Definition of Key Research Personnel

Tufts Medical Center/TUHS Guidance for Defining Your Research Team

The principal investigator (PI) and the institutions share responsibility for ensuring that PIs, co-investigators, and all other personnel (referred to as "research team members") involved in the conduct of human subject research fulfill basic education requirements in compliance with all applicable laws and regulations, and institutional policies.

The institutions define “research team members” as persons who have direct contact with subjects, contribute to the research in a substantive way, have contact with subjects’ identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or use subjects’ personal information.

For example, a nurse who ordinarily works in the clinical context but becomes involved in a research protocol obtaining informed consent from subjects and drawing blood for research would be considered a research team member. A lab technician, narrowly involved in a project, working only with de-identified data would not necessarily be a research team member. On the other hand, a biostatistician working with identifiable data would be considered a member of a research team.

Please Note: Because of the variability in research situations, it is impossible for the institutions to define precisely every category of employee who could be considered a member of a research team. Some interpretation by PIs will be needed. A PI is expected to make a good faith effort to meet the spirit of this requirement by assuring that all members of a research team receive education appropriate to their role in the project.

For additional information to help you determine who constitutes your research team and would therefore need to fulfill the education requirements, please refer to the Office of Human Research Protections (OHRP) “Guidance on Institutions Engaged in Research” at: http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm

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1 The information provided here is only intended to assist with the definition of a “research team member,” and is not intended to address issues associated with mentorship or authorship.

2 There will be some exceptions. For example, there will be individuals whose primary contact with the subject is in the context of clinical care but who might play a minimal role in the research. An example of this would be a nurse or phlebotomist drawing blood for a clinical purpose and taking an additional sample at the same time for someone else's research project. In this case, provided that someone other than the nurse or phlebotomist administered informed consent, and that the nurse/phlebotomist would not be playing any further role in the research, s/he would not be considered a research team member, and the research education requirement would not apply.

3 Employees that may be part of a research team could include, but are not limited to, co-investigators, nurses, research coordinators/assistants, fellows, residents, interns, students, recruiters, dieticians, laboratory technicians, data entry/analysis persons, administrative assistants, etc.