

Definition of Research Staff

The principal investigator (PI) and the institutions share responsibility for ensuring that PIs, co-investigators, and all other personnel involved in the conduct of human subjects research fulfill basic educational requirements in compliance with all applicable laws, regulations and institutional policies.

The University of Missouri Kansas City defines ‘research staff’ as persons who have direct contact with subjects², 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.

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

Social and Behavioral Sciences example, an instructor who ordinarily teaches in the classroom but becomes involved in a research protocol by obtaining informed consents and administering surveys for research would be considered a research team member. An instructor who allows a collection box for surveys to be placed in his/her classroom but has no active role in the study would not be considered a research team member. On the other hand, a statistician working with identifiable data would be considered a member of the research team.

Because of the variability in research situations, it is impossible for the University of Missouri Kansas City to define precisely every category³ of employee who could be considered to be a member of a research team. Some interpretation by PIs will be needed. The PI is expected to make a good faith effort to meet the spirit of this requirement by assuring that all members of the research team receive education to their role in the project.

For additional information to help you in determining who constitutes your research team and would therefore need to fulfill the educational requirements please refer to the OHRP “Guidance on Institutions Engaged in Research” by accessing the following link:
<http://ohrp.osophs.dhhs.gov/humansubjects/assurance/engage.htm>

¹[1] The information provided here is only intended to assist with the definition of the ‘research staff’, and is not intended to address issues associated with mentorship or authorship.

²There 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

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<http://ors.umkc.edu/research-compliance>

research. An example of this would be a nurse or phlebotomist drawing blood for a clinical purpose and taking an extra 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 research staff, and no educational requirement would apply.

³ Employees that may compose your research team could include research coordinators, nurses, recruiters, dieticians, laboratory technicians, data entry/analysis persons etc., that need to meet the educational requirements outlined the by the University Missouri Kansas City.