

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1. OBJECTIVE

Louisiana State University Health Sciences Center – New Orleans (LSUHSC) and its employees have braved many disasters. In order to maintain our status as one of the leading health care institutions in the nation, we must continue to prepare for potential disasters.

The Gulf Coast’s vulnerability to natural disasters, coupled with the threat of homeland terrorism in the United States since 9/11, make it more essential than ever for the university to ensure that plans are in place, tested true, and viable, should threatening situations develop-whether man-made or natural.

The primary objective in the Business Continuity Plan is to outline a well-structured and coherent plan to resume normal operations under the office of the Vice Chancellor of Academic Affairs as quickly and effectively as possible from an unforeseen service interruption.

2. RESPONSIBILITIES AND KEY STAFF

The LSUHSC Clinical Trials Office (CTO) develops, implements, and maintains this business continuity plan. The need to write a new or revise an existing business continuity plan is based upon changes to institutional policies, or procedures. This document will be provided to staff of the LSUHSC CTO.

The supervisor of the CTO is ultimately accountable for all CTO activities and is responsible for the appropriate delegation of tasks to individuals with adequate training and education to perform such tasks.

Key CTO Staff

Manager, Research Services (Supervisor)	Contracts Analyst
Budget Analyst	Clinical Research Coordinator
Clinical Research Nurse Coordinator	Regulatory Coordinator

3. BACK-UP AND RECOVERY STRATEGIES

The CTO has considered the following potential environmental disasters or emergency situations in developing this business continuity plan:

- Weather (i.e., hurricane, tornado, extreme heat, severe storms)
- Utilities Outage/ Gas Pipeline Risk/ Water Main Breaks
- Disease Outbreak
- Mass Casualty
- Chemical Spill
- Cyber-Threats
- Fire

In the event of a campus evacuation due to any of the above disasters or situations, staff members will keep in contact via text or email (*see 7. Emergency Contact Information below*). The supervisor of the CTO will ensure s/he is aware of the location of each staff member and any special circumstances that need to be accommodated.

The following are the essential activities of the office and the strategies for outages:

1. General Administration

The supervisor of the CTO will update the CTO website to redirect visitors to LSUHSC Emergency Preparedness website for an update on campus status.

For every study team the CTO is assisting with, a staff member will collect emergency contact information from the PI and store it in a file on the T:Drive, accessible to all staff members should one need to contact a PI who does not have access to their work phone or email. Alternate contact information for the CTO supervisor will be provided to study teams and Sponsors in the event of an emergency or disaster that disables the LSUHSC server and/or phone lines. Contact with the Sponsor will continue as is, unless the Sponsor informs the CTO that another form of communication is necessary.

2. Contract Negotiations

a. Potential Impact

As a result of potential environmental disasters or emergency situations, negotiation of contracts and agreements may experience delays.

b. Recovery/Resumption Strategy

During both scheduled and unscheduled outages, the contract analyst(s) will do his/her best to keep up to date with contract negotiations. If there are anticipated delays or absences, s/he will set an automatic response on emails and a pre-recorded message on voicemail to ensure all potential negotiating parties are informed.

As soon as the contract analyst(s) is able, negotiations of contracts will resume from the workspace or approved alternate site.

If it is determined that a project under negotiation will be unable to move forward due to the environmental disaster or emergency situation, the supervisor of the CTO will contact the Principal Investigator and Sponsor to explain the situation and cease negotiations.

3. Budget Development and Negotiations

a. Potential Impact

As a result of potential environmental disasters or emergency situations, development and negotiation of budgets may experience delays.

b. Recovery/Resumption Strategy

During both scheduled and unscheduled outages, the budget analyst(s) will do his/her best to keep up to date with budget development and negotiations. If there are anticipated delays or absences, s/he will set an automatic response on emails and a pre-recorded message on voicemail to ensure all potential negotiating parties are informed.

As soon as budget analyst(s) is able, development and negotiations of budgets will resume from the workspace or approved alternate site.

If it is determined that a project under negotiation will be unable to move forward due to the environmental disaster or emergency situation, the supervisor of the CTO will contact the Principal Investigator and Sponsor to explain the situation and cease negotiations.

4. Regulatory Coordinating

a. Potential Impact

As a result of potential environmental disasters or emergency situations, development and submission of regulatory applications may experience delays.

b. Recovery/Resumption Strategy

During both scheduled and unscheduled outages, the regulatory coordinator(s) will do his/her best to keep up to date with regulatory submissions to the compliance offices on behalf of the study team(s) s/he is assigned to assist. If there are anticipated delays or absences, s/he will alert the study team(s) and set an automatic response on emails and a pre-recorded message on voicemail.

As soon as the regulatory coordinator(s) is able, submission of regulatory applications will resume from the workspace or approved alternate site.

5. Clinical Trial Coordinating

a. Potential Impact

As a result of potential environmental disasters or emergency situations, clinical trials or research studies may have to be put on hold or other accommodations made. The first priority of the research/nurse coordinator should be subject safety.

b. Recovery/Resumption Strategy

For scheduled outages, the research/nurse coordinator(s) will work with the study team(s) s/he is assigned to in order to reschedule any subject visits that may be impacted and develop a study-specific plan for continued activities that can be done given the expected disaster/situation. S/he will also need to ensure someone alerts the sponsor to the possible delays in the study.

For unscheduled outages, the research/nurse coordinator(s) will work with the study team(s) s/he is assigned to in order to determine a plan for contacting subjects to ensure their safety and determine the plan for continued study activities; this may involve working with the sponsor to find alternative methods to continue subjects in a trial S/he will also need to ensure someone alerts the sponsor to the delays in the study.

If there are anticipated delays or absences, the research/nurse coordinator will alert the study team(s) and set an automatic response on emails and a pre-recorded message on voicemail.

The research coordinator and study team(s) should reference the CTO's [Clinical Trial Emergency Preparedness Guidance](#) for best practices when an emergency arises.

6. ESSENTIAL EQUIPMENT AND RECOVERY STRATEGY

The CTO’s only essential equipment is computers. Each staff member is equipped with a laptop computer, a docking station, and one or two additional monitors. In the event of an evacuation, each staff member will take their laptop with them off campus for use in an alternate work site, as needed.

Description of Equipment	Location	Cost Estimate to Replace
15” Dell Laptop (516756) + Docking Station	Suite 205A	\$1,745.00 (as of 2023)
24” Dell Monitor	Suite 205A	
15” Dell Laptop (517138) + Docking Station	Suite 205	\$1,745.00 (as of 2023)
2- 24” Dell Monitors	Suite 205	
14” Dell Laptop (517811) + Docking Station		\$1,667.00 (as of 2023)
2- 24” Dell Monitors	Suite 205	
14” Dell Laptop + Docking Station		\$1,667.00 (as of 2023)
2- 24” Dell Monitors	Staff Residence	
14” Dell Laptop + Docking Station	Suite 206	\$1,667.00 (as of 2023)
2- 24” Dell Monitors	Suite 206	

7. EMERGENCY CONTACT INFORMATION

Please see the ORS Emergency Calling Tree located on the Research T:Drive at T:\Pub\Administration ORS\ORS Emergency Calling Tree. A printed copy will be provided to CTO staff members at the time of training on this plan for them to easily access should LSUHSC servers go down during a disaster or emergency.

Other LSUHSC Emergency Contact Information

POLICE	Campus Police (504) 568-8999 or NOPD 911
FIRE	Samantha Lindsey, Fire Safety (504) 913-0507
MEDIA	Leslie Capo (504) 568-4806 or (504) 452-9166 (cell)
FACILITIES MAINTENANCE	Emergencies - Campus Police (504) 568-8999 Non-emergencies - (504) 568-7716
POISON CONTROL CENTER	Louisiana Poison Control – 1-800-222-1222

8. CRITICAL SUPPLIES AND CRITICAL VENDORS

The CTO does not have any critical supplies or vendors.

The CTO's Research Coordinators should contact the study teams they assist to identify where back-up supplies for their studies can be found, and which critical vendors should be contacted.

9. LOSS OF WORKSPACE AND ALTERNATE SITES

In the event of an emergency where the CTO experiences a loss of workspace, the following alternate sites may be utilized:

- Residence of the employee
- Hospital office space, for Research Coordinators

10. EDUCATION AND TRAINING OF STAFF ON BUSINESS CONTINUITY PLAN

All CTO staff will be trained in the business continuity and disaster recovery process for the CTO. This document, along with a formal presentation of the information included within, will be provided to the staff of the LSUHSC-NO CTO annually.

Employee Name	Date of Training	Employee Signature