



STEM CELL LABORATORY (STCL)



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STCL-GEN-012

SAFETY

1 PURPOSE

- 1.1 The purpose of this procedure is to provide the Stem Cell Laboratory employees with information so they may take a proactive approach to safety in the workplace.
- 1.2 This procedure addresses the following general health and safety requirements for the laboratory:
 - 1.2.1 Provisions for safe and adequate working conditions.
 - 1.2.2 Provision of appropriate personal safety equipment
 - 1.2.3 Environmental Safety Program

2 INTRODUCTION

- 2.1 The Stem Cell Laboratory shall provide a safe and adequate work environment for the laboratory staff while fulfilling all pertinent regulatory requirements
- 2.2 Each employee will participate in safety training programs as dictated by those duties performed by that employee
- 2.3 The Stem Cell Laboratory (STCL) is classified as a BSL-2 Laboratory

3 SCOPE AND RESPONSIBILITIES

- 3.1 The Medical Director, Laboratory Manager, and laboratory staff are responsible for ensuring that the requirements of this procedure are successfully met

4 DEFINITIONS/ACRONYMS

- 4.1 Laboratory Safety Officer - An employee who is designated by the Medical Director, and who is qualified by training or experience, to provide technical guidance on safety issues and in the development and implementation of the provisions of the Chemical Hygiene Plan and maintain all safety related documentation for the laboratory.
- 4.2 Chemical Hygiene Plan - A written program developed and implemented by the laboratory which sets forth procedures, equipment, personal protective equipment and work practices that are capable of protecting employees from the health hazards presented by hazardous chemicals used in the laboratory. The chemical hygiene plan includes the inventory, safe handling and disposal of chemicals; this plan is reviewed annually by employees. The Chemical Hygiene Plan is located in the receiving room of the Stem Cell Laboratory.
- 4.3 Safety Data Sheets (SDS) - These information sheets are produced by the manufacturer or distributor of the product and contain chemical safety information, including chemical, physical and toxicological properties, along with suggestions for safe handling, disposal and emergency first aid procedures.

- 4.4 OESO Occupational and Environmental Safety Office
- 4.5 OSHA Occupational Safety and Health Administration
- 4.6 STCL Stem Cell Laboratory
- 4.7 LN2 Liquid Nitrogen
- 4.8 BSL-2 BioSafety Level 2
- 4.9 BSC Biological Safety Cabinet
- 4.10 N/A Not Applicable
- 4.11 Fire Safety Plan / Fire Drill Manual - Manual containing records of the monthly fire drill activity. The site specific fire plan is also located in this manual, as well as online. Employee training records for fire extinguisher training is located in this manual as well as online on the OESO safety website.
- 4.12 Blood Borne Pathogen - Infectious microorganisms in human blood that can cause disease in humans. These pathogens include, but are not limited to, hepatitis B (HBV), hepatitis C (HCV), and Human Immunodeficiency Virus (HIV). Needle sticks and other sharps related injuries may expose employees to blood borne pathogens.
- 4.13 BSL-2 - Biosafety Level 2 - A laboratory suitable for work involving agents that pose moderate hazards to personnel and/or the environment. **The Stem Cell Laboratory is classified as a BSL-2 laboratory.** Refer to *STCL-GEN-012 JA3 Biological Safety – BioSafety Levels* for more details regarding this and other biosafety classifications.
- 4.14 PPE - Personal Protective Equipment - PPE is worn to minimize exposure to serious workplace illnesses and injuries.
 - 4.14.1 Personal Protective Equipment may include, but is not be limited to, gloves, safety glasses, face shields, sleeve covers, aprons, disposable gowns, and lab coats.
 - 4.14.2 Close-Toed / Non-perforated / Close-Heeled shoes MUST be worn while working in the laboratory. Wearing shoes with good tread is also important to avoid risk of injury associated with slips and falls. Wearing good shoes is very important.
 - 4.14.3 Disposable lab coats were occasionally used by the staff working in the STCL. Use of cloth lab coats, once laundered by Tarheel Linen Services, was discontinued in the STCL in February 2017.
 - 4.14.4 Do NOT wear lab coats, gloves, or other PPE in non-lab areas.
 - 4.14.5 Wear a lab coat when you may be in contact with potentially infectious materials and/ or contaminated surfaces or equipment. Remove or change a lab coat when it is overly contaminated, when work with infectious materials is completed, or when the integrity of lab coat has been compromised.

5 MATERIALS

- 5.1 STCL Safety Log
- 5.2 SDS Sheets (*formerly known as Material Safety Data Sheets (MSDS)*)
- 5.3 Fire Safety Plan Binder
- 5.4 Chemical Hygiene Plan Binder
- 5.5 Duke Safety Website

6 EQUIPMENT

- 6.1 N/A

7 SAFETY

- 7.1 All laboratory employees who work with materials (primary and well-characterized human cells, tissues and blood covered by OSHA's Bloodborne Pathogen Standard) are to receive initial safety training and annually thereafter. Bloodborne pathogens, General Laboratory Safety, and Biosafety Level 2 (BSL2) are available as on-line training modules via the Occupational & Environmental Safety Office (OESO) website.
- 7.2 All laboratory employees need to practice the rule of Universal Precautions. It is defined as handling all human blood, body fluids, and tissues as if they are infectious. This calls for the use of appropriate protective measures to reduce or eliminate the risk of occupational exposure.
- 7.3 Discard gloves when they are overly contaminated, when work with infectious materials is completed, or when the integrity of the gloves is compromised. Never wash, reuse or wear disposable gloves outside the lab. Alternatives to powdered latex gloves are available for employees that have latex allergies.
- 7.4 Hand washing is performed after removal of gloves and before leaving the work area. Use of hand sanitizers can be used in between activities.
- 7.5 NO food or drink is permitted anywhere in the processing, testing, or receiving sections of the laboratory. Food and drinks should be stored in lockers, refrigerators, or freezers in the break room.
- 7.6 NO PPE should be worn in the laboratory's break room, office areas, and/or conference rooms.
- 7.7 NO eating allowed in the processing, testing, or receiving areas of the STCL.
- 7.8 When needles must be recapped, employees should use the "**One-Handed Scoop Technique**" to reduce the risk of needle sticks.

8 PROCEDURE

- 8.1 New STCL employees will receive safety training conducted by the STCL safety officer using the STCL-GEN-012 (FRM1) *STCL New Laboratory Employee On-Site Safety Training Checklist*. OESO will provide hands-on fire extinguisher training for each new employee at a designated time and location.

- 8.2 Employee training is provided by OESO as an on-line training module. Each course required includes a quiz that must be passed for compliance. Employees must review on-line training at least review annually. The required basic courses are listed below:
 - 8.2.1 Biosafety Level 2 and BBP for lab workers
 - 8.2.2 Tuberculosis (TB) Safety training
 - 8.2.3 Radiation Safety for Blood Irradiators (only certain employees)
 - 8.2.4 Fire/Life Safety
 - 8.2.5 Laboratory Safety-General
 - 8.2.6 Shipment of Biological Materials (every 2 yr) (only certain employees)
 - 8.2.7 Compliance Update training
 - 8.2.8 Environment of Care
 - 8.2.9 HICS
 - 8.2.10 Infection Control
 - 8.2.11 HIPAA Privacy and Security Training
 - 8.2.12 Ergonomics Training
- 8.3 The STCL Safety Officer is required to attend the quarterly Laboratory Safety Officers' committee meetings to receive all the safety updates and regulation changes. The information received at these meeting will be disseminated to the STCL staff via meetings or emails to keep them informed of safety updates, on-going and new initiatives, and regulations.
- 8.4 Site Specific Emergency Response and Evacuation Fire Plan
 - 8.4.1 The STCL is located in Suite 1300, Plaza level in North Pavilion (Building 7593) at 2400 Pratt Street, Durham, North Carolina 27705.
 - 8.4.2 All employees are required to evacuate the building during a fire alarm. It is the STCL employees' responsibility to ensure that any visitors, volunteers, or other people in the laboratory, at the time of the drill, be shown the exit routes and/or evacuation procedures and be directed to the appropriate evacuation point outside the building. For persons with disabilities who may not be able to evacuate the building, please refer to the Duke Evacuation policy for the physically / medically challenged general guidelines. (SoftTech Health Lab Safety- Attachment- *A-13 Physically Challenged Evacuation Policy (LTR45040)*).
 - 8.4.3 If any employee sees smoke or flames, the RACE procedure should be followed.
 - 8.4.3.1 R = Remove all persons in the immediate area to a safe location; remember to use the stairs and not the elevator when evacuating.
 - 8.4.3.2 A = Activate the alarm / manual pull station and call 911.

- 8.4.3.3 C = Close all doors and windows to prevent smoke/fire from spreading throughout the building.
- 8.4.3.4 E = Extinguish the Fire **Please NOTE this procedure is also listed on the safety bulletin board in the main hall of the STCL.
- 8.4.4 If the fire alarm activates while employees are on the premises:
 - 8.4.4.1 Evacuation Plan: The STCL has 2 exits at either end of the lab that may be used to evacuate Suite 1300. A model of these exits and how to evacuate is posted on the safety board in the center of the STCL.
 - 8.4.4.2 Emergency Assembly Point (EAP) – People must evacuate the building and go to the EAP during a fire alarm. The designated EAP for the STCL is located at the sidewalk running parallel with Pratt St near the entrance of PG3. It is important to move as far away from the building as possible in the event that the building collapsed. People, who can't evacuate the building, due to a physical disability, should report to the security desk to ask for assistance.
 - 8.4.4.3 Fire Alarm Pull Station: Employees should be aware of the pull station nearest the lab; it is located by the elevators outside the main entrance of the lab. It is important to remember to call 911 as soon as possible even if the manual pull has been activated.
 - 8.4.4.4 Fire Blanket - A fire blanket is located in the flipper cabinet above the large biohazard trash boxes located down the main hallway of the Stem Cell Laboratory.
 - 8.4.4.5 Fire Extinguisher - The Fire Extinguisher for the STCL is located by the freezer room door in the center of the laboratory. This is checked weekly by a staff member for fullness, and is checked by OESO yearly as well. To operate the fire extinguisher use the PASS procedure (** Please note this procedure is also located above the fire extinguisher by the freezer room door.)
 - 8.4.4.5.1 P= Pull the pin
 - 8.4.4.5.2 A= Aim at the base of the fire
 - 8.4.4.5.3 S= Squeeze handles together
 - 8.4.4.5.4 S= Sweep extinguisher from side to side.
- 8.5 STCL Chemical Hygiene Plan - Standard operating procedures for specific chemicals used in the STCL can be found in this binder, which is located in the receiving room of the STCL. Safety Data Sheets (SDS) are located in this book, as well as the Chemical Inventory List.

- 8.5.1 Chemical Spills: a minor spill is less than 1 gallon and one that laboratory employees can handle safely without assistance of safety and emergency personnel. All other chemical spills are considered major.
- 8.5.2 If a chemical spill occurs employees should refer to the Emergency Response and Incident Reporting Guide flipchart that is located in the center of the laboratory by the Safety Board.
- 8.5.3 Chemical Waste Disposal: The STCL chemical waste disposal practice follows the guidelines of the Duke University/Medical Center waste policy
<http://www.safety.duke.edu/EnvPrograms/DOCS/ChemicalWasteMGTPractice.pdf>
and OESO guidelines for sink disposal of chemical substances
https://www.safety.edu.Envprograms/Docs/drain_disposal_practice.pdf
- 8.6 Blood borne Pathogen
 - 8.6.1 Employees observe Universal Precautions to prevent contact with blood or other potentially infectious materials. Universal Precautions is an approach to treat all human blood and body fluids as if unknown to be infectious for bloodborne pathogens.
 - 8.6.2 Employees with use appropriate PPE provided to minimize risks.
 - 8.6.3 STCL methods and controls to limit exposure of potentially infectious materials are as follows:
 - 8.6.3.1 Sharps Containers- Used for disposal of syringes, needles, and slides. When full, the containers will be placed in the large biohazard boxes located in the main hallway of the STCL. This trash will be removed on a regular schedule by Environmental Service Personnel.
 - 8.6.3.2 Biological Safety Cabinets are used to prevent release of infectious agents and protect employees from splashes and/or splatter of infectious material.
 - 8.6.3.3 Plexiglass shields, where applicable, are used to help prevent spray from blood tubes while testing.
- 8.7 Liquid Nitrogen and Dry Ice Safety
 - 8.7.1 Safety Glasses and/or face shields are required when working with liquid nitrogen in the liquid form since splashing could occur; these are not required when working in vapor phase of LN2. Cryogloves should be worn to protect employees' hands from extreme temperatures associated with dry ice and LN2. These items are located in the freezer room of the STCL.
NOTE: Use EXTREME CAUTION working around dry ice / LN2

- 8.8 Risk Evaluation and Mitigation Strategy (REMS) Training
 - 8.8.1 Designated processing staff will be required to complete REMS training before handling associated cellular products. REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. (*ie. CAR-T Cellular products – YESCARTA, KYMRIAH, etc*).
 - 8.8.2 Processing staff, who are required to complete REMS training for CAR-T Cellular products for YESCARTA, will have to complete on-line training via company link <https://www.yescartarems.com/wp-content/uploads/rem-s-program-knowledge-assessment.pdf> and Learning Management System module # 00129914.
 - 8.8.3 Processing staff, who are required to complete REMS training for CAR-T Cellular products for KYMRIAH, will have to complete on-line training via company link <https://www.kymriah-remska.com/> and Learning Management System module # 00134491.
- 8.9 Related Procedures
 - 8.9.1 Duke University Hospital’s Safety Program
 - 8.9.2 OESO oversees/reviews health status of new hires, mandates vaccination requirements based on the work environment, etc. OESO provides ongoing health needs for the employees and maintains their health records. “*Duke OESO Guidelines for Safe Use of Cryogens*” is available on-line for reference.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-GEN-012 (FRM1) STCL New Laboratory Employee On-Site Safety Training Checklist
- 9.2 STCL-GEN-012 JA1 Site Specific Fire Plan for Stem Cell Laboratory Plan I
- 9.3 STCL-GEN-012 JA2 OESO Site Specific Fire Plan Duke Hospital Plan II
- 9.4 STCL-GEN-012 JA3 Biological Safety – BioSafety Levels

10 REFERENCES

- 10.1 Occupational Exposure to Bloodborne Pathogens, Occupational Safety and Health Administration, U.S. Department of Labor, Washington D.C
- 10.2 Occupational Exposure to Hazardous Chemicals in Laboratories, Occupational Safety and Health Administration, U.S. Department of Labor, Washington D.C
- 10.3 Duke University Medical Center Laboratory Safety Manual

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
05	B. Waters-Pick	<ul style="list-style-type: none">• Section 4.14.3 Added “were occasionally” used by the staff• Section 8.2.12 removed “Service Recovery Training” and replaced with “Ergonomics Training”• Section 8.7 Added Liquid Nitrogen “and Dry Ice” Safety• Section 8.7.1 Added “dry ice” to this section (<i>in addition to LN2</i>)• Section 8.8 Added entire section regarding REMS training for designated processing staff for CAR-T Cellular products• Section 8.9 used to be labeled as 8.8

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