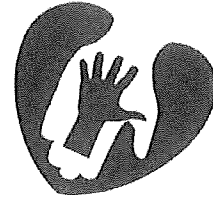


STEM CELL LABORATORY (STCL)



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STCL-SOP-035

CLEANING AND DECONTAMINATION PROTOCOL FOR STCL

1 PURPOSE

- 1.1 To establish and implement an appropriate written schedule for cleaning and a method of decontamination of the Stem Cell Laboratory (STCL) facility, in order to reduce the potential for exposure of both product and personnel to contaminants.

2 INTRODUCTION

- 2.1 To minimize the risk of contamination of the various products processed in the STCL, the entire processing procedure will be performed in a clean, semi sterile environment, achieved by using a Biological Safety Cabinet (BSC) for all product processing. To assist in obtaining the most sanitary environment possible, a daily cleaning and decontamination protocol is required.

3 SCOPE AND RESPONSIBILITIES

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

4 DEFINITIONS/ACRONYMS

- 4.1 Contaminated – The presence of blood or other potentially infectious materials on an item or surface.
- 4.2 Decontamination – the use of physical or chemical means to remove, inactivate or destroy bloodborne pathogens on a surface or item so that they are no longer capable of transmitting infectious particles, and in order to render the surface safe for handling, use or disposal.
- 4.3 Disinfectant – a chemical that destroys vegetative (living) forms of harmful microorganisms but does not ordinarily destroy bacterial endospores (dormant bacterial spores). Generally, a disinfectant is used on an inanimate surface (e.g., work surface, floor, instrument, etc.) and is not used on skin.
- 4.4 Other potentially infectious materials (OPIM)
- 4.5 Blood and body fluids
- 4.6 Any unfixed tissue or organ, other than intact skin, from a human (living or dead)

5 MATERIALS

- 5.1 70% Isopropyl Alcohol
- 5.2 Quaternary Detergent/Disinfectant
- 5.3 Clean Wipes or Towels
- 5.4 Mop

- 5.5 Broom (as needed)
- 5.6 Biohazard Material Container
- 5.7 Biohazard Plastic Bags for lining the Biohazard Material Container
- 5.8 Household Bleach (1:1, 1:5, or 1:10 Dilution)
- 5.9 Activate bleach system
- 5.10 100% ethyl alcohol
- 5.11 Madacide-1 disinfectant
- 5.12 Sani-Cloth® AF3 Germicidal Disposable Wipes (*or equivalent*)

6 EQUIPMENT

- 6.1 NA

7 SAFETY

- 7.1 Wear all appropriate personal protective equipment when handling any potentially biohazardous blood or body fluid to include, but not limited to, gloves, lab coats, goggles etc.

8 PROCEDURE

- 8.1 Immediate Cleaning/Decontamination:

- 8.1.1 Clean and decontaminate all equipment, environmental surfaces and working surfaces after contact with blood or other potentially infectious materials, using an acceptable disinfectant (refer to Table I).

Table I

Disinfectant	Minimum Contact Time
Household Bleach (1:1, 1:5, or 1:10 Dilutions) Note: Dilutions must be prepared each day of use	20 minutes
Activate bleach system	10 minutes
70% Isopropyl Alcohol	10 minutes – without evaporation
Madacide-1	10 minutes
Sani-Cloth® AF3 Germicidal Disposable Wipes (<i>or equivalent</i>)	3 minutes
100% ethyl alcohol	30 seconds
Any disinfectant product, used according to the manufacturer's directions, that contains all three of the following requirements:	
1. The Environment Protection Agency (EPA) registration number	
2. The words "hospital" and "disinfectant" or "disinfect"	
3. Specific claims of the effectiveness against <i>Mycobacterium tuberculosis</i>	

- 8.2 Decontaminate work surfaces with an appropriate disinfectant. This should be done after completion of procedures, immediately or as soon as feasible when

surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials.

- 8.2.1 Decontaminate scissors and hemostats by storing them in Madacide-1 liquid disinfectant jar when there are not in use. To use scissors or hemostats that have been soaking, remove them from the Madacide-1 solution and rinse them in 100% ethyl alcohol solution; wipe with sterile gauze or allow them to air dry and place them in the biological safety cabinet. Return to liquid disinfectant solution jars after each use or when visibly contaminated.

NOTE: The Madacide-1 and 100% ethyl alcohol solutions should be replaced on a monthly basis. It is acceptable to dispose of these solutions down the sink followed by copious amounts of water. Check labels on the containers for replacement dates.

- 8.2.2 Perform daily decontamination of the common work surfaces with an acceptable disinfectant and document on the appropriate form.
- 8.3 The following cleaning and decontamination should be performed:
 - 8.3.1 The working surface of the Biological Safety Cabinets should be cleaned after each use and decontaminated daily. The entire cabinet should be taken apart and thoroughly cleaned each month or more frequently if there obvious contamination below the grills, etc.
 - 8.3.2 All pipettes should be wiped down with a disinfectant when visible blood is present.
 - 8.3.3 Centrifuges should be cleaned thoroughly each week or any time there is a spill.
 - 8.3.4 Heat Sealers and Sterile Tube Welders should be cleaned and checked daily according to the manufacturer's recommendations.
- 8.4 The Environmental Services Personnel will empty non-bio-hazardous trash daily. If non bio-hazardous trash is not emptied, or is full, page 970-6355.
- 8.5 The Environmental Services personnel will sweep and wet mop the floors in the entire STCL facility every week.
- 8.6 The Environmental Services personnel will inspect all bio-hazardous material containers daily. Dispose of and/or decontaminate as needed. If trash has not been removed, or the container is full, page 919-970-4507 to reach the biohazard pick up employee.
- 8.7 All bio-hazardous materials are discarded per Duke University Medical Center's policy "Medical and Hazardous Medical Waste Disposal".
- 8.8 An outside cleaning agency has been contracted to clean the Stem Cell Laboratory one Saturday each month. The staff from that agency using *STCL-SOP-054 (FRM1) STCL Contracted Cleaning Services Checklist* to record their cleaning services. Currently the contractor is cleaning the STCL the first Saturday of each month but that schedule is subject to change based on availability and need (ie. If

water is not available in the North Pavilion due to a planned maintenance event, etc).

8.9 Cleaning/Decontamination at a later date:

- 8.9.1 Place a "QUARANTINE" label on the contaminated device any time the immediate cleaning of the device is not possible.
- 8.9.2 Document the quarantine status on the *STCL-SOP-035 FRM1 Quarantine and Decontamination Log* (date, time, initials).
- 8.9.3 After cleaning/decontamination, document the cleaning/decontamination of the device and the release for re-usage on the *STCL-SOP-035 FRM1 Quarantine and Decontamination Log* (date, time, initials). Remove the "QUARANTINE" label.
- 8.9.4 Supervisor or designee should sign form where indicated.
- 8.9.5 File logs in work area indefinitely.

9 RELATED DOCUMENTS/FORMS

- 9.1 STCL-SOP-035 FRM1 Quarantine and Decontamination Log
- 9.2 STCL-FORM-027 Maintenance Cleaning Schedule for Stem Cell Laboratory
- 9.3 STCL-SOP-054 Cleaning and Decontamination of STCL by External Vendor
- 9.4 STCL-SOP-054 (FRM1) STCL Contracted Cleaning Services Checklist

10 REFERENCES

- 10.1 Duke University Medical Center Bloodborne Infectious Diseases Exposure Control Plan
- 10.2 21 CFR 1271, Human Cellular and Tissue Based Products

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
07	Barbara Waters-Pick	<ul style="list-style-type: none"> • Added use of Sani-Cloth® AF3 Germicidal Disposable Wipes or equivalent to Section 5 and Table 1. • Added "<i>Currently the contractor is cleaning the STCL the first Saturday of each month but that schedule is subject to change based on availability and need (ie. If water is not available in the North Pavilion due to a planned maintenance event, etc).</i>" to Section 8.8 • Added <i>STCL-SOP-054 Cleaning and Decontamination of STCL by External Vendor</i> to Section 9.

Signature Manifest**Document Number:** STCL-SOP-035**Revision:** 07**Title:** Cleaning and Decontamination Protocol for STCL

All dates and times are in Eastern Time.

STCL-SOP-035 Cleaning and Decontamination Protocol for STCL**Author**

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