SECTION I. General

Chapter 6.2 Adult Non-Employees

Revision Date 3/2025

ADULT NON-EMPLOYEES IN WORK AREAS

INTRODUCTION

PURPOSE

Duke acknowledges that there are justifiable and productive reasons for the presence of Adult Non-Employees in work areas. Due to potential exposure to biological, chemical, radioactive, and physical hazards – particularly in research laboratories – the following guidelines are necessary to minimize risks.

This policy addresses activities for individuals 18 years of age or older who are not covered under existing policies and procedures. This policy does not apply to:

- Anyone under the age of 18 (see the Minors in Work Areas policy)
- Enrolled Duke Students
- Events open to the general public
- Patients or visitors in health care settings
- Employees of other companies providing contracted services or deliveries to Duke work areas
- Research study participants in studies approved by the Duke Institutional Review Board
- Affiliate students, Visiting Physician Observers or others covered by an authorized student clinical experience agreement, formal affiliation contract, Visiting Observer Agreement or other agreement or contract compliant with an applicable Duke University Health System policy

DEFINITIONS

Adult A person who is at least 18 years old.

Non-Employee A person who performs or observes work without compensation

from Duke. For the purposes of this policy, any requirements or restrictions applicable to "Non-Employees" in this document are also applicable to Volunteers, Unpaid Interns, or Visiting Research

Scholars as defined below.

Volunteer A person who volunteers or donates their services, usually on a

part-time basis, for public service, religious or humanitarian

objectives, not as employees and without contemplation of pay. The <u>Duke Volunteer and Unpaid Intern Policy Guidelines</u> on the Duke Human Resources Website list criteria for ensuring that a volunteer is not an employee.

Unpaid Intern

An individual who volunteers for purposes of educational or professional interest as part of a formal or informal educational program, assessed under specific factors from the Department of Labor (see <u>Duke Volunteer and Unpaid Intern Policy Guidelines</u> on the Duke Human Resources Website).

Visiting Research Scholar An individual coming to Duke to take part in research activities, whether funded or unfunded, who is not receiving payment (i.e., stipend, salary support, etc.) from Duke or enrolled in any official Duke Coursework as part of their visit. Other roles for this individual may include, but are not limited to: affiliate, research scholar, postdoctoral fellow, visiting scientist, visiting scholar, or visiting graduate or undergraduate students who are not "Affiliate Students" as defined in the <u>Guidance on Visiting Research Scholars</u> on the Duke Office of Research website.

Sponsor

For the purposes of this policy, Sponsor refers to a Principal Investigator in research settings, or a Responsible Employee in other areas.

Responsible Employee A fully trained Duke employee who is responsible for the work area (supervisor, manager, etc.).

RESPONSIBILITIES

<u>Heads of all Departments</u> shall take appropriate steps, as described in this policy, to ensure the safety of all adult Non-Employees in the areas under their supervision.

<u>Heads of Departments</u> which sponsor <u>volunteers in Duke Hospitals</u> must coordinate with <u>Duke University Hospital Volunteer Services</u> (or the appropriate contact for other Hospitals) for any volunteer positions within Duke Hospitals or Clinics and comply with their requirements.

<u>The Sponsor</u> (the Principal Investigator (PI) for research areas or a Responsible Employee for non-research areas) must:

• Only allow adult Non-Employees in their laboratories or related work areas that fulfill the requirements outlined in this policy.

- Provide for appropriate supervision of the adult Non-Employee and document confirmation of this on the <u>Workplace Safety Statement</u>.
- Sign the <u>Workplace Safety Statement</u> to acknowledge all applicable policies and certify that they will comply with any additional safety requirements or restrictions outlined by OESO on the approved Workplace Safety Statement.

<u>The Direct Supervisor for the adult Non-Employee</u> (or Sponsor, if unspecified) must:

- Ensure the Non-Employee completes all required safety training before entering any work areas with hazardous materials or physical hazards. The Direct Supervisor must also have their own required safety training completed.
- Assess the potential risk of exposure to hazards and direct the Non-Employee's
 access accordingly. If any other employees will be escorting or supervising the
 activities of the Non-Employee, the Direct Supervisor must also communicate
 these risks and directions to those employees.
- Ensure the Non-Employee has fully reviewed and signed any safety documentation relevant to the work area and tasks being observed or performed, such as a labspecific Chemical Hygiene Plan (CHP) and any additional safety SOPs or Guidelines.
- Ensure the Non-Employee is informed of where to go in case of a fire alarm or other emergency.
- Ensure the Non-Employee is familiar with the location of any safety equipment in the work area such as eyewashes, safety showers, handwashing sinks, as well as any relevant engineering controls.
- Ensure the Non-Employee wears the appropriate PPE for the work area or task being observed or performed.
- Provide supervision of the Non-Employee and ensure the Non-Employee is following all safety policies, SOPs, and Guidelines.
- Prohibit the Non-Employee from remaining in the work area if the Non-Employee cannot abide by safety policies and procedures.
- Sign the <u>Workplace Safety Statement</u> to acknowledge all applicable policies and certify that they will comply with any additional safety requirements or restrictions outlined by OESO on the approved Workplace Safety Statement.

The Occupational & Environmental Safety Office (OESO) is responsible for reviewing and determining approval for the activities documented on the Workplace Safety Statement and notifying the personnel listed on the Workplace Safety Statement when approval has been granted. Review of the Workplace Safety Statement may include obtaining additional information, performing a safety evaluation of the work area, and outlining any additional safety requirements, restrictions, or recommendations.

<u>Adult Non-Employees</u> who will be in laboratory settings or in other areas where additional safety procedures or regulatory requirements apply must complete all required safety training noted on the OESO-approved <u>Workplace Safety Statement</u> before entering those work areas.

Responsibilities from related policies and resources:

- Where applicable, adult <u>Non-Employees who are volunteers or unpaid</u> <u>interns</u> (and their <u>Sponsors</u>) will also abide by the "<u>Volunteer & Unpaid</u> <u>Intern Policy Guidelines</u>" on the Duke Human Resources Website.
- Where applicable, adult <u>Non-Employees who visit clinical areas</u> (and their <u>Sponsors</u>) will also abide by the "<u>Visiting Observer Policy (Non-Physician)</u>" policy found in the Duke Health Policy Center on the Duke Health Intranet.
- Where applicable, <u>Visiting Research Scholars</u> (and their <u>Sponsors</u>) will also abide by the "<u>Guidance on Visiting Research Scholars at Duke</u>" found on the Duke MyResearchPath secured website.
- Where applicable, <u>individuals who escort or supervise the activities of adult Non-Employees at research field sites</u> will also abide by the "<u>Fieldwork Safety Policy</u>" on the Duke OESO Website.
- Where applicable, adult <u>Non-Employees who will visit or work in Duke</u>
 animal care and use operations (and their <u>Sponsors</u>) will abide by the
 Institutional Animal Care and Use Committee (IACUC) "<u>Visitation, Animal</u>
 <u>Observations, or Photography of Animals Policy</u>", as well as any other
 relevant <u>Animal Care and Use Policies</u> on the Animal Care and Use Program
 secured website.

PROCEDURES

APPROVAL OF ADULT NON-EMPLOYEES IN THE WORK AREA

Non-Employees must not enter laboratory, animal care, patient care, makerspace, or industrial areas without written approval from Duke Occupational & Environmental Safety Office (OESO) for the activities the Non-Employee will undertake or observe. Written approval must first be obtained from the "Sponsor" (Principal Investigator for laboratory or other research locations, or a Responsible Employee for non-research locations). The Duke personnel requesting OESO approval for the adult Non-Employee must provide OESO with written evidence of approval by the Sponsor by using the Workplace Safety Statement on the OESO website.

The Duke personnel requesting OESO approval must indicate the following details on the Workplace Safety Statement:

- Whether the Non-Employee will be actively performing activities or solely observing
- A description of the activities the Non-Employee will engage in or observe
- Identification of any hazardous materials or potential risks that the Non-Employee may be exposed to in the work area

The Workplace Safety Statement must be signed by the Sponsor, as well as the employee who will be directly supervising the Non-Employee (Direct Supervisor, if not the Sponsor).

The Workplace Safety Statement should be submitted to OESO at least two weeks prior to the arrival of the adult Non-Employee.

Upon submission, the OESO will review the request to assess compliance with applicable safety regulations. The review process may include the following steps:

- Evaluation of the described activities, work areas, and associated risks
- Reguests for additional information as needed
- A site-specific safety evaluation of the proposed work area
- Collaboration with the Direct Supervisor or Sponsor to address any necessary safety measures required for approval of the described activities

Following the review process, the OESO will return a finalized Workplace Safety Statement to the Direct Supervisor and Sponsor which includes a summary of approval conditions for the proposed activities. Laboratories must be in compliance with Duke OESO's laboratory safety evaluation performance factors in order to receive final approval from OESO.

TRAINING AND SUPERVISION FOR ADULT NON-EMPLOYEES

In order to volunteer or otherwise be present in work areas at Duke, adult Non-Employees must be able to successfully complete all relevant safety trainings administered by Duke Occupational & Environmental Safety Office (OESO) and must review and sign any applicable lab-specific SOPs or general safety guidelines. Adult Non-Employees at Duke must complete safety training required for employees doing similar tasks in that work area and any other safety-related training indicated by OESO.

Adult Non-Employees must satisfactorily complete all applicable training and orientation appropriate to the role prior to commencing activities. Depending on the nature of the service, training may also include HIPAA requirements, additional health and safety precautions, lab protocols, animal lab requirements, or compliance or customer service requirements. Non-Employees will be prohibited from continuing to be in the work area if safety procedures are not followed.

Adult Non-Employees with approval to volunteer, observe, or otherwise be present in laboratory or other work areas must be supervised by responsible personnel from that area (the Sponsor or Direct Supervisor designated on the Workplace Safety Statement approved by OESO). Where deemed appropriate, the Direct Supervisor or Sponsor may place additional restrictions on the presence of adult Non-Employees in the work area.

Under no circumstance will an adult Non-Employee be allowed in any work area where they present a distraction to the employees in the area. Distractions may be due to the activities of the Non-Employee or due to the level of supervision the Non-Employee may require.

AREA RESTRICTIONS FOR ADULT NON-EMPLOYEES

Some work areas contain hazards that have the potential to be detrimental to the

adult Non-Employee's health or well-being and therefore have additional safety requirements that must be fulfilled prior to the Non-Employee entering those areas, including but not limited to:

- Non-Employees going to areas in the patient care environment must comply with the <u>DUHS Visiting Observer Policy for Non-Physicians</u> or other relevant policy as applicable. They will also need to take applicable safety training for being in the patient care environment such as but not limited to Environment of Care training and Tuberculosis training administered by OESO.
- For work in high-risk areas (such as operating rooms, infectious disease clinics, etc.), the Sponsor must work with OESO to perform a risk assessment before continuing.
- Adult Non-Employees who will be present in areas managed by the Division of Laboratory Animal Resources (DLAR) or PI-managed animal housing facilities must first be cleared as animal handlers and listed on the applicable IACUC Protocol (when relevant) and must complete all required training and occupational health activities.

RESTRICTED MATERIALS AND PROCESSES FOR ADULT NON-EMPLOYEES

Adult Non-Employees are not be permitted to observe, work, volunteer, intern, or perform research in a capacity where it is determined to be unsafe to the Non-Employee or in violation of government regulations or Duke safety policies, <u>including</u> but not limited to:

- Performing any activities not approved or outlined by the minimum safety guidelines established by the Occupational & Environmental Safety Office (OESO).
- Operating heavy equipment, including vehicles in a way that would violate the <u>Vehicle Safety Policy</u> (see the <u>Volunteer and Unpaid Intern Policy Guidelines</u> and the Duke <u>Vehicle Safety Policy</u> for more information).
- Working with stored energy (e.g. steam, electricity, hydraulics).
- Working with any Select Agents as identified by the <u>Federal Select Agent Program</u>.
- Engaging in an activity considered inappropriate for any employee.

Some materials or procedures require additional safety procedures to be in place before adult Non-Employee will be approved to handle or perform them, <u>including but not limited to</u>:

For any adult Non-Employee who will be exposed to materials that require
medical surveillance, the sponsoring department must arrange the proper
medical surveillance with <u>Duke Employee Occupational Health and Wellness</u>. The
costs of any required medical surveillance (e.g., for respiratory protection) for the
Non-Employee will be paid by the sponsoring department.

- Prior to any work with live animals or embryos, the adult Non-Employee must be added as personnel to the relevant animal protocol as required by the IACUC and must complete Animal Handler Health Surveillance and relevant training as required.
- Any adult Non-Employee who will be exposed to human blood, body fluids, or cell
 lines must be offered the Hepatitis B vaccine and must provide records of the
 vaccine, sign a declination waiver, or arrange to be vaccinated through the <u>Duke</u>
 <u>Employee Occupational Health and Wellness</u>. If vaccination is needed, the cost
 must be paid by the sponsoring Department.
- Any adult Non-Employee who will be in a Biosafety Level 2 (BSL-2) lab must complete the "Biosafety Level 2 and Bloodborne Pathogens for Lab workers" safety training administered by OESO. The Non-Employee must also fully review and sign any relevant biological safety SOPs or guidelines before entering the work area. For any work with biologicals, the lab must report the biological material in the Biological Materials Reporting System and, when applicable, have a lab-specific SOP approved by the OESO Biological Safety Division within the last three years. For any work with rDNA, the Principal Investigator (PI) must have a valid IBC registration.
- Any adult Non-Employee who will be working with sharps must follow the <u>Sharps</u>
 Management Plan provided by OESO.
- Any adult Non-Employee who will be working around ultraviolet light must review the information sheet on <u>Working Safely with Ultraviolet Light</u> provided by OESO.
- Any adult Non-Employee who will be working with chemicals beyond disinfectants
 will need to fully review and sign any safety documentation relevant to the work
 area and tasks being observed or performed, such as a lab-specific Chemical
 Hygiene Plan (CHP) and any additional safety SOPs or Guidelines.
- Any Non-Employee who could be exposed to a chemical which is identified as <u>Particularly Hazardous Substance</u> (PHS) based on the criteria published by the Duke Occupational & Environmental Safety Office (OESO) will need to fully review and sign the lab-specific SOP for that chemical. Any tasks that involve <u>Particularly Hazardous Substances</u> should limit the volume to 10 mL or less when possible. For chemicals classified as <u>Action A</u> (high risk), the lab must have an SOP for that chemical that has been approved by the PI (and OESO, when applicable), and the Non-Employee must review and sign the SOP before working with that chemical.
- Any adult Non-Employee who will be performing or observing tasks in research laboratories (beyond observing) must complete the "Hazard Communication for Laboratory Employees", "Laboratory Safety – General", and "Fire/Life Safety" trainings administered by OESO (at minimum).
- Any adult Non-Employee who will be working with or around formalin, paraformaldehyde, or formaldehyde must complete the "Formaldehyde Exposure Awareness" safety training administered by OESO.
- Any adult Non-Employee who will be working with autoclaves must be trained following the Safe Use of Autoclaves Training Checklist provided by OESO.

- Any adult Non-Employee who will be working with lasers or high-risk confocal microscopes must complete the "Laser Safety for Non-Clinical Users" safety training administered by OESO.
- Any tasks that involve flammable liquids (including ethanol) should limit volumes to 250 mL or less when possible.
- Any tasks that involve corrosive liquids (including bleach) should limit volumes to 100 mL or less when possible.

INCIDENT REPORTING FOR ADULT NON-EMPLOYEES

Any accidents, injuries, or exposures to hazardous materials must be reported by contacting OESO.

QUESTIONS

Questions about this policy should be directed to the Duke Occupational & Environmental Safety Office Laboratory Safety Division by calling (919)-684-8822 or sending an email to labsafety@duke.edu.

REFERENCES

Duke Health Policy Center 01.23, "Visiting Observer Policy (Non-Physician)"

Duke IACUC/OAWA Policy "Animal Care and Use Policies"

Duke University Policy 02.12, "Volunteer and Unpaid Intern Policy Guidelines"

Duke University Policy 06.18, "Visitation, Animal Observations, or Photography of Animals Policy"

Duke University Policy 10.18, "Vehicle Safety"
Duke University Policy 11.15, "Fieldwork Safety"

Duke University Policy 12.23, "Guidance on Visiting Research Scholars at Duke" Federal Select Agent Program list of "HHS and USDA Select Agents and Toxins"