



INTRODUCTION

The College of Medicine (COM) Research Volunteer Program (RVP) has been restructured to ensure compliance with applicable policy and law. These guidelines are **effective 1 January 2022**, and are **applicable to COM research**.

SECTION ONE: Research Contributors and Responsibilities

1. Former RVP participants who are not considered Youth Research Observers as described in **§ TWO**, are known as **Research Contributors** – not Research Volunteers (RV). The term Research Volunteer is no longer used, as it is synonymous with the terms Research Subject and Research Participant.

1.1 Research Contributors may be:

1.1.1 Persons under the age of 18 who are:

- 1.1.1.1 Currently enrolled for academic credit or accepted for enrollment at Ohio State;
- 1.1.1.2 Currently employed by Ohio State

1.1.2 Current Ohio State students and employees

- 1.1.2.1 Current students who are Research Contributors are:
 - 1.1.2.1.1 In a research-focused degree-seeking (or non-degree-seeking) program and participating as research study personnel (e.g., a student in the College of Nursing's Master of Clinical Research program)
 - 1.1.2.1.2 In a non-research-focused degree-seeking (or non-degree-seeking) program and participating as research study personnel (e.g., a student pursuing a degree in Criminal Justice)
- 1.1.2.2 Employees who are Research Contributors are:

1.1.2.2.1 In a non-research position and participating as research study personnel (e.g., an executive assistant who will interact with subjects and administer a research survey for an IRB-approved study)

1.1.2.2.2 In a research position at another college and participating as research study personnel (e.g., a research statistician in the College of Engineering who will provide statistical analysis specifically for a COM research study)

1.1.3 Non-Ohio State-affiliated researchers collaborating on an Ohio State research study via an Individual Investigator Agreement (IIA), Institutional Review Board (IRB) Authorization Agreement (IAA), or Memorandum of Understanding (MOU) (e.g., a researcher at the University of Miami collaborating on a COM research study or a researcher not affiliated with a home institution and collaborating on a COM research study)

2. Research Contributors may participate as research study personnel for research:

2.1 Subject to the oversight of the IRB, Institutional Biosafety Committee (IBC) and/or Institutional Animal Care and Use Committee (IACUC) following approval of the applicable board or committee; and/or

2.2 Not subject to the oversight of the IRB, IBC, and/or IACUC, (e.g., research not involving human subjects)

3. Research Contributor Responsibilities

3.1 The Research Contributor is responsible for ensuring that any prerequisites and requirements are met prior to participating as research study personnel and for carrying out their role with professionalism and integrity. Additional responsibilities are described in **5. Other Investigator and Research Study Personnel (including Research Contributors) Responsibilities.**

4. Principal Investigator (PI) Responsibilities

4.1 The PI or an appropriate designee is responsible for the following pertinent to Research Contributors:

4.1.1 Following applicable board or committee approval to add the Research Contributor (as required), initiating a request for an identification (ID) badge and background check in accordance with (IAW) the [Background Check, 4.15](#) policy. ID badges may not need to include a magnetic strip for building access, and can instead be used only as an ID badge. Departments/divisions are responsible for any fees associated with background checks, and related requirements;

4.1.1.1 Completing the [Badge Application Request Form](#) via eServices when both a badge and background check are required

4.1.1.2 If only a background check is required (e.g., a Research Contributor who will always work remotely, may not require an ID badge), completing the [Background Check Request form](#) via eServices

4.1.1.3 In addition, PIs or their appropriate designee will confirm:

4.1.1.3.1 That ID badges are visibly worn by Research Contributors for the duration of their participation;

4.1.1.3.2 Renewal of ID badge as required; and

4.1.1.3.3 Return of ID badge once the Research Contributor's participation has ended

4.1.2 That a guest account, if required, is obtained (e.g., to access the Online Risk Assessment Tool [ORAT]). In addition, the PI will:

4.1.2.1 Serve as sponsor of the Research Contributor's guest account or select an appropriate designee;

- 4.1.2.2** Ensure that the Research Contributor completes any required training IAW information technology (IT) policies and procedures and retain documentation of training;
- 4.1.2.3** Ensure that the Research Contributor completes any required onboarding IAW Ohio State policies and procedures;
- 4.1.2.4** Comply with any IT point of contact (POC) request for information (RFI) in relation to the Research Contributor's guest account;
- 4.1.2.5** Ensure that authorized Research Contributor guest accounts are not abused or otherwise used in a manner inconsistent with approval; and
- 4.1.2.6** Notify the appropriate IT POC when the Research Contributor's guest account is no longer required

4.1.3 Research Contributors who are Ohio State students:

- 4.1.3.1** May not require a guest account as described in **4.1.2**. Legitimate guest account requests are applicable to the Research Contributor's role and responsibilities as research study personnel (e.g., they are a student in the College of Arts and Sciences but their role as research study personnel requires them to have access to a COM system).

4.1.4 Research Contributors who are Ohio State employees:

- 4.1.4.1** Are not required to undergo a background check as described in **4.1.1** if their last background check occurred within one year.
- 4.1.4.2** May not require a guest account as described in **4.1.2**. Legitimate guest account requests are applicable to the Research Contributor's role and responsibilities as research study personnel (e.g., the Research Contributor is an employee of the College of Engineering but

their role as research study personnel requires them to have access to a COM system).

4.2 The PI is ultimately responsible for:

- 4.2.1** The ethical and humane conduct of research, and compliance with federal regulations, applicable state and local law, and university policies;
- 4.2.2** Knowing when proposed activities are defined as “research involving human subjects” IAW Human Research Protection Program (HRPP) policy [[Research Involving Human Subjects](#)] or for seeking guidance, as appropriate;
- 4.2.3** Delegating study-related tasks to appropriately qualified and trained research study personnel including Research Contributors, and maintaining oversight of and retaining ultimate responsibility for the conduct of those who perform delegated functions;
- 4.2.4** Ensuring that all research study personnel assisting in the conduct of the study are informed of their obligations for following the IRB-approved, IACUC-approved, or IBC-approved protocol, and applicable regulations, laws, and policies; and
- 4.2.5** Ensuring sufficient time to properly conduct and/or supervise their research and their research study personnel

5. Other Investigator and Research Study Personnel (including Research Contributors) Responsibilities

5.1 Other investigators and research study personnel are responsible for:

- 5.1.1** Adhering to the principles outlined in the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research report entitled, Ethical Principles and Guidelines for the Protection of Human Subjects of Research (“Belmont Report”) when conducting research involving human subjects;
- 5.1.2** Adhering to the statutes of the Animal Welfare Act and the guidelines of the Public Health Service (PHS) as outlined in the Guide for the Care and Use of Laboratory Animals when conducting research involving animal subjects; and

- 5.1.3 Conducting research IAW all applicable university, and Office of Responsible Research Practices (ORPP) policies, as well as federal, state, and local laws and guidance for the protection of human and animal subjects in research

SECTION TWO: Program Name, Youth Research Observers (YRO) and Responsibilities

1. The RVP is renamed the **COM Youth Research Observation Program (YROP)**.

- 1.1 COM YROP participants are referred to as **Youth Research Observers (YRO)** – not Research Volunteers (RV). The term Research Volunteer is no longer used, as it is synonymous with the terms Research Subject and Research Participant.

- 1.2 YROs are:

- 1.2.1 Ages 16-17 only

- 1.2.2 Not enrolled for academic credit and not accepted for enrollment at Ohio State;

- 1.2.3 Not employed by Ohio State

- 1.2.4 Not currently participating in other COM youth programs (e.g., Explorations in Neuroscience Summer Camp)

- 1.2.5 Not permitted to actively participate as research study personnel but are permitted to assist in the support of research, as observers (**see 1.2.5.4**), and at the discretion of the PI.

- 1.2.5.1 For research approved and overseen by the IRB, YROs may not perform activities that would engage them in human subjects research (HSR).

- 1.2.5.1.1 An individual (or organization) becomes engaged in HSR when for the purposes of non-exempt research (i.e., does not meet regulatory criteria for exempt review), the individual obtains any of the following: information or biospecimens about subjects

through intervention or interaction;
identifiable private information or
biospecimens about subjects;
informed consent of subjects.

- 1.2.5.2** For research approved and overseen by the IRB, YROs may observe human subjects after the researcher has obtained the subject's verbal consent for the observation. A note-to-file (NTF) should document that the subject verbally agreed to the YRO observation on X date/time.
- 1.2.5.3** For research approved and overseen by the IACUC, YROs may not handle animals, perform experimentation or observe euthanasia. Observation is limited to animal labs and not the vivarium. Note that a risk assessment as part of the Occupational Health Program is mandatory for those with direct or indirect exposure to animals used in research. This requirement is met via the ORAT. Note that a guest account is required to access the ORAT.
- 1.2.5.4** For research approved and overseen by the IBC, YROs may not perform experimentation with or be exposed to potentially pathogenic agents/toxins and/or human tissue and body fluid, including recombinant DNA (rDNA), gene transfer, human stem cells, microorganisms, and/or select agents.
- 1.2.5.5** Assisting in the support of research as an observer may include the performance of tasks such as literature reviews, background research, bioinformatics, or writing analyses. The PI will determine whether this type of support may be carried out remotely.
- 1.2.6** In addition to **1.2.5.2** and **1.2.5.3**, YROs must not be exposed to radioactive substances, ionizing radiation, chemical or biological agents, or have access to controlled substances, tobacco, or alcohol.

2. The COM YROP is considered an activity or program with youth, as described in the [Youth Activities and Programs](#) University Policy (herein policy).

2.1 COM Office of Research (COMOR) Responsibilities

2.1.1 IAW the policy, those sponsoring activities or programs with youth are required to register the activity or program with the Office of Institutional Equity (OIE) annually, prior to the beginning of the university academic year (late August). COMOR will assume responsibility for obtaining and maintaining registration for the COM YROP on or about the start of the fiscal year on 1 July.

2.1.2 COMOR will notify the COM research community of any pertinent information related to the COM YROP.

2.2 PI, Other Investigator, and Research Study Personnel (including Research Contributors) Responsibilities

2.2.1 PIs, other investigators, and research study personnel are responsible for understanding and complying with the policy and adhering to any obligations imposed by applicable law, including but not limited to Ohio Revised Code § 2151.421 and 2921.22.

2.2.2 PIs will ensure:

2.2.2.1 That COMOR is notified via email at (COMResearchCompliance@osumc.edu) of any research studies that YROs will observe, prior to the YRO's observation. This will be registered under the COMOR YROP with OIE Youth Activities and Programs as noted in 2.1.1. No COM research study or program should be registered with OIE Youth Activities and Programs as stand-alone studies or programs.

2.2.2.1.1 That a roster of staff present with YRO when observing will be submitted with information in 2.2.2.1 to COMOR, to include each individual's email address and most recent BCI Background check approval date

- 2.2.2.2** That individuals in **2.2.1** adhere to *Reporting* obligations as described in the policy;
- 2.2.2.3** That individuals in **2.2.1** adhere to *Background Checks* as described in the policy and confirms that required checks are performed. Note that these checks are separate and distinct from those described in the [Background Check, 4.15](#) policy. Departments/divisions are responsible for any fees associated with background checks, and related requirements;
- 2.2.2.4** The *care, custody, or control* of YROs, as defined in the policy;
- 2.2.2.5** That individuals in **2.2.1** are annually *trained* as described in the policy. COM prefers training provided by OIE;
- 2.2.2.6** That individuals in **2.2.1** sign and abide by the *Standards of Behavior* annually as described in the policy;
- 2.2.2.7** That *records* are maintained as described in the policy; and
- 2.2.2.8** Cooperation with any COMOR and OIE RFI and/or corrective actions
- 2.2.2.9** That a request for an ID badge with the title Youth Research Observer, and background check is made for the YRO IAW the [Background Check, 4.15](#) policy. Badges are strictly for the purpose of identification and not access. Departments/divisions are responsible for any fees associated with background checks, and related requirements;
- 2.2.2.10** Completion of the [Badge Application Request Form](#) via eServices when both a badge and background check are required.
 - 2.2.2.10.1** With regard to ID badges issued to YROs, PIs will ensure:

