Weill Cornell Medical College
Facility Safety Plan

a. Research Operations / Standard Operating Procedure

Weill Cornell Medical College (WCMC) maintains an Environmental Health and Safety Department (EHS) to address the institutional needs of complying with the Federal, State, and local laws regulating environmental, health and safety. The EHS Department provides comprehensive safety programs for the WCMC community which includes biological, chemical, radiation, industrial hygiene, construction, fire, emergency and general safety programs. EHS consists of a highly trained staff of Occupational Health and Safety professionals with areas of experience in General Safety, Fire Safety, Biosafety, Radiation Safety, Construction Safety, Emergency and Environmental Health and Safety.

EHS has established Program Manuals to maintain a safe and healthy work environment for all laboratory employees. These manuals cover all laboratory work involving the use of hazardous materials at WCMC. Required annual training and EHS program manuals encompass procedures that ensure compliance with the specific standards and regulations outlined below:

10 CFR US Nuclear Regulatory Commission Regulations
29 CFR (General Standards) 1910.1000, subpart Z
29 CFR 1910.1200 Hazardous Communication Act
29 CFR 1910.1030 Bloodborne Pathogens Standard
29 CFR 1910.1450 Chemical Hygiene Plan/Laboratory Standard
40 CFR Hazardous Waste Management (6NYCRR-NYS)
40 CFR 171.172 D.O.T. Regulations/Hazardous Waste Transport SARA – Title III
42 CFR Part 73, Possession, Use, Transfer of Select Agents Toxins
Guidelines for Research Involving Recombinant DNA—Molecules / NIH
CDC-NIH Biosafety in Microbiological and Biomedical Laboratories
New York City Administrative Code Title 29 New York City Fire Code
NYC Health Code 175.111

Every Principal Investigators in charge of a research laboratory at WCMC must complete an EHS Research Safety Checklist (RSC) as part of the grant application process. The EHS Research Safety Checklist serves two important functions: 1) it acts as a risk assessment tool for the Institution which is used to identify and address various hazard issues in research; and, 2) it provides Principal Investigators with a comprehensive checklist tool for recognizing hazards and compliance issues in the research environment.

Principal Investigators requesting a Certificate of Environmental Compliance must submit a description of the USAMRMC research proposal to EHS identifying all potential hazards associated with the project. Prior to issuing a certificate of environmental compliance, EHS reviews this submission, the listed laboratory facilities, all personnel training, and all safety equipment and procedures to ensure compliance with WCMC safety policies and procedures.
An Institutional Biosafety Committee is in charge of reviewing all biomedical research conducted at WCMC when a Principal Investigator submits an Institutional Biosafety Committee (IBC) Laboratory Registration form as part of the EHS Research Safety Checklist. This registration form provides a standardized submission process for Principal Investigators to meet the Federal, State, and local laboratory safety requirements.

Medical surveillance and support is provided to all WCMC students, faculty, and staff conducting work in a laboratory where hazardous materials are present through New York-Presbyterian Hospital’s Workforce Health (NYPH) and Safety (WHS) or WCMC Student Health Services (SHS). Prior to beginning work in a laboratory, a mandatory baseline examination is conducted for all students, faculty and staff prior to beginning work. Annual health assessments are conducted thereafter. In case of accident or exposure in the laboratory, medical assistance is available during working hours by WHS or SHS and after hours by the New York Presbyterian Emergency Department. EHS is available to respond to related emergencies 24/7 and to help coordinate exposure and/or spill response.

With respect to current considerations, the programs that pertain to this research document are further detailed as follows:

**Biological Safety Program**

- Registration and review by the IBC of a Laboratory Registration for work involving etiologic agents, recombinant DNA, select agents and toxins
- Periodic inspections of laboratories working with Recombinant DNA for compliance with Recombinant DNA Guidelines
- Semi Annual inspections of laboratories using M-TB and other Biosafety level 3 agents
- Annual inspections of laboratories using BSL2 agents
- Annual Training and Instruction for the WCMC Bloodborne Pathogen Exposure Control Plan and Research Biosafety Program for all Students, Faculty and Staff
- Biological Spill Planning and Response
- Biological material and dry ice shipping program and training
- Biological waste disposal, decontamination and regulated medical waste procedures
- Accident/incident investigation and mitigation

**Chemical Safety Program**

- Annual inspection of Laboratories for Compliance with WCMC’s Chemical Hygiene Plan requirements.
- Interface with New York City Fire Department Inspectors for laboratory inspections with regard to compliance with that agency’s Laboratory Fire Safety Directives.
- Training and Instruction for Chemical Hygiene Plan/Exposure Control Plan for all Faculty and staff.
- On-line ChemTracker Chemical Inventory System for the laboratories to maintain a complete inventory of all chemicals on the types, quantities and locations where these chemicals are being stored and used at the College.
- Material Safety Data Sheet Collection and dissemination.
All laboratories that store or use Highly Hazardous Substances (HHSs) must develop and implement a High Hazard Operating Procedure (HHOP) for each substance. The HHOP form serves as a tool to coordinate information and resources into a succinct procedure and facilitate review with lab staff.

Chemical Waste collection/packaging for recycling and disposal re: US EPA and DOT Regulations. All chemicals (solid and liquid waste) are collected from the research.

Reactive Hazard mitigation and “unknown” chemical identification by external consultant.

HAZ-MAT Emergency Response to chemical spills/accidents.

SARA compliance Title III Emergency Response Team. Activate Institution’s Emergency notification system.

USEPA RCRA, EPCRA, CERCLA, FIRFRA compliance activities and audits are conducted by EHS.

Annual Security Vulnerability Assessments as part of the Department of Homeland Security Chemical Facility Anti-Terrorism Standards.

Annual submission of the WCMC chemical inventory reports to the appropriate Federal and local government agencies as part of the Community Right-to-Know Program.

Health Physics Program

The Health Physics program at WCMC is supervised by the Radiation Safety Officer and executed by a team of qualified health physicists and technicians who are responsible for enforcing the regulations, statutes and policies of the City of New York, the State of New York, and other Federal or State agencies as applicable. The program must meet the qualification standards as set forth by the Nuclear Regulatory Commission in 10CFR35.50, and by NYC as set forth in Article 175 of the New York City Health Code. The functions of the Health Physics program include the following:

- Provide the centralized procurement, receipt, calibration, storage, issuance and disposal of all radioactive materials entering or leaving Weill Cornell Medical College and NY Presbyterian Hospital (WCMC/NYPH).
- Make personnel monitoring devices available to all staff members as designated by the Radiation Safety Committee (RSC) and provide instruction on the correct use of same.
- Maintain up to date records of all personnel exposures.
- Survey all areas where radiation is employed, determine exposure levels, and specify the appropriate and safest working conditions.
- Perform and document appropriate bioassay measurements on employees on a routine and, when necessary, on an emergency basis.
- Formulate regulations governing the use of radiation source (includes radiation machines as well as radioactive materials) so that such regulations are in conformance with those recommended by the National Council on Radiation Protection and Measurements, the Nuclear Regulatory Commission, and the City of New York and any other regulatory agencies having jurisdiction.
- Supervise and enforce the posting of appropriate warning signs in radiation areas.
- Review plans and protocols for the proposed use of radiation and make appropriate recommendations to the user and the RSC.
- Provide Radioactive accident/incident investigation and mitigation
- Process the decontamination of individuals or property and the disposal of radioactive waste.
- Provide periodic reports to the Administration attesting to the identity, classification and amount of all radioactive materials or sources entering WCMC/NYPH.
- Monitor all therapy and X-ray machines, including teletherapy units, capable of producing ionizing radiations.
- Provide training on proper use, storage and disposal of radioactive materials.

**b. Facility Equipment and Description** (as Related to the Research Environment)

Weill Cornell Medical College operates over 1000+ medical research laboratories, at over 10 different locations in New York City.

Laboratory facilities are issued a permit by the Fire Department of New York and are inspected for compliance by FD inspectors with respect to general fire safety and chemical safety and storage practices in each lab space. Noncompliance results in formal issuance of a violation order with a specified time limit to correct deficiencies. Permits can be revoked by the Fire Department.

All laboratories are 100% in - 100% out ventilated spaces, with more than 200 laboratories having chemical hoods available in continuous operation mode.

Lab facilities, access policies and material handling procedures fulfill the criteria established for biosafety level guidelines by the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories. Each laboratory is equipped as necessary with fumes hood(s), biological safety cabinet(s), emergency showers and eye wash stations, fire extinguishers, autoclaves, flammable storage cabinets, explosion proof refrigerators/freezers, oxygen sensors, radiation detectors, and personal protective equipment including laboratory coats, aprons, eye glasses or goggles, face shield, and chemical resistant gloves. Personal Protective Equipment is specified for each researcher in the departmental compliance policy, and within specific standard operating procedures prepared by the principal investigator for his/her projects.

At present, WCMC has one BSL 3 facility, and one Gene Therapy Core (GMP) Facility.

**c. Radioactive Materials**

Copies of the City of New York Radioactive Materials License(s) are attached.
d. **Hazard Analysis (Related to the Research Environment)**

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<thead>
<tr>
<th>Hazard Identified</th>
<th>Maximal Credible Event</th>
<th>Hazard Elimination/Control Plan</th>
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| Chemicals        | Chemical Spill or exposure to hazardous chemical | **Standard Laboratory Chemical Safety Program**<br> All laboratories require and implement WCMC’s laboratory chemical safety program. The WCMC Laboratory Chemical Hygiene Plan manual, Chemical Spill Planning and Response manual, and Waste Disposal manual serve as the standard operating procedures for chemical safety and disposal in laboratories. All laboratory workers are required to complete Laboratory Safety training which reviews chemical hazard identification, routes of exposure, exposure prevention and control methods, safe work practices, and facility/laboratory personal protective equipment and specialized safety equipment outlined in Section b. Facility Equipment and Description.  

**High Hazard Operating Procedure Program**<br> Laboratories that store or use Highly Hazardous Substances (HHSs) including but not limited to explosive, reactive, or acutely toxic chemicals must develop and implement a High Hazard Operating Procedure (HHOP) for each substance. High hazardous substances are identified in the Research Safety Checklist review process and assessments of WCMC’s campus-wide chemical inventory system. The HHOP identifies specific exposure hazards associated with the highly hazard substance; specific exposure controls needed to safely handle the material; unique medical attention and first aid requirements; specialized emergency and spill response procedures; and supplemental training requirements necessary before laboratory staff are authorized to use the highly hazardous substance. |
<table>
<thead>
<tr>
<th>Biological Agents</th>
<th>Accidental exposure to infectious agents</th>
<th>The Institutional Biosafety Committee approves all work involving infectious agents and recombinant DNA and sets the appropriate BSL. Class II biosafety cabinets or other engineering controls are required for work with infectious agents. EHS conducts periodic inspections to ensure facility and procedures are consistent with the WCMC Research Biosafety Manual. An exposure/incident reporting procedure is available within the WCMC Bloodborne Pathogens Exposure Control Plan. Exposures are managed by the EHS Emergency Response Team and Biosafety Professionals according to the Biological Spill Planning and Response Plan.</th>
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<tbody>
<tr>
<td>Radioactive Materials</td>
<td>Accidental exposure to radioactive materials</td>
<td>The Radiation Safety Committee approves all authorized users of radioactive materials for appropriate training and experience. Individuals involved with the direct handling of RAM must complete a training course with exam and attend annual refresher training. OHP conducts periodic inspections to ensure that the laboratory and procedures comply with institutional guidelines and regulatory mandates. Safety manual in available on-line and as hard copy. Emergency procedures are posted in each laboratory.</td>
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<tr>
<td>Lasers</td>
<td>Accidental exposure to direct or reflected beam</td>
<td>All lasers are registered with Office of Health Physics and undergo periodic inspections to ensure shielding integrity, safe operating procedures and appropriate protective equipment.</td>
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<tr>
<td>Physical &amp; Mechanical Equipment</td>
<td>Accident involving high pressures pumps, presses, centrifuges, compressed gasses, high voltage systems</td>
<td>EHS provides General Safety evaluation and practice review for lab research activities. Equipment which may pose physical and/or mechanical hazards is inventoried and a hazard analysis is completed for each piece of equipment. The hazard analysis is reviewed with the equipment supervisor and then with operators through training. General physical hazard training sessions are available through EHS and the lab supervisor/equipment supervisor is required to provide training to each equipment operator. A standard training outline has been developed to ensure adequacy of supervisor training programs. EHS audits all equipment in this program on a semi-annual basis.</td>
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e. Infectious Agents and Toxins (IAT) Research Program Requirements

We have no laboratories conducting research with Risk Group 3 or 4 agents which are supported by Biological Defense Research Program funded awards.