



SCHOOL OF PUBLIC HEALTH

ORARC Tip Sheet: AGENT OF HARVARD

Context:

Any agent of Harvard conducting human subjects research must have Harvard Longwood Campus (HLC) IRB review and approval (or reliance determination) in place prior to beginning the human research.

Definition of Agent:

As defined in the <u>Human Research Protection Plan</u>, an individual, who is an employee or student, is considered an agent of Harvard Faculty of Medicine or Harvard T.H. Chan School of Public Health for purposes of engagement in human research when that individual is on-duty in any capacity as an employee or student of the Harvard Longwood Medical Area (LMA) Schools.

Specifically, an agent is an individual who, by agreement or otherwise, may act on behalf of the Harvard LMA Schools and bind it by words or actions; a person who represents Harvard LMA Schools by its authority or delegated authority.

An individual who is not an employee is considered an agent of Harvard Faculty of Medicine or Harvard T.H. Chan School of Public Health for purposes of engagement in human research when that individual has been specifically authorized to conduct human research on behalf of Harvard LMA Schools.



Per Office of Human Research Protections (OHRP) guidance¹, "agent" refers to individuals who: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities.

"Employees and agents" can include faculty, staff, students, contractors, and volunteers, among others.

Examples:

- Your primary affiliation is at Harvard; Harvard is where you get your paycheck.
- Harvard is listed on study documents as the institution the Principal Investigator is from.
- You represent yourself as a Harvard affiliate while conducting the research; i.e. you're "wearing your Harvard hat" while conducting the research, you tell research participants you are from Harvard, etc.
- A collaborator is working on a Harvard research project and has been authorized to conduct research activities on Harvard's behalf; i.e. a community member will assist in conducting door to door recruitment, consent, and data collection for a local neighborhood survey.
- You are a student conducting research in fulfillment of a required Harvard course, degree program, and/or scholarly obligation.

Additional ORARC Toolkit Materials:

<u>Human Research Protection Plan</u>

¹ <u>https://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-engagement-of-institutions/index.html</u>

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