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GUIDANCE: **Study Team Roles and JHSPH IRB Requirements**

The organizational structure of every study involves personnel whose involvement with the human subjects and/or their data varies, depending upon their functional roles. The Institutional Review Board (IRB) is interested in ensuring that all personnel who come into contact with the human subjects and/or their identifiable data have appropriate human subjects research ethics training and are qualified to perform their assigned roles. Here are our definitions, training requirements, and process for changing study personnel.

Study Team Role	Description and Qualifications	Training	To Add/Change Personnel
Principal Investigator (PI)	JHSPH Full Time Faculty, responsible for overseeing the responsibilities described in the roles section of the research plan.	CITI Human Subjects Research Training; GCP (Good Clinical Practice) training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information	Submit an Amendment Application
Co-Investigator, JHSPH employee	Faculty, student (in the role as hired staff), staff involved in the project, and responsible for aspects of study operations	CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information	Submit an Administrative Amendment for Change in Study Personnel
Co-Investigator, non-JHSPH employee	Must have qualifications to perform delegated role and be responsible for aspects of study operations	CITI Human Subjects Research Training; Family Health International (FHI) Training; NIH training; or training from their home institution.	Submit an Administrative Amendment for Change in Study Personnel
Student Investigator	JHSPH student; the project must be associated with the student's academic objective	CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information	Submit an Administrative Amendment for Change in Study Personnel
Study Staff, JHSPH employee	Must have qualifications to perform delegated role. This category could include research coordinators, data coordinators, lab personnel who will see identifiers, interviewers, etc.	CITI Human Subjects Research Training; GCP training if conducting clinical trial; HIPAA training if accessing/using Protected Health Information	Submit an Administrative Amendment for Change in Study Personnel
Study Staff, non-JHSPH employee	Must have qualifications to perform delegated role. This category could include research coordinators, data coordinators, lab personnel who will see identifiers, interviewers, etc.	Any of the computer-based modules mentioned above, or an in-person research ethics training conducted by a qualified person, and approved by the IRB. Curriculum must be IRB approved , like the Field Training Guide found here: http://www.jhsph.edu/irb/Training.html	No need to name these personnel unless responsible for execution of study operation. Submit an Administrative Amendment for Change in Study Personnel.
Study Contact	Administrative role only – receives copies of IRB communications to PI	No training required. Should have no contact with study participants or data (unless listed in one of the above roles).	Send an email to irboffice@jhsph.edu

Note: We are limited by our current electronic database systems, which we constantly update and upgrade. For the time being, PHIRST offers only four roles to choose from: Principal Investigator (PI), Co-Investigator, Student Investigator, and Study Contact. For advice about who to list in PHIRST, and how, see below.

Study Role	List? Y or N	If Y, how?
Principal investigator	Y	In PHIRST and in research plan
Co-investigator	Y	PHIRST, and in research plan if relevant (for example, if managing specimen repository, data coordinating center, on the ground in country, etc.) A student co-investigator may be listed, if appropriate.
Research Coordinator/Project Director, and other study staff members with significant responsibilities who will come into contact with human subjects or their identifiable data.	Y	PHIRST (choose "co-investigator" role – for PHIRST purposes only)
Student Investigator (involved in the study design, implementation, and/or data analysis, including use of study data to meet dissertation or thesis requirements)	Y	PHIRST (choose "student investigator" role) and also check "Yes" to item 4.0 under "Study Information, Page 1" of the PHIRST application.
Student research staff member (performing routine staff duties like record keeping, data management, lab work, etc.)	N	These individuals, who will not come into contact with human subjects or their identifiable private information, are not "engaged" in human subjects research.
Non-professional consent designees and other data collectors who have direct contact with study participants	N, but…	They need not be listed individually - but the research plan must address how they will be trained in human subjects research ethics (the Field Ethics Training Guide is available for this purpose), trained to perform research duties, and how the PI will oversee their work.
Study Contact	Y	In PHIRST, and list on all submissions to the JHSPH IRB. The Study contact will receive copies of all automated messages (e.g., reminders that progress reports are due).