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1.0   Executive Summary

The Yale University Human Research Protection Program (HRPP), Business Continuity Plan (BCP) addresses the necessary actions required to conduct essential functions of research involving human subjects and to resume normal operations as quickly and efficiently as possible after an emergency, disaster, or other business interruption.   Yale University (Yale) has determined the requirement for a HRPP BCP that includes:

- Assisting in and supporting the overarching responsibility of Yale to assure protection and well-being of individuals who participate in research.
- Continuing support of research efforts that will provide innovative, potentially life-saving interventions (drugs, biologics, devices) and knowledge to the general public.
- Assuring continued funding support of essential research.

The HRPP BCP is intended to be as broad as possible so as to mitigating the effect of an emergency or disaster on the HRPP and research operations at Yale.

The Yale administration requires the active cooperation and commitment from all HRPP components and staff in the preparation and maintenance of this plan. The HRPP BCP is part of overall job responsibilities at all levels, and therefore necessary training will be provided in order to support the plan

Yale Senior Leadership support the HRPP BCP in the promotion of diligent mitigation and efficient response as well as maintaining and resuming business operations to the community as soon as possible after an emergency.

2.0 Importance, Purpose, and Scope of the Plan

2.1 Importance

A Business Continuity Plan (BCP) is a description of resources, actions, procedures, and information that is developed, tested, and held in readiness for use in the event of a major disruption of operations. Some may not consider the HRPP to be a "business", however, Yale supports continuity planning for all components of the organization, including the HRPP. This BCP will be used to assist Yale in maintaining essential HRPP functions after a disaster or other major disruption. The HRPP BCP is intended to supplement and support the broader Yale's BCP. In the event of a major disaster or other disruption, this plan will minimize the impact to the HRPP and assist in returning to normal operations as quickly as possible.

2.2 Purpose

This document describes the actions to be taken in case of a business interruption, emergency, or disaster that is, or soon will be, disrupting HRPP operations. It describes and outlines the activities to be undertaken within the HRPP components for a broad set of possible emergency scenarios that could occur that would impede the operations of the HRPP.

The intent of the plan is to provide management and staff with guidance on how the HRPP components should respond to the various emergency situations and to outline the activities that must occur in order to ensure the continuance of operations. The BCP also includes provisions to work in concert with those involved with development and maintenance of the other key components of the Yale to assure coordination in the overall organizational response to an emergency or disaster.

2.3 Scope

The scope of this plan is to provide guidance and direction to HRPP components and staff in responding to an emergency or disaster that requires activation of this BCP. The plan is also intended to coordinate with the broader Yale BCP.

3.0   Hazard Analysis and Essential Functions

3.1   Types of hazards

Emergencies and disasters of all types can occur and have a devastating effect on institutional operations that also affect research operations. In any emergency, there are both individual department and institutional responsibilities to ensure timely and efficient resumption of research activities after the emergency or disaster.

For purposes of this BC-DP Plan, a business interruption is defined as a loss of utility and services, equipment failure, environmental disaster, or deliberate disruption that causes an expected or unexpected business interruption to one or more critical business functions. Specific examples, include, but are not limited to, the following:

Loss of Utilities and Services	Equipment Failure
Electrical Power Failure; Loss of gas supply; Loss of water supply; Petroleum and Oil Shortage; Communication Services Breakdown; Loss of Drainage/Waste Removal; Equipment or System Failure; Internal Power Failure; and Air Conditioning Failure.	Serious Information Security Breach; Cyber Crime; Loss of Records or Data; Disclosure of Sensitive Information; IT System Failure.
Environmental Disasters	**Deliberate Disruption**
Tornado; Hurricane; Flood; Snowstorm; Drought; Earthquake; Electrical Storms; Fire (appliance fires, small fires, and large fires); Landslides; Snow/freezing conditions; Contamination and Environmental Hazards; Epidemic/Pandemic; and Volcano.	Terrorism (e.g., bombing or other attack; chemical attack, radiological, biological, or nuclear attacks); Sabotage; War; Theft; Arson; and Labor Disputes.

Other situations that could impact a critical business functions include: (1) workplace violence; (2) public transportation disruption; (3) neighborhood hazard; and (4) health and safety issues.

3.2   Assessment of Essential functions

During an emergency or disaster, it may not be possible to continue all HRPP functions. Therefore, HRPP functions must be assessed and prioritized, and a plan implemented that allows continuity of essential functions. Depending on the event and its extent, other less essential functions may be possible. Priorities are categorized as follows:

Priority	Impact/Importance
High	Must continue at normal level. Pausing for more than 24 hours may result in increased risks to research subjects and/or HRPP operations.
Medium	Should be continued, if at all possible, but in a reduced mode. Stopping for more than a few days, a week, etc. could have major effects on subject safety, downstream problems for resumption of normal HRPP operations or regulatory compliance.
Low	Could be suspended for up to a month, two months, etc. without a significant effect on safety, resumption of normal HRPP operations or regulatory compliance.
Deferrable	Function could pause and resume when conditions permit without significant effects on subject safety, resumption of normal HRPP operations or regulatory compliance.

The following chart is an assessment and prioritization of Yale's HRPP functions:

HRPP Function	Priority	Reason for Priority
Submission of new IRB protocols	Medium to High	Review, approval, and commencement of new research proposals can be delayed and resumed when other HRPP functions return to normal UNLESS the new submission(s) is related to assessment and mitigation of the emergency; e.g., study and treatment of a dangerous infectious agent or is Therapeutic research.
Submission of continuing review requests.	High	This HRPP function must continue to assure subject safety and prevent lapses or approval that would cause cessation or research activities.
Submission of unanticipated problem non-compliance reports	High	This HRPP function must continue to assure subject safety and resolution of problems.
Submission of amendment requests	Medium to High	This would depend on the amendment's relationship to subject safety.
IRB review of submissions	High	This HRPP function must continue to assure subject safety and resolution of problems. A new IRB may be established, complying with minimal regulatory requirements, to assure the

HRPP Function	Priority	Reason for Priority
		ability for compliant convened meetings, when necessary.
Reporting to regulatory agencies	Medium	Stopping for a relatively short period of time is not likely to compromise subject safety, downstream problems for resumption of normal HRPP operations or regulatory compliance. Regulatory agencies and AAHRPP should, however, be contacted to notify them of the situation and possible effects on operations as required.
IRB files and electronic access	High	File access and security are critical to IRB/HRPP operations. Files must be accessible at all times in either a paper-based or electronic format.
Pharmacy access, storage, security, dispensing of and accounting for investigational drugs/biologics.	High	Subject access to investigational drugs should continue, if possible for subject safety. If access is interrupted, alternative treatment must be provided. Appropriate storage and security must be in place to assure integrity. This might require relocation to another site. Also, the ability to receive investigational drugs/biologics must be maintained throughout.
Sponsored program administration	Medium to High	Continuance of funding is essential to assuring subject safety and the ability to continue research activities.
Conflict of interest disclosures, review and management	Low to Medium	Review and management of financial disclosures should not have a significant effect on subject safety.
Research education and training	Deferred	Non-essential during an emergency or disaster.

4.0 Emergency Contact List (Call Tree)

The HRPP has established an Emergency Contact List ("Call Tree") which will be available prior to an emergency situation in order to assure effective communication and coordination. The HRPP Emergency Contact List ("Call Tree") (**Appendix A**) may include:

1. Institutional Official
2. Office of Research Administration Leadership
3. HRPP staff
4. IRB and other Committee Chairs
5. IRB and other Committee Members
6. Federal agencies and AAAHRP Contacts
7. Information technology staff that support the IRB/HRPP systems

The list will be updated on an ongoing basis and verified and tested annually by the [HRPP Director or designee. The list will contain more than one contact person for many of the emergency contacts to assure that communication can be assured as soon as possible.

The HRPP Director and other HRPP staff will keep a written (or other form of back-up) copy of the list in a location that can be readily accessed assuming that normal [internet, intranet] services will be lost.

5.0 Plan Activation

5.1   Assessing the emergency or disaster

The IO, HRPP Director will assess the emergency situation and determine whether activation of the Yale's BCP is necessary. If the Yale BCP is activated, the HRPP BCP will be activated to the extent necessary. Communication and coordination will be established with those involved with implementing the Yale's BCP. The HRPP Director or designee will be responsible for activating the HRPP BCP and communicating with HRPP components by predetermined methods (see below).

5.2   Communications

Internal communications will occur via one or more of the following methods:

HRPP Office Main Number

Use of this method of communication may not be possible depending on the specific emergency or disaster situation. If this method is available, the HRPP Director or designee BCP will leave a message on the main HRPP office telephone number to be used in the event of an emergency or disaster.

Email or some other web-based communication system (internet, intranet)

Use of this method of communication may not be possible depending on the specific emergency or disaster situation. If this method is available, the HRPP Director or designee will use email or some other web-based communication.

Organizational website

Use of this method of communication may not be possible depending on the specific emergency or disaster situation. If this method is available, the HRPP Director or designee will use the HRPP's website for communication.

Emergency Contact List (Call Tree)

The HRPP Director or designee will activate the Emergency Contact List ("Call Tree") (**Appendix A**). If the HRPP Director or designee are unavailable, the Assistant Director, HRPP Operations or designee will activate the Emergency Contact List and follow the following steps:

1. When an individual is contacted, that individual will call, text, and email the person below them on the list and so on until the last person is contacted.
2. If an individual does not respond, the individual should call, text, and email, the next person on the list.

3. The last person on the list calls, texts, and emails the HRPP Director and the person who activated the Emergency Contact List (Call Tree) to notify them that the call tree was completed. The time of this notification should be documented.
4. When an individual is unavailable, it should be reported to the HRPP Director or designee, by phone, email, or text message as soon as possible.
5. The HRPP Director or designee will attempt to contact these individuals using text messaging, leaving a message on an answering machine or by leaving a message with a third person, which should be documented.

5.3   Testing the Emergency Call Tree

The HRPP Emergency Contact List (Call Tree) will be updated regularly and tested at least annually. Documentation of the Emergency Contact List (Call Tree) will be completed by the HRPP Director or designee. An example of documentation of the results of the call tree test is in **Appendix B**.

6.0   Continuity of Operations During a Business Interruption, Emergency, or Disaster

6.1   Essential Functions

See **Section 3** above for a list of essential functions and the priority for each function.

6.2   Responsibilities

HRPP staff are responsible for knowing the location of the HRPP BCP and being familiar with the plan. In the event of an emergency or disaster, HRPP will be able to continue working from their normal work location or may be asked to work from another location or on-site. The HRPP Director or designee will communicate specific duties for HRPP staff during the emergency. HRPP staff will have access for administering electronic files (and direct access for paper files if necessary). Direct access may be possible in the normal workplace or the files and offices may be relocated to an off-site location depending on the specific emergency or disaster if necessary.

6.3   Location

Depending on the specific emergency situation, it may be possible for staff to work from their normal work location. However, relocation to another location, that may or may not be in organizational facilities, may be required. Relocation will be coordinated by the HRPP Director, IO, or designee. Regardless of the specific site, security is essential. The HRPP Director or designee will work with appropriate organizational staff to assure that the work site is secure and safe; i.e., physical security, fire detection and suppression systems are functioning, etc.

Note: Yale HRPP is designated as a remote office all (or a majority of the office's work can be conducted remotely. HRPP staff have secure remote access and also have access to the physical office location if necessary.

6.4   Communication

Communication with and between HRPP staff will occur by one or more of the methods described in **Section 5**.

6.5   Management of HRPP Operations During Emergencies

It is possible that normal operations will not be possible during a business interruption, emergency, or disaster and adjustments to study review activities 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 BCP. As much as possible, the interruption, emergency or disaster should 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 accepted and processed to assure that protection of research subjects is not interrupted.

- To be as efficient as possible, the Yale IRB may need to meet more frequently to review the time-sensitive submissions, assure subject safety and well-being and prevent lapses in IRB approval. 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.

- For studies with investigational drugs, arrangements will need to be made 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.

- In the event of infrastructure destruction or loss of operational capability or in the interest of staff safety, IRB and other HRPP activities will continue to operate remotely, but may also be relocated to an onsite or sites in other areas of the institutional facilities or remote from institutional facilities.

- During a business interruption, disaster, or emergency, the HRPP will collaborate with other organizational components to access and manage human subjects research.

6.6. University Electronic Systems and Applications that Support Human Subjects Research and Emergency Preparedness

Huron IRES-IRB
The electronic IRB records files are stored and backup as outlined in the Yale IT Disaster Recovery Plan (DR-289210 IRES IRB). See, **Appendix C**.

Other Yale University Systems Used to Support Human Subjects Research
Yale University also has an overall IT Disaster Recovery Program with a Plan for key applications: Yale ITS Disaster Recovery Service. Certain applications are hosted on the Cloud and therefore the Business Continuity/Disaster Preparedness Plans are maintained by the vendor we contract with.

Yale University Emergency Management and Disaster Recovery
For more information, see General Preparedness | Emergency Management (yale.edu).

Yale University Minimum Security Standards

The Minimum Security Standards (MSS) for how Yale IT Systems are protected are based on risk. See Yale's Minimum Security Standards (MSS).

Yale University Research Data Support

Support for research data at Yale is a collaboration between units across the university including Yale University Library, Yale Center for Research Computing, Information Technology Services and the Poorvu Center for Teaching and Learning. Staff are available to work with researchers at each stage of the data life cycle. See, Solutions | Research Data Support (yale.edu).

7.0 Restoration of Normal Operations

Recovery from the emergency situation and resumption of normal operational functions and procedures will proceed at the fastest possible rate but complete recovery will be dependent on the extent of procedural changes that were made for the emergency. If the HRPP offices and files were relocated, arrangements will be made to return staff and files to the on-site location. The HRPP Director or designee] will coordinate with organizational security and facilities management to complete the task. Communication of specific tasks and activities will be accomplished using the same methods used for plan activation as described in Section 5.

Note: Yale HRPP is designated as a remote office all (or a majority of the office's work can be conducted remotely. HRPP staff have secure remote access and also have access to the physical office location if necessary.

8.0 Plan Maintenance and Testing

The HRPP Director is responsible for assuring that the BCP is constantly up-to-date and will test specific aspects of the plan generally annually; i.e., Emergency Contact List (call Tree), VPN access for HRPP staff, etc. In order to assure a more realistic assessment of the BCP, tests will not be announced. If needed, revisions to the BCP will be made based on testing results and results of the testing will be documented.

9.0 Training

To assure that all HRPP staff are aware of might be required of them during an emergency or disaster, periodic 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 designee.

10. Special Considerations regarding Pandemics and Epidemics

Yale actively takes measures to mitigate the spread of influenza and other types of communicable diseases by routinely referring to the recommendations set forth in guidelines published by the Federal Emergency Management Agency, Department of Health and Human Services (Centers for Disease Control and Prevention), U.S. Department of Labor (Occupational Health and Safety Administration), Connecticut State Department of Health, World Health Organization, and other governmental agencies. Information regarding communicable diseases can be found on the governmental agency website links listed below. The general websites for these agencies also provide information for individuals and employers regarding disasters, epidemics, pandemics, and general health emergencies.

Designated Yale Public Health, Safety Committee or other designated committees are responsible for staying apprised of laws, regulations, and guidance regarding workplace preparedness and safety. The HRPP Director and designated staff are kept apprised of information that may impact HRPP staff, IRB chairs, IRB members, and other designated committee members under the oversight of the HRPP and human subjects research.

State of Connecticut Website
Pandemic Information (ct.gov)

Centers for Disease Control
Centers for Disease Control and Prevention (cdc.gov)

Federal Emergency Management Agency
http://www.fema.gov/

Department of Health and Human Services, Centers for Disease Control and Prevention
http://www.cdc.gov/flu/pandemic/healthprofessional.htm

U.S. Department of Labor, Occupational Health and Safety Administration
http://www.osha.gov/Publications/influenza_pandemic.html

World Health Organization
http://www.who.int/topics/en/index.html

11. Appendices

11.1   Appendix A - Emergency Contact List (Call Tree)

11.2   Appendix B - Emergency Call Tree Test Results Template

11.3   Appendix C - Yale IT Disaster Recovery Plan (DR-289210 IRES IRB)

Appendix A
Emergency Contact List (Call Tree)

Location of Emergency Contact List (Call Tree): <u>HERE</u> (note, this is only available to authorized personnel).

Appendix B
Emergency Call Tree Test Results Sample Template

Date of Test:

Time of Test: _____

Individuals listed Emergency Contact List (Call Tree)	Total Number	Percentage	Direct Contacts (Available for the call or Responded to text or email)	Indirect Contacts (Text message, answering machine Left message with a third person)	Number of Unable to Contact
Institutional Official					
ORA Leadership					
HRPP Director					
HRPP Staff					
HRPP Consultants					
External IRB Members (Expedited Review and Exempt)					
Committee Chairs – IRB					
Committee Chairs - RDRC					
Committee Chairs – RIDC					
Committee Chairs – ICIO					
Committee Chairs – ESCRO					
Committee Members– IRB					
Committee Members - RDRC					
Committee Members – RIDC					
Committee Members – ICIO					
Committee Members – ESCRO					

Issues Identified	Corrective Actions

Appendix C
Yale IT Disaster Recovery Plan

Location of Yale IT Disaster Recovery Plan for Huron's IRES IRB (DR-289210 IRES IRB) is HERE (note, this is only available to authorized personnel).