental Health and Safety Emergency Contingency Plan](https://research.wayne.edu/oehs/hazardous/emergency-plan) and the WSU Emergency and Safety Procedures.

The HRPP Emergency Preparedness Plan contains the following:

* + This policy,
	+ IRB Continuity of Operations Plan (COOP)
		- Essential Services & Critical Functions,
		- Essential internal and external service providers,
		- Mitigation Strategies,
		- Key Contact List,
		- Contingent Decision Makers,
		- Location of Vital Records,
		- Critical Hardware/Software,
	+ Division of Research Office of Environmental Health and Safety Emergency Contingency Plan
	+ WSU Emergency Safety Procedures
	+ IRB Administration Office Phone Tree
	+ Each Committee Roster contact list

**1.1 Accessibility of the HRPP Emergency Preparedness Plan:**

To ensure all IRB Staff and members are able to easily access the HRPP Emergency Preparedness Plan to refer to in the event of an emergency:

* An electronic copy of the HRPP Emergency Preparedness Plan is posted on Canvas or a central electronic platform where it is available to all IRB staff and IRB Members .
* A paper copy of the HRPP Emergency Preparedness Plan is available within the IRB Administration office.
* Members will be notified of the plan annually and informed of the location of the plan.

**2.0 Wayne State University Emergency and Safety Procedures**:

An electronic version of the WSU Emergency and Safety Procedures is available on the Enterprise Risk Management and Insurance Programs (ERM) website at <https://risk.wayne.edu/procedures>

This has been developed by the ERM to help Wayne State employees and students residing on campus minimize the negative effects from emergencies, disasters, accidents, injuries and crimes that can occur without warning. It contains emergency phone numbers on the cover of the chart, and there are written procedures for the following:

* + Civil disturbance
	+ Water damage/loss
	+ Safety procedures
	+ Tornado/severe weather
	+ Explosives
	+ Power outage
	+ Biological/radioactive spills
	+ Crime prevention tips
	+ Bomb threats/suspicious packages
	+ Medical emergencies
	+ Fire
	+ Workplace violence
	+ Chemical spills/chemical fires
	+ Evacuation

**3.0 IRB Continuity of Operations Plan (COOP):**

The Wayne State University Human Research Protection Program (HRPP) and IRB maintain a Continuity of Operations Plan (COOP) that outlines the essential services and critical functions of the HRPP and IRB that are to be prioritized and maintained in an emergency situation. The IRB COOP identifies each essential service and critical function and lists the individuals responsible for maintaining each essential service and critical function. The IRB COOP designates a primary, alternate and second alternate individual responsible for each essential service and critical function.

The HRPP Director and AVPR/IO are responsible for updating the IRB COOP annually.

**3.1 Essential Services and Critical Functions**

The HRPP/IRB provides essential services and critical functions guided by the mission of the HRPP that must be prioritized and continued to the extent permitted by the unique challenges and limitations faced by the emergency.

**3.1.1 IRB Essential Services:**

1. **Protection of human participants enrolled in research:**
	* + The WSU IRB informed consent templates include the contact information for the Wayne State Research Subject Advocate so that research participants can contact the Subject Advocate with questions and concerns related to the research.
		+ The phone line, 313-577-1628, will be forwarded and monitored by the designated IRB staff member.
2. **Management of the Emergency Use of a Test Article requests**
	* + The emergency use of a test article (drug, biologic or device) may be required during this time.
		+ The request for an emergency use of a test article (drug, biologic, or device) will be processed as per IRB policy 11-3: Emergency Single Time Use of a Test Article.

**3.1.2 IRB Critical Functions:**

1. **Management of the review and approval of research protocols by the IRB, including expanded access protocols.**
	* Maintaining IRB Staff functions:
		+ The designated individual for maintaining critical functions will communicate with IRB staff regularly and adapt plan according to functioning resources available at the time.
	* In the event IRB staff are not able to report to their office, IRB staff will follow the current “work from home” standard operating procedures. IRB Submissions:
		+ - Assuming internet service is not disrupted, the IRB staff and reviewers will use the electronic platforms per the usual process from their remote location.
			- In the event internet service is disrupted, manual documentation of IRB activities will be conducted. Hard copies of IRB forms and submission requirements will be available in-person at the IRB office location. All manual documentation will be integrated to the appropriate electronic files when internet service is restored.
	* IRB Meetings:
		+ - Assuming internet service is not disrupted, the IRB meetings will continue to be convened virtually using the Wayne State University Enterprise Zoom license as described in IRB policy 05-01: Expectations of IRB Membership.
			- If internet service is disrupted, the IRB may conduct meetings via teleconference as described in IRB policy 05-01: Expectations of IRB Membership or in person at the IRB office or designated secure off-site location.
		+ Rapid turnaround of IRB review:
			- The IRB may call an ad-hoc meeting to facilitate review of novel test article research protocols, including expanded access protocols that provide investigators with important information to address the public emergency such as a public health crisis, or to provide rapid approval of potentially life-saving investigational or expanded access treatment for patients (See IRB Policy 5-1: Expectations of IRB Membership; [11-1 Research and Expanded Access Involving Investigational Drugs](https://research.wayne.edu/irb/docs/11-01-research-and-expanded-access-involving-investigational-drugs-update-82024.docx), IRB policy [11-2 Approved and Unapproved Devices in Research](https://research.wayne.edu/irb/docs/11-02-approved-and-unapproved-devices-in-research_10_2019.doc) & IRB Policy [11-3 Emergency Single Time Use of a Test Article (Drug, Biologic, Device)](https://research.wayne.edu/irb/docs/doc144_policy_11-03_emergency-single-time-use-of-test-article_11_2019.doc)
2. **Management of unanticipated problems and adverse events**
	* The unanticipated problem and adverse event reporting will be managed per IRB policies 13-1: Unanticipated Problems and Other Reportable Events, and 13-2: IRB Reporting of Unanticipated Problems, Suspensions and Terminations, Serious and Continuing Non-Compliance.
	* The reports will be emailed to the IRB Associate Director for review and processing.

**3.2. Key Decision Makers:**

The IRB COOP lists the individuals responsible for making key operational decisions and the contingent decision makers when the head of operations is absent.

* Head of Operations: AVPR
* First Successor: HRPP Director

Second Successor: Associate IRB Director

**4.0 Emergency Communication Plan**

All investigators and staff are responsible for keeping informed of emergencies by monitoring media reports and keeping informed through the University’s main website, the Division of Research & Innovation website as well as the IRB website. To rapidly communicate with employees in an emergency, the IRB maintains a phone tree that is updated annually. The IRB Phone tree containing individual contact information is stored in a secure location that is easily accessible by all staff and confidential. (See section 8 of this policy: Phone Tree Appendix).

Assuming that cell phone coverage is intact, communications will be conducted using cell phone service and the call tree. Anticipating that the volume of cell phone calls will increase during an emergency, for less emergent calls, the plan may also include specified call times to attempt to communicate at times where call volumes are expected to be lower (e.g., early or late in the day).

Assuming that cell phone coverage and internet service will be disrupted, the plan will also include other methods of contacting HRPP/IRB and key organizational staff. These methods might include meeting in-person at off-site locations at specified times. If phone and internet services are disrupted, emergency announcements will be publicized through WDET-FM Public Radio 101.9 and by local radio and television stations.

**4.1 Phone Tree Procedure:**

To ensure effective and timely communication during an emergency or disaster, the HRPP Director and IRB Associate Director will maintain the IRB “phone tree” that is a hierarchy or “tree” of people in which each person calls and forwards a message to the next person down the tree. For example, the AVPR is listed at the top of the call tree and calls the person below them on the tree, and so on. The “tree” can be branched for efficiency and expediency to reduce the number of calls any single person is required to make and assist in getting everyone notified as quickly as possible. If a person on the list does not answer, the caller skips to the next person on the tree to ensure that as many people as possible are contacted. The caller should go back and attempt to contact any individuals on the call list who did not answer the first time. The last person(s) on the phone tree contacts the first person on the phone tree to confirm that the phone calls/messages went through the entire phone tree. This assures that all individuals on the tree receive the communication. See section 8 of this policy: Phone Tree Appendix for details about the structure of the IRB phone tree.

**4.1.1 Periodic Phone Tree Test**

The HRPP Director is responsible for assuring that the phone “tree” is updated on a regular basis . Individuals can be added or removed as necessary to represent the most current staffing. The HRPP Director will test the phone tree at least annually to assure that all individuals are available at the numbers listed. In order to assure a more realistic assessment of the phone tree, tests may not be announced. All individuals on the tree should have immediately available to them, a copy of the tree in the event a test is initiated, or an actual emergency occurs.

**4.2 Key Contact List:**

When the IRB learns of an emergency that may impact standard operating procedures and research operations, key emergency contacts listed in the IRB COOP will come together to assess the risks particular to the emergency being faced and draft various contingency plans guided by this policy to prepare for any potential disruptions in standard operating procedures.

The IRB Continuity of Operations Plan (COOP) contains a list of key emergency contacts and their contact information to aid in communication and coordination during an emergency. The list includes cell phone numbers assuming that the contacts may not be able to be on-site during the emergency. The list includes:

* HRPP and IRB staff and Institutional Official
* Information technology staff that support the HRPP/IRB systems

**5.0 Maintaining IRB Operations Essential to Protecting Research Participants:**

The WSU IRB relies on several IRB application & management systems to conduct business. Convened Full Board meetings are primarily conducted virtually. If an emergency event such as a widespread power outage or cyber-attack impedes the IRB’s ability to conduct business that is essential to protecting research participants, the IRB office will adjust procedures as needed to adapt to the limitations and focus operations on the IRB’s essential services and critical functions. This may require working remotely, changing the format of the IRB meeting to a teleconference, or meeting in-person in the IRB Administration office or at a safe off-site location (See IRB Policy 5-1 Expectations of IRB Membership).

It is likely that normal operations will not be possible during an emergency and adjustments to HRPP/IRB operations will need to be made. The HRPP will inform stakeholders (staff, organizational officials, researchers, etc.) as to what the adjustments will or might be, how emergency operations will be conducted during an emergency or disaster and the potential impact of implementing the COOP. The HRPP/IRB will communicate emergency procedures and HRPP/IRB operations changes with researchers through list serv email announcements, virtual IRB Update webinars and updates on the IRB website. As much as possible, the emergency or disaster will be “triaged” to determine the types and extent of adjustments that must be made. There can be many possibilities. For example:

* In a severe emergency with significant infrastructure loss or disruption, suspension of new protocol submissions and/or review and execution of new contracts, except in extraordinary circumstances, will likely be required, however, continuing review and amendment requests, unanticipated problem reports and other time-sensitive reviews will have to be accepted and processed to assure that protection of research subjects is not interrupted.
* To be as efficient as possible, an appropriate committee’s ad-hoc process will be implemented per IRB policies 5-2 Selection and Review of IRB Members and Staff, 5-2 Selection and Review of Institutional Review Board Members and Staff and 5-4 Selection of Alternative IRB Member for Duly Constituted Meeting.
	+ IRB meetings may be conducted face-to-face, by tele- or videoconference or by a combination or all three but may change from meeting-to-meeting due to loss or restoration of internet and phone service (See IRB Policy 5-1 Expectations of IRB Membership).
* For studies with investigational drugs, Investigators will need to make arrangements as to where the drugs should be shipped (alternate pharmacy) and how investigational drugs will be stored (refrigeration available, locked area for controlled drugs, etc.) and segregated (separate location from non-investigational drugs) at the alternate location, how security at the new location will be assured, how the drugs will be dispensed to research subjects and other functions that assure FDA regulatory compliance relating to receipt, storage, dispensing and accountability are in place and appropriate (see IRB policy 11-1 Research and Expanded Access involving Investigational Drugs).
* In the event of infrastructure destruction or loss of operational capability or in the interest of staff safety, IRB and other HRPP activities may need to be relocated to sites in other areas of the institutional facilities or remote from institutional facilities. Advance arrangements must be in place that assures site availability so several contingent sites may need to be identified. The sites should have appropriate security, HVAC, electrical power, water, internet service (if possible) and be easily accessible, if in-person operations are required. Consult with the WSU Office of Environmental Health and Safety (OEHS) to identify a safe alternative location to operate: OEHS Phone: 313-577-1200; email: oehs@wayne.edu; Website: www.oehs.wayne.edu.
	+ All essential IRB records are stored on a server used for day-to-day operations that is not at the organization’s physical location and are backed up at least daily via WSU IRB’s encrypted server (COEUS) or the cloud-based electronic IRB submission and management platform- eProtocol.
	+ All IRB staff have secure access to electronic files through the WSU Virtual Private Network (VPN) to allow access to essential records from home or another remote location.

### 5.1 Training of HRPP staff on the Emergency Preparedness Plan:

To assure that all HRPP staff are aware of what might be required of them during an emergency or disaster, annual training will be provided and may be required for specific individuals. Training will include how normal operations could be affected, the adjustments that may have to be made and specifically how operations may have to be carried out during the emergency or disaster. The training will be developed and conducted by the HRPP Director or IRB Associate Director.

## 5.2 Continuity:

To assure continuity of operations as much as possible, the emergency preparedness plan will be followed to the extent required to assure continued HRPP/IRB operations and assure that subjects remain protected. Modifications to the COOP and/or implementation of temporary HRPP/IRB Standard Operating Procedures may be required as emerging conditions develop.

As mentioned in Section 5.0, IRB continuing reviews, amendments and unanticipated problem reports will be processed and reviewed so that approval for research studies does not lapse and that human participant research protections remain in place. Reviews may be conducted through an expedited process, when applicable, or through review at a convened meeting of the IRB (See IRB Policy 4-5 Expedited Review Procedures & 4-7 Continuation/Renewal of Protocol).

**6.0 IRB COOP Plan Input:**

The AVPR/IO of Research Integrity in conjunction with the Vice President of Research for the Division of Research and Innovation will review and modify the COOP plan according to the University’s emergency requirements.

**7.0 Public Health Crisis Emergency Response:**

**7.1 Considerations for Ongoing Research**:

* Whether the research involves in-person contact with participants.
* The locations and facilities where research activities take place.
* 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.).
* 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.).
* The study population and their risk profile.
* The risk profiles of investigators and staff, and their likely availability.
* The possibility and likelihood of investigators, staff, and supplies or equipment being diverted to meet a critical need.
* 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).
* Whether investigational product and any subject materials may be delivered directly to participants rather than having them come on-site.
* Whether and how any interruptions in standard care will impact the research and participant safety.
* Whether there are opportunities to coordinate research activities (e.g., safety assessments) with other essential patient care visits.
* Whether all or a subset of research activities may be safely paused.
* The necessity or importance of continuing the research during the public health crisis (e.g., is the research essential or non-essential).
* The risks of exposure (for all) compared to the potential for benefit.
* The availability of emergency medical services.

**7.2 Public Health Crisis: 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:
				1. 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.
				2. 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.
				3. Whether the research plan continues to make adequate provisions for monitoring data to ensure the safety of participants.
				4. Whether the research plan continues to provide adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
			4. Providing participants with any information that may impact their willingness to continue participation (such as any changes to their risk and any changes to research procedures).
			5. Prompt reporting and management of health crisis unanticipated problems involving risks to participants or others.

**7.3 Public Health Crisis: 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 and protection of research participants.

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.

**7.3.1 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 comply with all applicable federal, state, and local recommendations and restrictions to reduce the risk of infection to research participants, researchers, IRB administrative staff, IRB members and the community.

Research activities that involve face-to-face interactions without any direct therapeutic benefit to research participants may be restricted to protect the community and focus IRB operations on essential services and critical functions. These restrictions will be communicated to investigators and research community via the IRB webpage and through listserv email notifications.

**7.3.2 Public Health Crisis: 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 (See IRB policy 13-1: Unanticipated Problems and Other Reportable Events).

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.

**7.3.3 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 a 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.

**7.4 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

**8.0 Phone Tree Appendix:**

Note: This is not an organizational chart. This serves solely as a phone tree for emergency situations only as a part of the HRPP/IRB emergency preparedness plan.

IRB Training Coordinator

IRB Student Assistant #2

IRB Student Assistant #1

RCA #4

RCA #3

RCA #2

RCA #1

Assigned Committee Chair

Senior Research Compliance Administrator (RCA)

IRB Associate Director

IRB Program/Project Assistant

IRB Coordinator

HRPP Director

AVPR or designated successor- see section--- of this policy

Research Assistant

External IRB Reviewer

 **Note**: Dotted lines signify the return call to notify the designated individuals at the top of the phone tree that the branch of calls has been completed.