COLUMBIA UNIVERSITY

COMPLIANCE AND TRAINING REQUIREMENTS FOR VISITORS INVOLVED IN RESEARCH ACTIVITIES

A. Introduction

Columbia University (**Columbia** or the **University**) benefits from the presence of many visitors who come to the University for limited periods of time to be involved in research-related activities (**Research Visitors**). Although the majority of such Visitors are students, established scholars or practitioners may also want to spend time at the University to learn new skills and techniques, collaborate on research projects, observe research activities or conduct independent research. Other individuals who are not students, scholars or practitioners occasionally wish to volunteer their time to the University by assisting in certain research activities. Finally, some individuals come solely to observe research or clinical programs conducted at the University.

While the presence of Research Visitors promotes the mission of the University, we have an obligation to ensure that their activities are conducted in a safe and responsible manner, in compliance with federal, state and local laws and regulations and all University policies. These Guidelines cover only those compliance and training requirements relating to all Research Visitors; they do not cover requirements relating to employment, compensation, academic appointments and designations or visas. It is important to note that all visitors at the University must have the proper appointment pursuant to the <u>Faculty Handbook</u> or must be registered in accordance with the <u>Visiting Student Interns</u> policy or the <u>Short-Term Visitor Guidelines</u>, as appropriate. In addition, there may be other specific requirements for clinical research activities at Columbia University Irving Medical Center (**CUIMC**).

A. Overall Responsibility of Sponsors.

It is the responsibility of sponsors of Research Visitors, and applicable investigators and departmental administrators, to ensure that all Research Visitors: (1) have received the necessary training and/or approvals and (2) comply with all relevant University rules and policies during their stay.

The Research Compliance Training Finder can help determine what trainings an individual is required to take. The Training Finder is available at: http://www.columbia.edu/cu/compliance/docs/training/index.html.

B. Additional Requirements

The following additional requirements apply to Research Visitors to the extent that they relate to

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the activities that the Visitor will be engaged in at the University.

1. Environmental Health and Safety; Radiation Safety

All Research Visitors who plan to participate in or observe research in a laboratory must attend the applicable Environmental Health and Safety (EH&S) training sessions or take the applicable EH&S online courses. Individuals may identify safety training through the Research Compliance Training Finder referenced above. See https://rascal.columbia.edu. Sponsors and other investigators with whom the Research Visitor will be working must make Research Visitors aware of basic institutional safety policies and procedures that are applicable to regular employees. Research Visitors must read the University's Laboratory Safety and Chemical Hygiene Plan, available at

https://research.columbia.edu/sites/default/files/content/EHS/Manuals/ChemicalHygienePlan.pdf as well as the host laboratory's Laboratory Assessment Tool and Chemical Hygiene Plan (LATCH).

The Research Visitor's sponsor, or his/her designee, will provide task-specific training in handling hazardous materials:

- Research Visitors with no prior experience may not handle hazardous materials until they can demonstrate technical proficiency obtained through initial work with non-hazardous materials. (e.g., use of water to demonstrate and teach dilution techniques at the outset of activities). A progression of activities will be assigned as techniques are learned and proficiency developed to the satisfaction of the principal investigator or the Visitor's sponsor.
- For those with prior experience in handling hazardous materials, the principal investigator or the Research Visitor's sponsor, or his/her designee, will assess the level of competency and provide further training as needed if a progression of work activities is required.

Research Visitors may not perform any clean-up activities relating to spills other than those necessary for the immediate protection of themselves and others.

The involvement of Research Visitors in the handling of hazardous waste is limited to placing the waste in designated containers; they may not be involved with labeling, identification or storage of the waste. Those are responsibilities of trained laboratory staff members.

Research Visitors who may be exposed to radioactive material or ionizing radiation must contact EH&S to enroll in the dosimetry program that monitors radiation exposure.

2. Privacy and Access to Health Records

No Research Visitor may have access to patient or research subject records or protected health information without completing the University's HIPAA Privacy and Security Essentials training. This includes access to electronic clinical information, hard copy records, or protected health information in any other format. To register for HIPAA training, the Research Visitor

should send an email to HIPAA@columbia.edu.

Research Visitors are generally not permitted to have access to any Electronic Medical Records (EMR); however, access may be granted to on a case-by-case basis for the Visitors to perform their assigned tasks. To obtain access, a department chair or administrator may submit a written request to CUIMC's Chief Medical Information Officer. The request must include a justification for permitting access, the information that must be accessed and the duration of the access, as well as the name and title of the individual responsible for supervising the Visitor's access.

3. Medical Surveillance

Visitors at CUIMC who may be present in patient care settings are subject to the University's Medical Surveillance Policies and Procedures through Workforce Health and Safety. If any Visitor will come into contact with patients in Article 28 space at NewYork-Presbyterian Hospital (NYP) or NYP's Ambulatory Care Network, the Visitor is also subject to the NYP Medical Clearance process.

Visitors performing laboratory research with human-derived materials are subject to the University's bloodborne pathogen exposure control program. Medical clearance is required for participation in the program.

Scheduling of medical surveillance appointments is through use of an online special indicators form: https://secure.cumc.columbia.edu/hrforms/node/add/medical-surveillance-form.

Any specific questions or concerns regarding the CUIMC Medical Surveillance process must be raised with the CUIMC Human Resources Office, which will work with Workforce Health and Safety to address concerns and review special circumstances.

4. Human Subjects Research

Research Visitors may engage in human subjects research with the approval of the University's Human Research Protection Office (HRPO) through an Institutional Review Board (IRB) or Administrative Review Committee. Each Research Visitor must be listed in the Personnel section of the Rascal application relating to the relevant IRB protocol. In addition, each Research Visitor must complete all applicable training, including on-line training in human subjects protection and, for CUIMC research and other research involving protected health information, both general HIPAA training (see Section B(2) above) and on-line HIPAA Training for Researchers (available in Rascal). See https://rascal.columbia.edu

In general, Visitors who are employed by or studying at non-Columbia institutions, and are participating in human subjects research at Columbia to satisfy employment or academic requirements, may not be named on a Columbia IRB protocol. Such Visitors should provide documentation of IRB approval from their home institution. Contact the HRPO to discuss these situations.

5. Animal Research

Research Visitors may not participate in activities that directly involve vertebrate research

animals without the prior approval of the University's Institutional Animal Care and Use Committee (IACUC). The principal investigator is required to include the names, qualifications and activities of all Visitors in his/her animal protocol form, together with a description of the activities in which the Visitor will participate. Veterinary students and veterinary technician students who are at the University's Institute of Comparative Medicine (ICM) are excepted from this requirement.

Prior to undertaking any activities involving animals, Visitors (including veterinary students and veterinary technician students) must attend the IACUC regulatory lecture, take any required webbased species-specific training courses, and/or attend any required wet lab training offered by the ICM. See https://rascal.columbia.edu. In addition, all Visitors who work with animals are subject to the University's Medical Surveillance Policies and Procedures. Veterinary students and veterinary technician students, as well as any other Visitors who work with animals, may use the Visiting Non-MD Attestation of Medical Fitness form.

See http://www.cumc.columbia.edu/hr/policies-procedures.

C. Minors

Visitors under the age of eighteen are "minors" for purposes of New York State law. Sponsors should familiarize themselves with Columbia's policy on the Protection of Minors. For more information, please visit the Protection of Minors website at http://www.compliance.columbia.edu/minors.html.

Where minors participate in research-related activities in University laboratories (as opposed to being present during a tour for strictly observational purposes), the following must be considered:

- No Visitor under the age of fourteen is allowed in any University laboratory (except if present on an organized tour or field trip for strictly observational purposes, provided hazards are minimized).
- Minors between ages 14 and 18 may participate in certain research-related activities in a laboratory, so long as they have completed applicable safety training and they are directly supervised by the principal investigator, sponsor or his/her designee.
- No Visitor under the age of 18 should be alone in a laboratory.
- No Visitor under the age of 18 may handle human blood, human cell lines or any other material defined as "other potentially infectious materials" by OSHA (Bloodborne Pathogens Standard 29 CFR 1910.1030).
- No Visitor under the age of 18 may handle laboratory animals.

It is University policy that any adult who interacts with, supervises, chaperones or otherwise oversees minors in programs or activities at the University or sponsored by the University is required to take a Protection of Minors course to familiarize members of the Columbia community with University policy and relevant law and will be background checked every two years. In addition, it is mandatory that all adults must register their programs (whether formal or informal) that involve minor Visitors with the Protection of Minors Office. Please

contact pomtraining@columbia.edu for more information.

D. Accidents and Emergencies

In the event of an accident or emergency, the same procedures used for employees should be used for Visitors. The individual should be treated (a) for the Morningside Heights and Manhattanville campuses, at Student Health Services, the Emergency Room at Mt. Sinai Morningside or the Emergency Room at NYP, (b) for the Lamont-Dougherty Earth Observatory Laboratories, at the Emergency Room at St. John's Riverside Hospital, Dobbs Ferry Pavilion, or (d) at CUIMC, Workforce Health and Safety or the Emergency Room at NYP. In each case, the appropriate Human Resources office should be notified and a Departmental Accident Report Form should be completed and sent to University Risk Management.

All Visitors must be covered by adequate medical insurance and must provide documentation of such insurance. Visitors will be personally liable for any medical costs that are not covered by insurance.

E. Miscellaneous

The University reserves the right to cancel any Visitor's application or observership if such Visitor fails to comply with University policies.