FACILITY SAFETY PLAN INSTRUCTIONS

Approval of the Facility Safety Plan is granted on an institution basis rather than on a proposal basis. Facility Safety Plan approvals are granted for a 5-year period with annual updates required. An institution with multiple research sites, subcontractors, or a consortium must submit a separate Facility Safety Plan for each research site. Go to the following link to determine if your institution has an approved Facility Safety Plan: https://mrmc.amedd.army.mil/assets/docs/SSE/Facility_Safety_Plan_Approved_Institutions.pdf

If your institution has an approved Facility Safety Plan, submit only the Principal Investigator Assurance in this Attachment with your proposal.

If either your organization's name, research site, or subcontractor's name does not appear on the Institutional Facility Safety Plan listing or the approval of your institution's Facility Safety Plan has expired, your Facility Safety Manager/Director must provide the U.S. Army Medical Research and Materiel Command's (USAMRMC's) Safety Office with a Facility Safety Plan. The plan will be prepared in accordance with the instructions provided at https://mrmc.amedd.army.mil/index.cfm?pageid=researcher_resources.safety and will be submitted directly to the USAMRMC Safety Office. Submit all applicable documents in this Attachment, except the Facility Safety Plan Status Report, with your proposal.

If either, your organization, research site, or subcontractor has no laboratory research and falls under one or more categories listed below, then a Facility Safety Plan would not be required. Submit only the Principal Investigator Assurance and a statement that there will be no laboratory research at the facility and identify which category for administrative safety approval.

— Performing program management and administrative oversight
— Providing Consultation as an Administrative Collaborator (symposium)
— Data collection/mining/analysis involving computer science
— Computer-based modeling, analysis and training
— Developing computer signal processing and analysis
— Developing Imaging software
— Designing Medical Equipment without testing
— Medical testing using virtual software
— Creating Modules for research training program
— Research conducted at DoD laboratory
— Establishment of Research Programmatic Office
— Conducting Patient Surveys

Safety Program

Table of Contents

Safety Program

1. **Introduction**

This appendix contains a description of the requirements, forms, approvals, and assurances relating to safety in the research environment. To ease the burden of submitting general institution safety program information with each proposal, the USAMRMC has developed a Facility Safety Plan program. If you have any questions concerning this appendix please contact the USAMRMC Safety Office at 301-619-6035 or email to USAMRMC MRMC SS.

A Facility Safety Plan is a 2-10 page document that summarizes the institution's safety program. Approval of the Facility Safety Plan is granted on an institution basis rather than on a proposal basis. The Facility Safety Plan shall be institution-based, consist of six parts as outlined the Facility Safety Plan, part 2 of this appendix, and be prepared by the Facility Safety Director/Manager of the institution. Each institution is required to submit only one Facility Safety Plan. An institution with multiple research sites, subcontractor, or a consortium must submit a separate Facility Safety Plan for each research site. The Facility Safety Plan submission for each site will include signed assurances from both the Facility Safety Manager and Principal Investigator Assurance (part 2F and part 2G of this appendix).

Facility Safety Plan approvals are granted for a 5-year period with annual updates required (part 4 of this appendix). To determine if your organization has an approved Facility Safety Plan, check our website listing at:
https://mrmc.amedd.army.mil/assets/docs/SSE/Facility_Safety_Plan_Approved_Institutions.pdf

a. If your organization's name appears on this Institutional Facility Safety Plan listing and approval of the Facility Safety Plan has not expired, then your institution's Facility Safety Plan need not be sent with the proposal submittal.

b. If either your organization's name does not appear on this Institutional Facility Safety Plan listing or the approval of your institution's Facility Safety Plan has expired, your Facility Safety Manager/Director must provide the U.S. Army Medical Research and Materiel Command's (USAMRMC) Safety Office with a Facility Safety Plan and a signed assurance, as outlined below (part 2 of this appendix).

Safety Program

2. Facility Safety Plan (Institution-Based)

The Facility Safety Director/Manager must provide information from the institutional perspective, as appropriate, for each of the six parts listed below. **This Facility Safety Plan should not reference the specific proposal**. A list of the first five components with a brief description of each is acceptable. **Do not send** institution safety manuals, although they may be referenced in your submission (a web site address is also acceptable). **Do not label** "Not Applicable" or "N/A". Each element shown below of the Facility Safety Plan should be addressed by providing a statement as it applies to your institution as a whole. **Example:** (see Radioactive Materials, part c) If your institution does not use Radioactive Materials and does not have a copy of the Nuclear Regulatory Commission (NRC), state-approved license, or the equivalent in cases of institutions outside the continental US then provide a statement to that effect.

a. Research Operations/Standing Operating Procedures (SOPs)
Provide a brief description of the safety procedures relating to the infectious agent and toxin research operation of the facility. These should include (a) a description of any special skills, training and SOPs that assure safe research operations (Biosafety Committee, Radiation Committee, HAZCOM, Blood-borne Pathogens, Chemical Hygiene Plan, etc.) and (b) a description of medical surveillance and support.

b. Facility Equipment and Description (Related to the Research Environment)
Provide (a) a description of the facility; (b) a description of personal protective equipment used within the facility; and a list of specialized safety equipment such as biosafety cabinets (BSC), chemical fume hoods, exhausts, and ventilation systems.

c. Radioactive Materials
Provide a current copy of the Nuclear Regulatory Commission or state-approved license.

d. Hazard Analysis (Related to the Research Environment)
Provide a description of each hazard identified in the preparation of the SOP, the hazard analysis performed based on maximum credible event and the plan to minimize or eliminate each hazard and control risk to laboratory personnel. DA Pam 385-30 provides descriptions of conducting hazard analysis.

e. Infectious Agents and Toxins (IAT) Research Program Requirements
*(Only applicable to the DTRA Biological Defense Research Progra*m *funded award*s)
For those institutions where Principal Investigators are supported by the USAMRMC and are conducting research with **Risk Group 3 and 4 agents** and the research is being conducted to support Army Medical Biological Defense Programs, a Facility Safety Plan must be prepared as defined on page 3. The Facility will receive a initial site inspection and periodic inspections by MRMC SSE to ensure continued compliance for the life of the award.

f. Facility Safety Director/Manager Assurance
The Facility Safety Director/Manager must provide the following signed assurance:

Facility Safety Director/Manager Assurance

♦ I assure that this institution has an existing institutional safety and occupational health program that meets appropriate Federal, State, and Local regulations as required by law, as well as the National Institute of Health Guidelines for Research Involving DNA Molecules, dated April 2002.

♦ I assure that all hazards associated with the research laboratories have been identified, eliminated, and/or controlled in such a manner as to provide for a safe research laboratory environment.

♦ I accept full responsibility for submitting the annual **Facility Safety Plan Status Report** including significant changes in facility, safety equipment, and safety procedures by fax to 301-619-6627, by e-mail to USAMRMC MRMC SS, by mail to the following address: DEPARTMENT OF THE ARMY, ATTN: MCMR-SS, HQ USAMRMC, 810 Schreider Street, Fort Detrick, MD 21702-5012.

♦ I assure that I have consulted with all current PI's holding USAMRMC awards concerning this institution's safety policies and procedures and will consult with all future PI's holding USAMRMC awards concerning this institution's safety policies and procedures.

♦ I assure that all Facility Safety Plan requirements are in compliance with Local, State and Federal general industry standards.

♦ If applicable, I assure Infectious Agent and Toxin (IAT) research programs will follow the recommended guidelines established in the latest editions of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL); Army Regulation 385-10, Chapter 20 (Biological Safety); and DA Pamphlet 385-69 (Safety Standards for Microbiological and Biomedical Laboratories).

♦ Use of Infectious Agents and Toxins (IAT) as defined below: ☐ Yes ☐ No

"Infectious Agent or Toxin = a viable microorganism, or its toxin which causes or may cause human disease, and includes those agents and includes those agents classified as Risk Group 2 or higher as defined in the latest edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)."

_____

Name of Institution's Safety Director/Manager (print)

_____ _____

Signature Date

Mailing Address: _____

Street

_____

City State Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____ Web Site: _____

Principal Investigator Assurance

♦ I assure that I have involved the Facility Safety Director/Manager in the planning of this research proposal, discussed with him/her all aspects of the proposal that relate to occupational health and safety, and will help him/her prepare the annual Facility Safety Plan Status Report.

♦ I assure that I will comply with my institution's safety program and its requirements.

♦ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.

♦ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.

♦ I assure that hazards associated with my research have been identified eliminated and/or controlled.

♦ I assure that all Facility Safety Plan requirements are in compliance with Local, State and Federal general industry standards.

♦ If applicable, I assure Biological research programs will follow the recommended guidelines established in the latest editions of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL); Army Regulation 385-10, Chapter 20 (Biological Safety); and DA Pamphlet 385-69 (Safety Standards for Microbiological and Biomedical Laboratories).

♦ Use of Infectious Agents and Toxins (IAT) as defined below: □ **Yes** □ **No**
"Infectious Agent or Toxin = a viable microorganism, or its toxin which causes or may cause human disease, and includes those agents and includes those agents classified as Risk Group 2 or higher as defined in the latest edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL)."

_____
Name of Principal Investigator (print)

_____ _____
Signature Date

Mailing Address: _____
Street

_____
City State Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____Web Site: _____

3. Facility Safety Plan Status Report

A Facility Safety Plan Status Report must be submitted **annually** starting no later than 1 year **after** obtaining the initial approval of the institution's Facility Safety Plan. To determine if your organization has an approved Facility Safety Plan, check our website listing at:
https://mrmc.amedd.army.mil/assets/docs/SSE/Facility_Safety_Plan_Approved_Institutions.pdf

The Facility Safety Director/Manager must provide a brief description of any parts of the Facility Safety Plan that may have changed during the past 12 months. (Additional pages may be attached.)

During the past 12 months:

1. Have any change(s) in Research Operation Safety Procedure(s) been made?
Yes _____ No _____
If yes, briefly describe:

2. Have any modifications to the facility, equipment, and description (e.g., new equipment purchased, hood ventilation certification) been made?
Yes _____ No _____
If yes, briefly describe:

3. Hazard Analysis: Have any new hazards been identified for any of the awards supported by the USAMRMC?
Yes _____ No _____
If yes, provide a hazard analysis for each new hazard.

4. Radioactive Materials: Have any significant change(s) occurred in the use of the radioactive materials?
Yes _____ No _____
If yes, briefly describe:

Are there any additional radioactive materials in use?
Yes _____ No _____
If yes, list additional material(s).

Is the radioactive material licensure current?
Yes _____ No _____
If no, please explain.

I certify that all of the above elements are true and correct to the best of my knowledge, and I assure that this institution provides a safe environment for its employees working in research laboratories in accordance with Federal, State, and local government regulations. This safety office provides employee safety training and periodic laboratory inspections in an effort to minimize, eliminate, or control potential hazards to the employees and the public.

I understand that the Safety Office, USAMRMC, may conduct periodic site visits in order to ensure the indicated elements are in compliance with regulatory requirements if this award is associated with funding received from DTRA in support of the DoD Medical Biological Defense Program.

Name of the Institution: _____

Name of Safety Director/Manager: _____

Signature: _____ Date: _____

Safety Director/Manager

E-mail Address: _____

Phone Number: _____

Fax Number: _____

Initial Facility Safety Plan approval by USAMRMC Safety Office: _____ Date _____

Submit the annual **Facility Safety Plan Status Report** including significant changes in facility, safety equipment, and safety procedures by fax to 301-619-6627, by e-mail to USAMRMC MRMC SS, by mail to the following address: DEPARTMENT OF THE ARMY, ATTN: MCMR-SS, HQ USAMRMC, 810 Schreider Street, Fort Detrick, MD 21702-5012.

4. Change of Principal Investigator or Institution

a. Change of Principal Investigator

In the event that the Principal Investigator changes, the new Principal Investigator shall complete a Newly Appointed Principal Investigator Assurance form (see **Newly Appointed - Principal Investigator Assurance**)

b. Change of Institution

In the event that an institution involved in this proposal changes, the new institution shall have an approved Facility Safety Plan on file at the USAMRMC Safety Office. To determine if your organization has an approved Facility Safety Plan, check our website listing at:

https://mrmc.amedd.army.mil/docs/rcq/sohd/facility_safety_plan_approved_institutions.pdf

If it is determined that a Facility Safety Plan needs to be submitted for approval, follow the guidelines set in part 2 of this appendix.

Newly Appointed - Principal Investigator Assurance

♦ I assure that I have coordinated with the Facility Safety Director/Manager in the research, and have discussed with him/her all aspects of the research-related specific safety issues, and will help him/her prepare the annual Facility Safety Plan Status Report.

♦ I assure that I will comply with my institution's safety program and its requirements.

♦ I understand that I am directly responsible for all aspects of safety and occupational health specific to my research protocol.

♦ I assure that I will report to the Facility Safety Director/Manager any changes in the safety or occupational health practices due to changes in my originally planned research.

♦ I assure that hazards associated with my research have been identified eliminated and/or controlled.

♦ I assure that all Facility Safety Plan requirements are in compliance with Local, State and Federal general industry standards.

♦ If applicable, I assure Biological research programs will follow the recommended guidelines established in the latest editions of the CDC-NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL); Army Regulation 385-10, Chapter 20 (Biological Safety); and DA Pamphlet 385-69 (Safety Standards for Microbiological and Biomedical Laboratories).

_____

Name of Principal Investigator (print)

_____ _____

Signature Date

Mailing Address: _____

Street

_____

City State Zip Code

Phone Number: _____

Fax: _____

E-mail Address: _____Web Site: _____