

## **What constitutes study personnel on a protocol involving human subjects?**

The following outlines what constitutes study personnel in regards to Institutional Review Board (IRB) protocols involving human subjects. This information is also related to the mandatory training requirement that the University of Kentucky has on human subjects protection.

A person listed as study personnel, in the IRB application, is an individual who is interacting and/or intervening with human subjects or handles personally identifiable data of a human subject.

Study personnel, if any, are required to be listed in the IRB application on any research protocol that involves human subjects. The study personnel that are involved in the informed consent process should also be distinguished on the IRB study personnel list.

All study personnel listed in the IRB application must complete initial human subjects protection (HSP) training and continuing HSP training at least every three years before the IRB will issue initial or continuing approval on a research protocol.

The University of Kentucky accepted options for both the initial and continuing HSP training are available on the [Human Subject Protection \(HSP\) Training](#) website. Links are provided for HSP training for non-UK collaborating researchers and lay study personnel involved in community-based participatory research (CBPR).

Study personnel listed on the IRB protocol, at continuation review, must have up-to-date HSP training or be removed as study personnel from the IRB protocol.

Addition of new study personnel to an IRB approved protocol via [modification request](#) will only be approved if the proposed study personnel have completed the required HSP training.

Please note that funding agencies may have their own definition of study personnel as it applies to grant or other funding applications.

In some cases, individuals may be involved in the research as both subjects and study personnel.

### Minors as Study Personnel

High school students who participate as study personnel are subject to the UK [Minors Involved in University-Sponsored Programs Policy](#). The policy includes a [UK Program Involving Minors Notification Form](#) and a mandatory parental [Informed Consent, Voluntary Waiver, Release of Liability and Assumption of Risk Form](#). [UK Risk Management](#) may require training for supervisors of minors. Contact UK Risk Management at (859) 257-3708 for guidance.

The student may also need to sign an IRB [Individual Investigator Agreement](#) to abide by all applicable human subject regulations and institutional requirements.

Questions regarding study personnel should be directed to Helene Lake-Bullock in the Office of Research Integrity at 859-257-9428 or email: [hbullo@uky.edu](mailto:hbullo@uky.edu).