



STEM CELL LABORATORY (STCL)



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Stem Cell Laboratory Disaster Plan

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STCL-GEN-008

STEM CELL LABORATORY DISASTER PLAN

1 PURPOSE

- 1.1 The purpose of this document is to describe the infrastructure and procedures that have been established to respond to a local, national or international disaster affecting activities and products associated with the Stem Cell Laboratory (STCL) at Duke.

2 INTRODUCTION

- 2.1 Unexpected natural, physical, and man-made disasters can occur without warning. These disasters can affect people, property, and cellular products that are stored by the STCL on behalf of our patient population.
- 2.2 Some disasters can be anticipated and managed with advanced planning. Such events include, but are not limited to, floods, power outages, water contamination, ice storms, etc. These disasters would impede or delay the delivery of dry ice, liquid nitrogen, laboratory supplies, etc. These disasters could also result in a delay of incoming cellular products being shipped to the STCL from other collection facilities to support our patients.
- 2.3 Contingency plans need to be in place in order to respond to these disasters, in advance whenever possible, so every effort is made to ensure the safety of our employees/patients/visitors, to ensure that physical property is not damaged, and to ensure that cellular products are maintained in a controlled environment at all times

3 SCOPE AND RESPONSIBILITIES

- 3.1 It is the responsibility of the Laboratory Director (or designee), Program Directors, Laboratory Manager, and STCL staff to ensure that the requirements of this procedure are successfully met.
- 3.2 In addition, the Stem Cell Laboratory and the Adult and Pediatric Blood and Marrow Transplant Programs participate formally in the National Marrow Donor Program Core Contingency Networks for Nuclear Disasters Program.

4 DEFINITIONS/ACRONYMS

- 4.1 NMDP National Marrow Donor Program
- 4.2 HRSA Health Resources and Services Administration
- 4.3 NIH National Institute of Health
- 4.4 FDA Food and Drug Administration
- 4.5 CIBMTR Center for International Blood and Marrow Transplant Research
- 4.6 UNC-CH University of North Carolina at Chapel Hill
- 4.7 HHS United States Department of Health and Human Services
- 4.8 RDU Raleigh/Durham

- 4.9 LN2 Liquid Nitrogen
- 4.10 DUMC Duke University Medical Center
- 4.11 UCB Umbilical Cord Blood
- 4.12 SOPs Standard Operating Procedures
- 4.13 STCL Stem Cell Laboratory
- 4.14 PPE Personal Protective Equipment

5 MATERIALS

- 5.1 NMDP Core Contingency Network database.
- 5.2 Cesca Therapeutics, Inc. - BioArchive Dewar Replacement Contract.

6 EQUIPMENT

- 6.1 Portable satellite phone stored and maintained in the North Pavilion Room 9011.
- 6.2 Cesca Therapeutics Inc. BioArchive Dewar Replacement Plan (*dewars, cranes, etc. as specified*).
- 6.3 Back-up dewars, refrigerators, freezers, etc. can be obtained from Barlow Scientific located in Hillsborough, North Carolina. Barlow Scientific, Inc is also contracted to service designated temperature-sensitive equipment in the Stem Cell Laboratory.

7 SAFETY

- 7.1 Use all necessary personal protective equipment (PPE) when handling potentially infectious blood and body fluids to include, but not limited to, latex or latex-free gloves, cryogenic gloves, goggles, lab coats, and face shields.
- 7.2 **Always consider safety FIRST!** Any disaster could pose harm so it is imperative that employees **FIRST** work collectively with senior staff so a “game plan” can be devised that will minimize risk to lives and property.

8 PROCEDURE

- 8.1 When a disaster occurs (*or is forecasted*), notify the Laboratory Manager immediately, *if not already aware*.
 - 8.1.1 The laboratory manager (*or designee*) will notify Dr. Joanne Kurtzberg, MD, Dr. Nelson Chao, MD, Dr. Gwynn Long, MD, STCL senior staff, etc.
 - 8.1.2 The type(s) of disaster(s) and the extent of the damages will be determined while gathering information from steps 8.2 thru 8.10.11.
 - 8.1.3 A plan of action will be determined in collaboration with those members listed above to determine what actions are needed to protect cellular products that are in-process, to determine if planned procedures (*ie. apheresis, bone marrow harvest, etc*) need to be canceled or rescheduled, etc.

- 8.1.4 The laboratory manager, with help from senior STCL staff, will oversee the execution of the plan(s) for the duration of time necessary and communicate information accordingly to medical directors, etc.
- 8.2 Check affected locations to ensure that safety and wellness of staff, patients/visitors, or other occupants is not compromised.
- 8.3 Assess the physical damage of any/all affected location(s).
- 8.4 Establish essential chains of communication so that updates can be relayed in a timely manner in an effort to handle the disaster as quickly as possible.
- 8.5 Perform assessments to determine whether or not phones, pagers, wireless communication devices, computers, fax machines, and local, regional, national, and international networks are working properly.
- 8.6 Check with Radiation Injury Treatment Network (RITN) group at Duke for guidance. Contact person is Joel Ross, RhD, Project Planner, Radiation Countermeasures Center of Research Excellence (919-668-1722).
- 8.7 Assess whether the disaster is a threat to the Stem Cell Laboratory on a local, regional, and/or national level. This assessment will help determine if requests for support need to be made to Duke University Medical Center or if requests for assistance need to be made on a national and/or international level.
- 8.8 Assess and evaluate the type of disaster to determine if it is natural (e.g. floods, hurricanes, tornados, ice storms), man-made (e.g. explosion, fire), nuclear, biological (e.g. anthrax), etc.
- 8.9 Assess the appropriate networks available at DUMC, NIH, HHS, and/or the NMDP so that disaster teams can be activated, if appropriate.
- 8.10 For specific disasters that threaten the integrity of the cellular products housed in or by the Stem Cell Laboratory:
 - 8.10.1 Check the integrity of all freezers housing cellular products in affection locations.
 - 8.10.2 Check the source of LN2 to ensure that the LN2 bulk tanks have not been compromised. If there has been any breach, contact Airgas National Welders (800-242-0105 for Emergencies).
 - 8.10.3 Check levels of LN2 in those freezers housing cellular products.
 - 8.10.4 Check temperatures of ultra-low mechanical (electric) freezers.
 - 8.10.5 Check the function of alarm systems to ensure they are still functional.
 - 8.10.6 Check the back-up power source (generator) to ensure that it is functional.
 - 8.10.7 If damage to any BioArchive LN2 freezer has occurred, contact Cesca Therapeutics, Inc. to activate the Dewar Replacement Contract.
 - 8.10.8 Communicate with Barlow Scientific (919-245-1129) to get equipment loaners in place, as needed.

- 8.10.9 Contact Duke Maintenance (919-684-3232) and ask that Duke's Refrigeration Department be notified if there is something they can do to assist us within the Duke system.
- 8.10.10 Communicate with the Stem Cell Processing Laboratory at UNC-CH (919-966-7820) or the UNC Blood Bank (919-966-4011), if needed, to discuss sharing of space and/or equipment.
- 8.10.11 If UCB units must be provided to other areas experiencing nuclear threats, communicate directly with the Carolinas Cord Blood Bank so they can communicate with the NMDP (or other designated agency) so selection and distribution of donor units can be determined.

9 RELATED DOCUMENTS/FORMS

- 9.1 Refer to "*STCL-GEN-008 JAI Radiation Injury Treatment Network (RITN) Duke SOPs* (Contact person: Joel Ross, RhD, Countermeasures Center of Research Excellence (919-668-1722 or <http://www.radccore.org>
- 9.2 Cesca Therapeutics Inc. Dewar Replacement Contract
- 9.3 Hospital Emergency Incident Command System (HICS)
<https://intranet.dm.duke.edu/duhsemergency/duhemergencyprep/DUH%20Disaster%20Plans/Forms/AllItems.aspx>
- 9.4 Clinical Lab / Pathology Labs /Hospital Labs - Safety-related SOPs
- 9.5 SEC02 Emergency Response
<http://softtech.duhs.duke.edu/labFrame.asp?DID=9653&FLDVr=1755>
- 9.6 SEC03 Reports of Incidents and Accidents
<http://softtech.duhs.duke.edu/labFrame.asp?DID=9654&FLDVr=1755>
- 9.7 SEC13 Cryogenic Materials
<http://softtech.duhs.duke.edu/labFrame.asp?DID=9664&FLDVr=1755>
- 9.8 Event Management Policy
<http://softtech.duhs.duke.edu/labFrame.asp?DID=10940&ScH=T>

10 REFERENCES

- 10.1 Fliedner TM, Dorr HD, Meineke V. Multi-organ involvement as a Pathogenetic Principle on the Radiation Syndrome: A Study Involving 110 Case Histories Documented in SEARCH and Classified as the Bases of Haematopoietic Indicators of Effect. *Brit J Radiology* 78:1-8, 2005.
- 10.2 Weisdorf D, Chao N, Waselenko JK, Dainiak N, Armitage JO, McNeice I, Confer D. Acute Radiation Injury: Contingency Planning for Triage, Supportive Care, and Transplantation. *Biology of Blood and Marrow Transplantation* 12:672-682, 2006.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
06	B. Waters-Pick	<ul style="list-style-type: none"> • Corrected grammatical and formatting errors

		<p>throughout the document.</p> <ul style="list-style-type: none"> • Updates Section 2 and Section 3 • Section 4 Fixed formatting • Section 4.15 Added RITN • Section 6 “Special phone, web-based site for Core Contingency Communication activities” replaced with “Portable satellite phone stored and maintained in the North Pavilion Room 9011”. • Added the following to Section 8.1 <ul style="list-style-type: none"> • The laboratory manager (<i>or designee</i>) will notify Dr. Joanne Kurtzberg, MD, Dr. Nelson Chao, MD, Dr. Gwynn Long, MD, STCL senior staff, etc. • The type(s) of disaster(s) and the extent of the damages will be determined while gathering information from steps 8.2 thru 8.10.11. • A plan of action will be determined in collaboration with those members listed above to determine what actions are needed to protect cellular products that are in-process, to determine if planned procedures (<i>ie. Apheresis, bone marrow harvest, etc</i>) need to be canceled or rescheduled, etc. • The laboratory manager, with help from senior STCL staff, will oversee the execution of the plan(s) for the duration of time necessary and communicate information accordingly to medical directors, etc. • Section 8.6 “Activate Core Contingency Communication phone, if indicated. (See Government Emergency Telecommunications Service Calling Card Memorandum of Understanding in Core Contingency notebook)” changed to “Check with Radiation Injury Treatment Network (RITN) group at Duke for guidance. <u>Contact person</u> is Joel Ross, RhD, Project Planner, Radiation Countermeasures Center of Research Excellence (919-668-1722.” • Replaced Thermogenesis with Cesca Therapeutics, Inc. • Section 9.1 Changed “NMDP Core Contingency Network Notebook (See Maureen Kester, Jackie McPherson, or other designee) to “Refer to “<i>STCL-GEN-008 JA1 Radiation Injury Treatment Network (RITN) Duke SOPs (Contact person: Joel Ross, RhD, Countermeasures Center of Research Excellence (919-668-1722 or http://www.radccore.org</i>.”
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All dates and times are in Eastern Time.

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