BR.1497 Central Laboratory Downtime Operations

Copy of version 1.0 (approved and current)

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Organization Bailey Road

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
Approval	Lab Director	4/12/2022	1.0	WR Burack Richard Burack M.D., Ph.D.	

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
1.0	Approved and Current	Initial version	3/28/2022	4/26/2022	Indefinite

I. TITLE:

Downtime Operations

II. PURPOSE:

A. The purpose of this policy is to provide a plan for staff to maintain critical services to customers and patients and protecting sample integrity during service outages to the 211 Bailey Road facility.

III. SCOPE:

A. The scope of this policy is limited to operations at the Bailey Road facility, including all laboratory and Clinical Trials sections.

IV. RESPONSIBILITIES:

Approval and Signatories for this document are determined in accordance with the MediaLab Document Management Policy.

Responsibilities in regards to document management practices are outlined in the MediaLab Document Management Policy. Responsibilities specific to the process outlined in this document are listed below.

Role(s)	Responsibilities
Quality Assurance	• Supports the development of this document.
Employees	• Follows the downtime plan as needed.
Supervisor/Manager	• Ensures this policy is followed.
Medical Director	• Ensures the development of this document.

V. LIMITATIONS: N/A

VI. ACRONYMS/KEY TERMS:

Acronym / Key Term	Definition
URMC	University of Rochester Medical Center
BR	Central Laboratory – 211 Bailey Road
HH	Highland Hospital
SMH	Strong Memorial Hospital

VII. GENERAL GUIDELINES/POLICY:

This Downtime Operations Policy will provide a system to ensure continuity of laboratory services during situations that disrupt normal operations, including but not limited to, failures of analytical equipment, computer networks, and telecommunications.

VIII. PROCEDURE:

A. Alternate Operational Sites

1. Clinical Laboratories at Strong Memorial Hospital (SMH) and Highland Hospital (HH) are the designated alternate operational locations.
2. In the case of a system wide failure that renders all three sites inoperable for an extended period of time, specimens may be routed to another regional or national laboratory for

analysis. Regional laboratories include Rochester General System Laboratory and ACM Medical Laboratory. National Reference Laboratories include ARUP and Mayo Medical Lab. Contact Information for these laboratories may be found in the Downtime Binder described in Section 7 below.

3. Operational activities may be re-routed or re-located to one of these sites at the discretion of department management in the event that the Bailey Road facility cannot perform a required function or service for a length of time that will compromise patient care or service to customers. This length of time will be determined by management based on the nature of the downtime, the time of day and day of week, and the amount and type of pending work that will be impacted by the downtime.
4. Downtime Operations will be formally declared and communicated to employees and to the supervisors of the alternate operational sites prior to re-location of services.
5. In some cases, such as computer network failure, employees may be able to perform administrative functions from a home office and staff may be re-located accordingly.
6. In the event that paper records must be moved to an alternate site the location will be documented. Records will be handled through established standard record retention processes.

B. Power Failure

1. Critical building systems are on natural-gas generators that will continue to deliver power in case of a localized electrical power supply failure.
2. Where required or recommended by manufacturer, analytical and pre-analytical equipment is placed on Uninterruptible Power Supply (UPS) devices to prevent abrupt power loss to the equipment.
3. The Bailey Road facility is expected to support critical laboratory services in the case of a power failure, although non-critical activities may be postponed until normal power supply resumes.

C. Telecommunications Failure

1. In case of a localized telecommunications failure that impacts telephone service at the Bailey Road facility, local communications will be routed through cell phone service.
2. Staff members may be relocated to an alternate operational site to facilitate communications between facilities and with customers.
3. Many telecommunications devices are now computer dependent (Voice Over IP or VOIP), but a number of analog lines are still available at each site should the telecommunications failure be limited to VOIP services.
4. Should a local telecommunications failure impact all three sites and both analog and VOIP services, a 2-way radio system or laboratory couriers carrying physical messages between sites will be utilized.
5. Should a local telecommunications failure impact the entire region, staff members may be re-located to an unaffected geographical area in order to provide notification to customers outside the region.

D. Computer Systems and/or Network Failure

1. Computer Servers are located at the University of Rochester Data Center, which utilizes multiple levels of system redundancy to ensure stable operations.
2. The most likely type of failure is a localized interruption in connectivity to the University network.
3. Should a network connectivity failure occur during the time of normal operations, staff members may be re-located to an alternate operational site to access information and computerized applications.

4. Should a computer system failure impact the ability to accession laboratory samples into the lab information system:

    i. Samples that have a unique identifier (barcode label) may be analyzed prior to accessioning.
    ii. Laboratory results will be printed and maintained in hard copy until full sample accessioning may be completed
    iii. Critical values will be called to appropriate individuals, or faxed on a handwritten report if required. All handwritten reports will be verified for accuracy by a second individual.
    iv. Samples that do not have a unique identifier will be held for accessioning, unless sample integrity will be adversely impacted by the delay. In this case, a unique downtime identifier will be assigned to the sample(s) to allow testing to occur. The downtime identifier will be recorded on the laboratory test request form(s) to ensure a link to the results produced.

E. Analytical Equipment Failure

1. Should a laboratory instrument fail, and no back-up analyzer is available to perform the same function on site at Bailey Road, laboratory management will evaluate the specimens awaiting analysis to determine whether samples must be routed to an alternate location for testing.
2. If sample stability and patient care will not be adversely impacted, samples will be stored at the appropriate condition until the affected equipment is returned to an operational status.
3. If samples must be routed to an alternate location, department management will consult with the alternate testing locations to determine the best course of action. In general, Strong Memorial Hospital will be the primary back up location for routine testing (chemistry, hematology, urinalysis, and coagulation) and Highland Hospital the secondary back up location.

    a. Samples will be tracked using existing computerized tracking systems or manual worksheets, as applicable

F. Customer Notification

1. In the event of a downtime period that affects service to customers, a notification will be sent to customers regarding the nature of the downtime, the expected duration of the downtime, the impact to their business, and any instructions regarding operations during downtime.
2. Regular updates on the downtime status will be provided to customers.
3. Customers will be contacted at the time normal operations are resumed.

G. Access to Critical Phone Numbers and Other Information

1. A Downtime Binder containing hard copies of departmental telephone numbers, external laboratory contact information, communication forms, and information about the location of customer contact numbers is available in Room B207E at Bailey Road.
2. A duplicate copy of this binder will be kept by the on-call administrator for the Clinical Trials Department. Downtime Binders are updated by the Clinical Trial's Manager with the addition and/or closing of a study.

H. RE ESTABLISHING LABORATORY OPERATIONS AND SUPPORT SERVICES

Upon resolution of the Downtime event all equipment necessary to resume operations will be verified to ensure it is functioning properly. All laboratory equipment will be deemed operational in accordance with analyzer/analytical operating procedures.
Specimens and/or documents that may have been sent to an alternate testing location will be returned to Bailey Road location, if required.
Customers and vendors will be notified that the Bailey site or department is operational upon recovery from the Downtime event.

I. REVIEW AND TESTING

The Downtime Operations policy will minimally be reviewed annually in conjunction with additional administrative policies. A risk assessment and evaluation for effectiveness will be incorporated into the policy annual review process using the Business Continuity/Downtime Operations Review form. The need for testing of any of the above components will be included as part of the annual risk assessment/evaluation. In addition, the policy will be reviewed/revised as needed based event outcomes.

J. RISK ASSESSMENT

Component	Risk Assessment	Testing or Evaluation Performed
1. Relocation of Testing and staff to an Alternate Operational Site	Severity Level: Low Probability of Occurrence: Low Explanation: Common equipment platforms with adequate capacity are available at two alternate locations to back up existing testing. Work loads may be re-directed to protect specimen integrity during planned and unplanned equipment or facility downtime.	Workstation re-direction between sites is executed regularly to accommodate outpatient testing during planned and unplanned equipment downtime. No specific testing necessary unless significant system changes are implemented that impact capacity or equipment platforms.
2. Power Failure	Severity Level: High Probability of Occurrence: Low Explanation: Critical equipment and systems are on emergency power supplied by two natural gas generators.	Back up generators tested weekly at Bailey Road. Current weekly testing is adequate.
3. Telecommunications Failure	Severity Level: High Probability of Occurrence: Low Justification: Alternate communication devices such as analog phone lines and cell phones are available on site and staff may be re-located to an alternate location in the event of a localized telecommunications failure. In the case of a localized system failure the main phone trunk to the Bailey Rd. facility is automatically switched	Staff members regularly work from off-site locations and utilize cell phones for communications. Phones are automatically switched and forwarded to our alternate 24/7 location daily after normal business hours. No specific testing necessary unless significant system changes are implemented that impact telecommunication platforms.

	and forwarded to our alternate 24/7 location.	
4. Computer Systems and/or Network Failure	Severity Level: High Probability of Occurrence: Low Explanation: Critical Systems run on servers with triple redundancy at the University of Rochester Data Center. An adequate data back-up and back-up retrieval process is in place.	Files have been routinely restored successfully from back up tapes on multiple occasions. In addition, clinical trials databases have been successfully cloned and utilized for the creation of new test and validation environments.
5. Analytical Equipment Failure	Severity Level: High Probability of Occurrence: Low Explanation: Common equipment platforms with adequate capacity are available at two alternate locations to back up existing testing. Work loads may be re-directed to protect specimen integrity during planned and unplanned equipment or facility downtime.	Workstation re-direction between sites is executed regularly to accommodate outpatient testing during planned and unplanned equipment downtime. No specific testing necessary unless significant system changes are implemented that impact capacity or equipment platforms.
6. Downtime Communication Plans	Severity Level: High Probability of Occurrence: Low Explanation: Study contact information is available in electronic and paper format to allow communications during service interruptions or downtime operations.	Communications are sent to investigator sites and study personnel on a regular basis as part of standard operations. These notices are usually sent via e-mail, fax, or hard copy and cover topics such as holiday shipping instructions or changes in study procedures.

XI. TRAINING:

Role(s)	Responsibilities
List role(s) of applicable staff	Note which of the following are applicable: Read/review, Quiz (Knowledge Check), and/or Skills Assessment.
All employees permanently assigned or rotating assignment to Bailey Road Laboratory	Read

X. REFERENCES:

Established by URMC Labs

NYS DOH Clinical Laboratory Standards Of Practice, Part 1 General Systems, (Public Health S2) Preparedness

Business Continuity/Disaster Recovery Plan Review Log (BR.CP.GL.frm.0008)

IX. REVISION HISTORY:

Previous Version Number	Revised Document Version Date	Reason for Revision
BR.CP.GL.Adm.0002.0001	3/22/22	*New MediaLab Document. *Revised to be in format for MediaLab Document Control.