ATTACHMENT 4 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/docs/rcq/sohd/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/rodsohd.asp 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

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 Commanding General, U.S. Army Medical Research and Materiel Command, ATTN: MCMR-SS, 504 Scott 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 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 etiologic agents as defined below: ☐ Yes ☐ No

"Etiologic agent = 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).

_____
Name of Principal Investigator (print)

_____ _____
Signature Date

Mailing Address: _____

Street _____
City State Zip Code

Phone Number:
_____

Fax:
_____

E-mail Address:
_____

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/docs/rcq/sohd/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.
Name of the Institution:

_____

Name of Safety Director/Manager:

_____

Signature: _____ Date: _____
Safety Director/Manager
E-mail Address: _____
Phone Number: _____
Fax Number: _____
Facility Safety Plan approved by USAMRMC Safety Office: _____ Date _____

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: _____