

Guidance for defining who is a Member of Your Research Team

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

CHA defines "research team members" as people who contribute to the design, conduct, or reporting of a research study, have direct contact with study participants¹, contribute to the research in a substantive way, have contact with a study participant's identifiable data or biological samples (e.g., tissue, blood, urine, plasma, saliva), or uses participants' personal information.

For example, a nurse who ordinarily works on an in-patient unit, but becomes involved in a research protocol by obtaining informed consent from participants or follows-up with study participants admitted to the unit to collect study data would be considered a research team member. However, a laboratory technician who works only with de-identified data and does not have any direct study participant contact would not necessarily be a research team member. On the other hand, a biostatistician working with identifiable or coded data would be considered a member of a research team.

Due to the variability in situations, it is impossible to define precisely everyone² who could be considered a research team member. Some interpretation by PIs will be needed. CHA expects a PI to make a good faith effort to meet the spirit of the research education training requirement by assuring that all members of a research team receive research-related education and training 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 "[Guidance on Engagement of Institutions in Human Subjects Research](#)."

¹ Exceptions may exist; there will be individuals whose primary contact with a subject is in the context of clinical care, but who may play a minimal role in the research. An example is a phlebotomist drawing blood for a clinical purpose and collecting an additional sample at the same time for someone else's research project. In this case, provided that someone other than the phlebotomist obtained informed consent, and that the phlebotomist is not playing any further role in the research, s/he would not be considered a research team member; the research education requirement would not apply.

² People that may be part of a research team could include co-investigators, nurses, research coordinators/assistants, fellows, residents, interns, students, recruiters, dietitians, laboratory technicians, data entry/analysis persons, administrative assistants, etc.