

The Ohio State University College of Medicine

Research Guidelines (00237618).DOCX

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THE OHIO STATE UNIVERSITY

COLLEGE OF MEDICINE

Updated on 8/13/2015

This packet contains the Research Volunteer Application that must be completed for each research volunteer registered with the College of Medicine (COM) or Office of Health Sciences (OHS) and additional guidance and checklists for faculty and department administrators managing research volunteers within their department.

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 the 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.

Please note this Research Volunteer Application and process does not apply to postdoctoral fellows, visiting scholars, observers, contractors, students performing research for academic credit at OSU, employees providing services in the same or similar area in which they are employed, or clinical research subjects enrolled in a research study. 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.

The faculty principal investigator (PI) and department 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 volunteering. Documentation of this information must be maintained by the department and available for review upon request.

Volunteers must be instructed in the appropriate departmental and institutional safety guidelines applicable to their activities and PIs are fully responsible for the volunteers in their area/lab. Volunteers are responsible for abiding by OSU/OSUWMC policies and applicable regulations that govern their actions. Employees of OSU/OSUWMC may not volunteer to perform services in the same or similar area in which they are employed.

The Research Volunteer Application must be completed signed and submitted to the College of Medicine Department of Human Resources for all COM/OHS research volunteers. *Any changes to the application information must be reported to the COM/OHS HR office within 30 business days.* Supporting documents must be maintained within the department and producible for audit at any time.

Additional Guidance Documents

- Appendix A: Resources & Policies
- Appendix B: Appropriate Tasks for Volunteers
- Appendix C: Working with Minors
- Appendix D: Volunteer Checklists
- Appendix E: Training and Health Requirements

College of Medicine/Office of Health Sciences Research Volunteer Application

College of Medicine Department of Human Resources DEPARTMENT INFORMATION – To be completed by department			
Date of Application:		PI Name:	
Department:	CCC	Daily Supervisor:	
Org Number:	46050	Cost Center:	46050
Anticipated Start Date:		Anticipated End Date:	
Type of Volunteer? <u>OSU Student, Rotating GRA High School Student, or Contactor</u> *If the volunteer is involved with human subjects, please note only OSU students may be involved with observing or shadowing. Additional requirements are required; please contact the OSUWMC Privacy Office at 293-4477.			
Office/Lab Building:		Office/Lab Room Number:	
IRB Approval Number(s), if applicable:			
VOLUNTEER INFORMATION			
Full Name:			
Permanent Address:			
Date of Birth:	Gender:	US Citizen or Permanent Resident	
Email: <i>non-OSU</i>		Visa Type (if applicable):	
Currently an OSU Student?			
If yes, type of degree:			
If yes, provide student ID & BuckID:			
Is volunteer a minor? If yes, see Appendix C.	Please contact CCC HR before submitting		
EMERGENCY CONTACT			
Name:		Relationship:	
Phone:		Alternate Phone:	
Name:		Relationship:	
Phone:		Alternate Phone:	

REQUIREMENTS FOR RESEARCH VOLUNTEERS

- 1. Eligibility:** Adult research volunteers must be at least 18 years of age. Minors (16-17) may volunteer with limited hours and parental/guardian consent. See Appendix C of this packet for specific requirements for working with minors per university policy. Current employees may not volunteer to perform the same or similar work for which they are employed with The Ohio State University (“OSU”) or The Ohio State University Wexner Medical Center (“OSUWMC”).
- 2. Volunteer Status:** Volunteers are not covered under the Fair Labor Standards Act and are not considered employees for any purpose. A volunteer may not displace a current employee, replace a past employee or position, or impair the employment of an employee holding a position at OSU/OSUWMC. A volunteer may not perform functions traditionally handled by an OSU/OSUWMC employee, and may not provide services that are substantially the same as those provided by an employee in a paid position. All OSU/OSUWMC departments and units are prohibited from permitting a volunteer to perform such functions or provide such services. Volunteer status may not be used as a way to avoid or defer compliance with employment eligibility requirements of federal immigration laws, including allowing an individual to volunteer in situations where they are not authorized to work.
- 3. Application:** All research volunteers must file this application at the academic department office and with the College of Medicine Department of Human Resources.
- 4. Background Check:** All research volunteers are required to obtain a background check through OSUWMC ID Processing department located in the main hospital. The background check will include an identity check and fingerprinting. Documentation of the completed background check must be maintained and stored by the academic department in accordance with Departmental and OSU/OSUWMC policies.
- 5. Health:** All research volunteers must have appropriate health assessments and vaccinations. Proof of health insurance and vaccinations are required. See Appendix E for all health requirements. It is the department’s responsibility to ensure all health requirements are met prior to the volunteer engaging in research activities. All health records and proof of insurance must be maintained and stored by the academic department in accordance with departmental and OSU/OSUWMC policies.
- 6. Training:** All research volunteers must complete required training prior to engaging in research activities. See Appendix E for a list of all required training. Training completion records must be maintained and stored by the academic department in accordance with departmental and OSU/OSUWMC policies.
- 7. Biosafety:** Research volunteers and visiting scientists may not work in BSL 3 facilities, unless an agreement is made with the Institutional Biosafety Officer and background checks are completed. PIs will impose restrictions on the activities of minor volunteers in labs that are posted for radioactivity. Minor research volunteers may not use radioactivity. PIs with posted labs must complete Radiation Safety Form RS-14 “Acknowledgement of Radiation Exposure: Limitations for a Minor,” SECTIONS III and IV, OSU Radiation Safety Guidebook. PIs may impose additional restrictions on the activities of minor research volunteers in research labs that use and store other hazardous materials ([OSU Safety Management Guidebook](#)).

General Access: OSUWMC identification badges are required for all volunteers and must be worn at all times. Volunteer badges will not contain a magnetic strip and thus volunteers will not have building access. OSU/OSUWMC keys and door codes may not be issued to volunteers. Volunteers are expected to be accompanied by the faculty advisor or a qualified individual designated by the faculty member at all times. Volunteers may not obtain access to the electronic medical record or have access to PHI.

- 8. Uniform:** Volunteers should dress appropriately. Protective equipment provided must be worn while in the lab. No open-toe or high heeled shoes, shorts or torso-bearing shirts are permitted in the lab.
- 9. Compensation:** The research volunteer understands and agrees that the relationship between the volunteer and OSU/OSUWMC is not that of employer and employee, that he/she shall have no authority to bind or act on behalf of OSU/OSUWMC, that he/she is not entitled to receive compensation as a result his/her activities at OSU/OSUWMC, and that he/she is not entitled to any benefits, including but not limited to health care, sick leave, vacation pay, retirement benefits, social security, disability benefits, unemployment benefits, workers compensation benefits or any other benefits that OSU/OSUWMC provides for its employees.
- 10. Intellectual Property:** While volunteering, the 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 volunteer agrees that no information acquired by the volunteer during his/her volunteer time at OSU/OSUWMC will be transmitted by the volunteer in any form to any third party.
- 11. Patents:** In the event that discoveries result from the volunteer's efforts at OSU/OSUWMC, such discoveries and any resulting know-how, patent application or patent will be the property of OSU/OSUWMC. Furthermore, OSU will be the owners of all intellectual property generated by the Volunteer during his/her tenure at OSU/OSUWMC. This will include, but will not be limited to, know-how, patents, original data, computer programs and records of work. The timing, extent and content of all publications regarding the results of the activities under this Agreement shall be at the discretion of OSU/OSUWMC and the principal investigator.
- 12. Confidential Information:** A primary responsibility of every volunteer is confidentiality of information. This is defined as information, written or spoken, whose unauthorized or indiscreet disclosure could be harmful to the interests of a patient, an employee or OSU/OSUWMC. Such information is strictly confidential. In all circumstances, such information may not be shared with unauthorized persons. Patient records, employee personnel records, or personal data such as addresses or phone numbers, and organization financial and operating data are examples of information of a private or sensitive nature considered to be confidential.

I understand that my placement as a research volunteer for the College of Medicine/Office of Health Sciences/OSUWMC can be terminated at any time by me or OSU/OSUWMC. I understand that I am a research volunteer and am not considered an employee of OSU or OSUWMC for any reason and I will not be covered under worker's compensation insurance or receive any employee benefits. I also understand that OSU/OSUWMC is not responsible for required vaccinations/tests, illness or injury, or for payment to a physician or emergency department encountered during my volunteer service. I agree to conform to the same high standard of behavior as the professional staff and to abide by all rules and regulations that apply

this waiver and release precludes my right to recovery of damages in the event I am injured in the course of performing my volunteer duties.

I agree to defend, hold harmless and indemnify OSU/OSUWMC, its directors, officers, employees, agents and other volunteers, from and against all damages, claims, liabilities, causes of action, judgments, settlements, costs and expenses (including reasonable expert witness and attorney fees) that may at any time arise or be claimed by any person as a result of bodily injury, death or property damage, or as a result of any other claim or cause of action of any nature whatsoever, arising from or in any manner connected with, directly or indirectly, the negligent or intentional acts or omissions of volunteer in performing his/her duties.

I will keep confidential any confidential information provided to me during my volunteer service I, concerning research, patients, doctors, staff, employees, and volunteers. I understand that my volunteer services will be terminated as a result of any breach of confidentiality.

The above information is accurate and correct to the best of my knowledge. I understand that OSU/OSUWMC is not responsible for injury or illness encountered during my volunteer service, or for payment to physicians or the Emergency Department resulting therefrom. My signature gives approval for OSU/OSUWMC to perform a background check, check any references, and contact my physician regarding my physical and emotional health. Completing this application does not guarantee placement nor does it obligate me to become a volunteer. I understand that the only way to receive paid employment is to apply by submitting an application on-line, on OSU or OSUWMC career page.

I have read the above requirements, understand them, and wish to apply to be a research volunteer.

Volunteer Signature: _____

Volunteer Printed Name: _____

Date: _____

Parent/Guardian Signature: _____

(Required for Minor Volunteer, under 18)

Parent/Guardian Printed Name: _____

Date: _____

I agree to ensure that the volunteer completes and sends ALL required documentation including training and health documentation to our academic/administrative office prior to allowing the volunteer to begin any work. I will notify my academic/administrative department 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/administrative department. 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 Appendix C and am willing to comply with all requirements regarding working with minors.

PI Signature: _____

PI Printed Name: _____

Date: _____

Department Chair Signature: _____

(To be signed by Chris Scarcello)

Department Chair Printed Name: _____

Date: _____

CCC Research Volunteer Form
To be Completed by the Research Volunteer

Please explain why you are applying to be a Research Volunteer:

Will you be receiving class credit?

Yes No

**Do you want door access to be put on your Buck ID rather than your Medical Center ID?
If yes, please make sure your Buck ID is listed on your application:**

Yes No

Have you ever worked or volunteered in the CCC or Medical Center in the past?

Yes No

*** Once you have been notified to complete your trainings, please complete them within a 3 week period or your application will be cancelled.**

Initials and Signatures are required below:

_____ I understand that I cannot physically be present in the lab until I have cleared a background check, completed my safety trainings, and have received a clearance e-mail from CCC HR.

Print Name _____

Date _____

Sign Name _____

**COMPREHENSIVE CANCER CENTER
NON-EMPLOYEE REQUEST
(Volunteers, Rotating GRAs, Contractors)**

Name of Candidate: _____

Type of Request: Volunteer Rotating GRA Contractor through staffing agency

Is the candidate under the age of 18? Yes No

Preferred Start Date: _____ Anticipated End Date: _____

Daily Supervisor: _____ Hours per week needed: _____

Office/Lab Location: _____ Phone Number: _____

IT Access Needed (Med Center ID and OSU Name.#) Yes No

If Access for research, please list Research IRB#: _____

OSUMC Badge Needed? Yes No

Does the candidate currently have access on their BuckID? Yes No

If Yes, transfer the access to the OSUMC badge? Yes No

Will candidate be exposed to blood and/or bodily fluids? Yes No

Other occupations hazards? _____

I agree to notify the CCC-HR Office when any non-employee leaves the lab to make sure that all accesses are deactivated. I understand that any IT access granted will terminate on the listed anticipated end date or I must request an extension for continued access beyond this date. I will be responsible for returning any OSUMC badges to the CCC-HR Office and ensure the badge will not be used by any other person. I understand the COM-HR Office and CCC-HR Office will assume the volunteer's services has ended on the date indicated on the original application unless otherwise contacted.

Supervisor Signature: _____ Date: _____

If you have questions, please contact the CCC-HR office at CCC.HR@osumc.edu.

Important Information Related to Processing your Volunteer Request with the CCC

All items on this checklist should be signed and completed and attached to the HRA. Please note that even if all of the required paperwork and documentation has been submitted, the Research Volunteer is not permitted in the lab until they receive clearance from CCC HR.

	Items to Attach to the HRA Request
	Research volunteer application (including CCC Research Volunteer form) completed and signed
	Proof of age (copies of identification)
	Proof of health insurance
	Copy of Visa (if applicable)
	CCC Non-Employee Request form completed and signed

The HRA will be reviewed and when approved the volunteer will be contacted to complete a background at ID Processing. After that has cleared, HR will request the IT account so that online training can be completed. Please remember that all research volunteers must complete required training prior to engaging in research activities. Please refer to Appendix E for required training of all research volunteers as well as any additional training you may be responsible to identify as required.

APPENDIX A: Resources & Policies

[U.S. Department of Labor Fair Labor Standards Act Volunteers](#)

[U.S. Department of Labor, Wage, & Hour Division Fact Sheet #71 \(April 2010\)](#)

[U.S. Department of Labor 29 CFR 553.101-103](#)

[State of Ohio Minor Labor Laws](#)

[OSU Office of Responsible Research Practices](#)

[OSU Environmental Health and Safety](#)

[College of Medicine, Office of Research](#)

[OSU Records Management](#)

[Identification Badges](#)

[Tobacco Free Ohio State](#)

[Drug-Free Workplace](#)

[Sexual Harassment](#)

[OSUWMC Influenza Vaccination Policy](#)

[Fire Emergency and Safety](#)

[Nepotism](#)

[Preventing and Reporting Abuse in Programs with Minor Participants](#)

Appendix B: Inappropriate Tasks for 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 HR 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 department chair are responsible for ensuring adequate training and education prior to conducting any of these tasks. Volunteers should be under direct supervision at all times.

Inappropriate Tasks:

- Work with stored energy such as steam, hydraulics, electricity
- Operate heavy equipment including vehicles
- Work with radiation-emitting devices
- Work with or have access to export-controlled materials
- Work with or have access to controlled substances
- Work with infectious or potentially infectious agents, including human source material
- Consent and screen subjects for interventional or therapeutic research studies
- Dispense or manage research products to subjects
- Access patient medical record for research
- Complete research billing
- Draw blood or perform other research tests/procedures on subjects
- Entering into any contract on behalf of OSU/OSUWMC
- Activities considered inappropriate for any employee
- Work with select agents or toxins
(<http://www.selectagents.gov/SelectAgentsandToxinsList.html>)
- ONLY students enrolled at The Ohio State University may be involved with shadowing or observing patients in any setting. For more information please contact Dr. Andrew Thomas or Elizabeth Bowman directly (293-8357).

APPENDIX C: Working with Minors

Below are additional requirements that must be completed to have minors serve as research volunteers.

Activities and programs for minors per [university policy](#) 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.

1. Parental consent must be provided.
2. Only minors age 16-17 may volunteer. Any minor under 16 years of age may not be considered for volunteering in the research setting.
3. Hour restrictions:
 - When school is in session, minors may not volunteer before 7 a.m. on a school day.
 - Minors may not volunteer before 6 a.m. when they have volunteered past 8 p.m. the night before.
 - Minors may not volunteer after 11 p.m. on any night preceding a day that school is in session.
4. Requirements for faculty or staff working with minors:
 - All one-on-one interactions are prohibited.
 - The College of Medicine will register the volunteer program with the university to eliminate the need for all researchers to individually register. The departments and researchers are responsible for meeting the additional requirements set forth in the university policy referenced above.
 - Faculty and staff working with minors are required to complete a BCI check every four years.
 - Faculty and staff working with minors must complete university required training on Carmen.

Appendix D: Volunteer Checklists

Please use this as a guide to ensure all required information is collected and filed. Not all items will be applicable to your research volunteer. Items with asterisks (*) are required for all research volunteers. All items under Research volunteer inactive checklist should be considered at the time the volunteer service has ended.

Research Volunteer Checklist	
	Research volunteer application completed and signed*
	Copy of completed and signed research volunteer application
	Proof of age and health insurance (copy photo identification)*
	Copy of Visa (if applicable)
	OSUWMC background check completed*
	OSUWMC badge obtained by research volunteer*
	Training requirements completed*
	Health requirements completed*
	Added as Key Personnel and completed External Investigator Agreement as applicable (individuals with no OSU affiliation)
Research Volunteer Inactive Checklist	
	Collect OSUWMC ID badge
	Deactivate any network access
	Contact COM HR to report volunteer service has ended if date differs from application. COM HR will assume the volunteer's service has ended on the date indicated on the original application unless otherwise contacted.
	Remove as Key Personnel
Research Volunteer (Minors) Additional Requirements Checklist	
	Registration of program with university
	Faculty and Staff complete required training for working with minors
	Faculty and Staff complete BCI, if not completed in the past four years

APPENDIX E: 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 research volunteer experience. It is the responsibility of the administrative unit to ensure required training is completed and records are maintained appropriately.

To obtain access to the Computer-Based Learning (CBL) system contact [Carole Mench](#). You must provide the following information: volunteer's full name, ID badge number, Social Security Number, department cost center number.

Computer-Based Learning (CBL) [NetLearning](#) Required Training

Please note **all research volunteers are** required to complete the following annual NetLearning CBLs:

- Annual HIPAA Privacy & Security
- Institutional Data Training
- Sexual Harassment
- Introduction to Cultural Sensitivity
- Fire Safety
- Hazard Communication (HazCom)
- Emergency Preparedness
- Compliance Program
- Influenza Pandemic Prevention & Response Plan (required for flu shot exemptions only)
- OSU BEAP (Building Emergency Action Plan) (one time: [EHS Online Training](#))
- Infection Control (non-clinical module)
- Patient Safety (non-clinical module)
- Preventing TB module

The department and Principal Investigator are responsible for ensuring clinical, basic and/or animal research volunteers complete additional training or health assessments specific to research tasks an individual may perform. These may include but are not limited to the following (below). For questions, please contact College of Medicine Department of Human Resources.

Additional Research Training and Health Assessments	How to Complete Training or Assessment
Vaccinations or Demonstration of Hepatitis B, Rubella, Rubeola and Documented history of Chicken Pox and Current Tetanus	Family Physician/ Student Health
Negative PPD Tuberculosis Test	Family Physician/ Student Health
OSU Financial Conflict of Interest Disclosure	eCOI
CITI Training (Basic Human Research Course)	CITI
10-Hour Laboratory Safety Class	EHS Class Training
Applicable Occupational Health & Safety Program Training	EHS Class Training
Applicable Research Safety Program Training	EHS Class Training
Applicable Biosafety Program Training	EHS Class Training
Applicable Chemical Security Awareness Training	DHS Training
Animal Care and Use	Office of Research
Office of Research Occupational Health Registry	Office of Research
Occupation Health & Safety Training	Office of Research
Facility Training	Office of Research
Animal Training & Experience	Office of Research

The documentation should be obtained from a family physician, or if the volunteer is a current OSU student, they could obtain such documentation from Student Health.