GUIDELINES FOR WORKING WITH COMPLETE FREUND’S ADJUVANT

➢ To go to the section of interest, hold your cursor over the section in the table of contents below and click on the name of the section while pressing the control button.

1. PURPOSE ................................................................................................................................... 1
2. SCOPE ........................................................................................................................................ 1
3. PI RESPONSIBILITIES ............................................................................................................... 1
4. OCCUPATIONAL HAZARDS ...................................................................................................... 1
5. WORK PRACTICES ................................................................................................................... 2
6. DISPOSAL OF CFA .................................................................................................................... 2
7. PERSONAL PROTECTIVE EQUIPMENT (PPE) .......................................................................... 2
8. EMERGENCY PROCEDURES ..................................................................................................... 2
9. OCCUPATIONAL MEDICINE REQUIREMENTS ......................................................................... 2
10. REFERENCES ............................................................................................................................ 2

1. PURPOSE

1.1. This document establishes guidelines for working with Complete Freund’s Adjuvant (CFA). CFA is a water-in-oil emulsion containing heat-killed mycobacteria or mycobacteria cell wall components and is an effective means of potentiating cellular and humoral antibody response to injected immunogens in research animals.

2. SCOPE

2.1. This guideline applies to all personnel conducting work with CFA at Emory University.

3. PRINCIPLE INVESTIGATOR (PI) RESPONSIBILITIES

3.1. Ensure that personnel understand the hazards associated with CFA, appropriate precautions to minimize risk, and procedures to follow in the event of an emergency.

3.2. Develop and implement standard operating procedures (SOPs) for CFA preparation and administration. Review SOPs with laboratory personnel.

3.3. Review of the experimental protocol, including all necessary precautions, with laboratory personnel.

3.4. Provide direct oversight of inexperienced staff members until mastery of proper techniques has been demonstrated.

4. OCCUPATIONAL HAZARDS

4.1. Primary routes of occupational exposure to CFA include accidental injection, conjunctival contact via splashing, and skin contact. See table below for documented health consequences for each of these accidental occupational exposure routes:

<table>
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<tr>
<th>Routes of Exposure</th>
<th>Health Consequences</th>
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| Injection          | • Severe swelling, granulomatous inflammation, pain, lesions, abscesses, necrosis, and ulceration of tissues surrounding the injection site.  
|                    | • Related skin maladies and severe pain that may persist for several years following the initial exposure incident and are typically unresponsive to antibiotic therapies.  
|                    | • Influenza-like symptoms that may persist for several weeks.  
|                    | • Chronic systemic effects including persistent fever, neurological abnormalities, tuberculoid granulomas, and arthritic symptoms.  
|                    | • Hypersensitivity and interference with the Mantoux test. |

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| Ocular             | • Severe ocular irritation, scar tissue formation, and temporary/permanent vision impairment.  
|                    | • Hypersensitivity and interference with the Mantoux test. |
| Dermal             | • Hypersensitivity and interference with the Mantoux test. |

4.2. Individuals who have a history of testing positive in Mantoux tests are inherently more sensitive to CFA.

5. **WORK PRACTICES**

5.1. Laboratory SOPs are followed for the preparation and administration of CFA.

5.2. Safe sharps procedures are practiced, including the use of safe sharps devices. Sharps are immediately disposed of in an approved sharps container.

5.2.1. See Emory University Sharps Guidelines for more information.

5.3. Work areas are decontaminated with a 10% bleach solution following each procedure involving CFA.

5.4. Resuspension of the mycobacteria in CFA (i.e., vortexing, shaking) is conducted in a biological safety cabinet.

5.5. Animals are chemically or physically restrained during administration of CFA to reduce the potential for accidental exposure. When it is necessary to use physical restraint, a mechanical device is encouraged.

6. **DISPOSAL OF CFA**

6.1. CFA and CFA-contaminated items (i.e., contaminated sharps, contaminated animal carcasses and bedding) are disposed as regulated medical waste.

6.1.1. See the Emory University Biosafety Manual for more information.

7. **PERSONAL PROTECTIVE EQUIPMENT (PPE)**

7.1. At a minimum, the following PPE is worn while working with CFA:

7.1.1. **Eye Protection**: Goggles are worn at all times. An optional face shield may be worn in addition to goggles when the potential for splashing exists.

7.1.2. **Gloves**: Latex or nitrile gloves.

7.1.3. **Protective Clothing**: Appropriate laboratory attire (long pants, closed toed shoes, etc) and a lab coat.

8. **EMERGENCY PROCEDURES**

8.1. All exposures are reported to the supervisor and a STARS report is completed.

8.2. Refer to the “Just in Time” Guide to Campus Emergencies for emergency response procedures.

9. **OCCUPATIONAL MEDICINE REQUIREMENTS**

9.1. Personnel working with CFA should have a baseline TB test and consider annual Mantoux testing.

10. **REFERENCES**

10.1. Biosafety in Microbiological and Biomedical Laboratories, 5th Edition
10.2. National Institutes of Health Guidelines for Research Use of Adjuvants
10.3. Virginia Commonwealth University CFA Guideline Document
10.4. Emory University Biosafety Manual
10.5. Emory University Sharps Guidelines
10.6. “Just in Time” Guide to Campus Emergencies
10.7. Emory University Environmental Health and Safety Office Website