

COLLEGE OF MEDICINE

College of Medicine and Office of Health Sciences Guidelines for Research Volunteers

Website: https://medicine.osu.edu/research/opportunities/volunteers

Research Volunteer Application: http://go.osu.edu/comresearchvolunteers

Contact: ResearchVolunteers@osumc.edu

Updated September 2019

What is a research volunteer?

A research volunteer is anyone who volunteers or donates her/his services by observing or assisting with research projects on behalf of OSU/OSUWMC, without receiving course credit or compensation from OSU/OSUWMC for these activities. This may include students, community members and employees (in limited circumstances). Qualified research volunteers can provide meaningful assistance in laboratory, clinical or translational research settings. Protecting volunteers from injury or illness is of the utmost importance to OSU/OSUWMC while providing volunteers with educational enrichment opportunities.

These guidelines do NOT apply to Postdoctoral fellows, visiting scholars, observers, contractors, students performing research for academic credit at OSU, or clinical research subjects enrolled in a research study.

What if I am employed by OSU/OSUWMC?

Under the <u>Fair Labor Standards Act</u>, employees may not volunteer services in the same or similar area in which they are employed. You may be eligible to volunteer if your volunteer activities are distinct from your responsibilities as an employee.

What if I am not a U.S. Citizen or permanent resident?

Foreign nationals must have an appropriate visa type and work authorization may be required. Foreign nationals may not volunteer while awaiting work authorization or change in status. For questions related to volunteer activities for foreign nationals, please contact the Office of International Affairs at 614-292-6101.

What is required?

The faculty principal investigator (PI) and departments/units are directly responsible for ensuring volunteer compliance with health assessments, training requirements, background checks, and other items required to be performed prior to engagement. They are also directly responsible for ensuring the appropriateness of the specific volunteer activities. The Research Volunteer Application, health assessments, training, background checks and institutional research approval requirements must be completed prior to the individual performing any volunteer activities. These may need to be repeated depending on the length of the volunteer's service. Documentation of this information must be maintained by the department/unit and available for review upon request. Volunteers must be instructed in the appropriate departmental/unit and institutional safety guidelines applicable to their activities and under the direct supervision of the PI.

The Research Volunteer Application and Research Volunteer Requirements document must be completed, signed, and submitted to the College of Medicine Office of Research (COMOR) for all COM/OHS research volunteers. Any changes to the application information must be reported to the COMOR within 30 Business Days. Volunteers are responsible for abiding by OSU/OSUWMC policies and applicable regulations that govern their actions, including the Self-Disclosure of Criminal Conviction policy. Supporting documents must be maintained within the department/unit and producible for audit at any time.

Training and Health Requirements for Research Volunteers

College of Medicine (COM) and Office of Health Sciences (OHS) research volunteers are required to complete specific training and assessments prior to engaging in research to comply with local, state and federal regulations and institutional and accreditation agency standards. The purpose of this document is to provide an outline of the training and assessment requirements that must be completed prior to beginning a research volunteer experience. It is the responsibility of the administrative unit to ensure required training is completed and records are maintained appropriately.

Training modules and class registration are available on <u>BuckeyeLearn</u>. BuckeyeLearn is an online training tool for use university-wide, enabling learning and training opportunities to be easily accessed and tracked for the university and Wexner Medical Center community.

An OSU name.# and password or Medical Center ID credentials are required to login to BuckeyeLearn. Some training is only available for those with a Medical Center account.

Information regarding how to create an OSUWMC guest account is available through my.osu.edu here (OSU logon required).

Unless noted otherwise below, training requirements must be completed annually. Each administrative unit is responsible for maintaining and reconciling training and health records with unit rosters. Each research volunteer's duties should be reviewed and assigned the appropriate training and assessments as needed.

eLearning is available through BuckeyeLearn unless noted otherwise.

Annual requirements:

- 1. Annual HIPAA Privacy & Security
- 2. HIPAA Privacy & Research
- 3. Understanding the Sexual Misconduct Policy
- 4. Report = Support: Identifying and Responding to Sexual Misconduct
- 5. Introduction to Cultural Sensitivity (part of the Cultural Competency curriculum, but only this course is required)
- 6. Safety and Emergency Preparedness
- 7. Compliance: Your Responsibilities
- 8. Infection Prevention (non-clinical or clinical module, depending on role)
- 9. Patient Safety (non-clinical or clinical module, depending on role)
- 10. Influenza Pandemic Prevention & Response Plan (required for flu shot exemptions only)
- 11. Code Silver Preparedness
- 12. Medical Center Security In-Service
- 13. Institutional Data Policy
- 14. OSU Financial Conflict of Interest disclosure (eCOI)

Initial training requirements (one time only):

- 1. Building Emergency Action Plan (BEAP)
- 2. Hazard Communication (HazCom) if *not* working with hazardous chemicals OR Laboratory Standard if working with hazardous chemicals
- 3. Fire Extinguisher Training
- 4. Responsible Conduct of Research CITI training (Office of Research Compliance)

Health requirements:

- 1. Hepatitis B vaccination
- 2. Current tetanus vaccination
- 3. Health insurance
- 4. Annual influenza vaccination (highly recommended, but not required)

The applicant's private physician or the Health Department can provide these records/ services. If vaccinations/tests and other medical treatment are obtained at OSUWMC, the research volunteer will be responsible for payment.

Additional Training

The department/unit and principal investigator are responsible for ensuring research volunteers complete additional training or health assessments specific to research tasks an individual may perform. These may include but are not limited to those listed below. For questions, please contact College of Medicine Office of Research.

Training or Health Assessment	Resource
Health screenings or vaccinations	Occupational Health Program
CITI Training (Basic Human Research Course, Good Clinical Practice)	Office of Responsible Research Practices
Applicable Biosafety Program Training	EHS Training
Applicable Chemical Security Awareness Training	EHS Training
Animal Care and Use	Office of Responsible Research Practices
Animal Training & Experience	University Laboratory Animal Resources

Inappropriate Tasks for Research Volunteers

Below is a list of tasks that are deemed inappropriate for research volunteers. This is not an exhaustive list. If there are questions or concerns regarding a particular task, please contact the College of Medicine Office of Research or your Human Resources representative. Although these tasks are outlined as inappropriate, there are situations where these tasks may be carried out by a volunteer with appropriate approvals, training, and oversight. The PI and chair/director are responsible for ensuring adequate training and education prior to conducting any of these tasks. Volunteers should be under direct supervision at all times.

- Using stored energy such as steam, hydraulics, electricity
- Operating heavy equipment including vehicles
- Using radiation-emitting devices
- Using or having access to export-controlled materials
- Using or have accessing to controlled substances
- Using infectious or potentially infectious agents, including human source material
- Consenting or screening subjects for interventional or therapeutic research studies
- Dispensing or managing research products to subjects
- Accessing patient medical records for research
- Completing research billing
- Drawing blood or performing research tests/procedures on human subjects
- Entering into any contract on behalf of OSU/OSUWMC
- Participating in activities considered inappropriate for any employee
- Using select agents or toxins http://www.selectagents.gov/SelectAgentsandToxinsList.html

ONLY students enrolled at The Ohio State University may shadow personnel or observe patients in any setting. For more information please contact Karen Barrett, Director of Physician Relations (614-293-5174).

Research Volunteers Who Are Minors

Activities and programs for minors per <u>university policy</u> are defined as any event, operated by Ohio State, or by non-university groups using university facilities, that are geared toward minors in which parents or guardians are not expected to be responsible for the care, custody or control of their children.

Details regarding the training and requirements are available on the <u>Minors on Campus</u> website. Please also see the <u>State of Ohio Minor Labor Laws</u>.

- 1. A parent or legal guardian must provide consent.
- 2. Only minors age 16-17 may volunteer. Minors under 16 years of age will not be considered for volunteering in the research setting.
- 3. Hour restrictions:
 - a. When school is in session, minors may not volunteer before 7 a.m. on a school day.
 - b. Minors may not volunteer before 6 a.m. when they have volunteered past 8 p.m. the night before.
 - c. Minors may not volunteer after 11 p.m. on any night preceding a day that school is in session.
- 4. All one-on-one interactions are prohibited.
- 5. The College of Medicine will register the volunteer program with the university to eliminate the need for all researchers to individually register. The departments/units and researchers are responsible for meeting the additional requirements set forth in the university policy referenced above.
- 6. Requirements for faculty or staff working with minors:
 - a. Complete a fingerprint background check every four years. Please note that this is different from the university's employment background check.
 - b. Complete university required training each year.
 - c. Sign the Standards of Behavior for Employees/Volunteers each year.

Research Volunteer Requirements

The Research Volunteer and Parent/Legal Guardian (if applicable), Principal Investigator, and Chair/Director must sign to acknowledge agreement to the following requirements.

- 1. **Age:** Adult research volunteers must be at least 18 years of age. Minors (16-17) may volunteer with limited hours and parental/legal guardian consent.
- 2. **Application:** All prospective research volunteers must submit this application to the College of Medicine Office of Research. Submitting the application does not assure placement. The choice of applicants is determined on the basis of personal qualifications and traits as judged by the Principal Investigator and Chair/Director.
- 3. **Resume/References:** Adult research volunteers must submit a resume. Minors must supply names and contact information of two personal references who are not relatives.
- 4. **Background Check:** All research volunteers must successfully pass a background check through electronic fingerprinting in Medical Center ID Processing prior to starting their activities.
- 5. Letter of welcome: The Chair/director or unit administrator should write a letter welcoming the applicant to department/unit and outlining his/her position description, the name of the Principal Investigator, a brief description of the research project, techniques used, scheduled hours of operation, duration of assignment, potential hazards, and a statement that the Research Volunteer will be supervised by the Principal Investigator or qualified designee.
- 6. **Safety Training:** All research volunteers are required to take the same safety training classes required of regular laboratory employees appropriate for their activities. Classes should be completed in the eLearning system by the start date or no later than one week post-start date. To obtain access to eLearning, a request for a guest medical center account (e.g. JOHN99) must be submitted fist through the Service Now site. The form is called Non Hospital Employees Account Request. Once the non hospital employee account is created, the eLearning account will be created within 48 hours.
- 7. **Biosafety:** Research volunteers may not enter BSL 3 facilities unless an agreement is made with the Institutional Biosafety Officer and background checks are completed.
- 8. **Keys:** University keys and door codes may not be issued to research volunteers.
- OSUWMC ID Badges are required for all research volunteers. They must first pass their background check through fingerprinting with Medical Center ID Processing in order to be issued an OSUWMC ID badge or given computer access.
- 10. Health: All research volunteers are expected to be in good physical and mental health. He/she must have appropriate health exams and vaccinations before entering the research area/laboratory. Proof of health insurance and current tetanus and Hepatitis B vaccinations are required. Other vaccinations and health screenings should be completed as required by the volunteer's activities. The applicant's private physician or the Health Department can provide these records/services. If vaccinations/tests and other medical treatment are obtained at OSUWMC, the research volunteer will be responsible for payment.
- 11. **Uniform/Personal Protective Equipment:** All research volunteers must, when appropriate, wear a full-length lab coat or any other personal protective equipment (PPE) provided by the Principal Investigator. High heeled shoes, open toe shoes or sandals, or shorts are not allowed to be worn in the laboratory. Clothing should completely cover the torso (no bare midriffs).

Intellectual Property

In the course of his/her volunteer activities with the Principal Investigator, the Research Volunteer may acquire information that is the intellectual property of OSU. This intellectual property may consist of unpublished results, know-how, non-patentable information, patentable or other written or orally transmitted information. The Research Volunteer agrees that no information acquired by the Research Volunteer during his/her tenure at OSU will be transmitted by the Participant in any form to any third party.

Patents

In the event that discoveries result from the Research Volunteer's efforts at OSU, such discoveries and any resulting know-how, patent application or patent will be the property of OSU. Furthermore, OSU will be the owners of all intellectual property generated by the Research Volunteer during his/her tenure at OSU. This will include, but will not be limited to, know-how, patents, original data, computer programs and records of volunteer activities. The timing, extent and content of all publications regarding the results of the activities under this Agreement shall be at the discretion of OSU and the Principal Investigator.

Compensation

The Research Volunteer understands and agrees that the relationship between the Research Volunteer and OSU is not that of employer and employee, that he/she shall have no authority to bind or act on behalf of OSU, that he/she is not entitled to receive compensation as a result his/her activities at OSU, and that he/she is not entitled to any sick leave, vacation pay, retirement benefits, social security, disability benefits, unemployment benefits, workers compensation benefits or any other benefits that OSU provides for its employees.

The Research Volunteer will initial to indicate agreement with the following requirements:

initials	I understand that my placement as a volunteer in a research laboratory in The College of Medicine/Office of Health Sciences/OSUWMC will be mutually probationary and that it can be revoked at any time.
initials	I also understand that The Ohio State University is not responsible for required vaccinations/tests, illness or injury, or for payment to a physician or emergency department encountered during my volunteer service.
initials	I agree to hold OSU, their Regents, officers, agents and employees, harmless from any loss, claim, damage, or liability of any kind involving the Volunteer arising out of, or in, connection with this Agreement, except to the extent that it is directly due to the negligent acts or omissions of any of the Regents, officers, employees or agents of OSU.
initials	I understand that information collected and maintained on patients or research subjects is confidential. I agree to keep confidential all information made available to me.

(Signatures on next page)

Research Volunteer's Signature

By signing here, I acknowledge that I have read the above requirements, understand them, and wish to apply to be a Research Volunteer.

Signed: Research Volunteer

Parent/Legal Guardian's Signature (Required for minor volunteers only)

By signing here, I acknowledge that I have read the above requirements, understand them, and agree that my child can volunteer his/her time.

Signed: Parent/Legal Guardian

Principal Investigator and Chair/Director

I agree to ensure that the volunteer completes and sends ALL required documentation including training and health documentation to our academic office prior to allowing the volunteer to begin any activities. I will notify my academic department/unit when the volunteer leaves to ensure all access is deactivated. I am responsible for getting the volunteer's badge back from the volunteer and returning to my academic department/unit. I confirm the volunteer will not be displacing or replacing another OSUWMC staff member. I understand that volunteers are not covered under the Fair Labor Standards Act and are not considered employees for any purpose. If the volunteer is a minor, I have reviewed and am willing to comply with all requirements regarding interacting with minors.

Signed: Principal Investigator

Signed: Chair/Director