Guidance for Staffing of Personnel on Research Studies

Oftentimes in inpatient clinical research there is a need for continuous staff coverage to perform study-related procedures such as administering study drug, and performing blood draws and study assessments.

Whether staff are Jefferson employees, volunteers, or hired from an agency, the following guidelines should be applied to determine whether or not the staff should be considered research personnel and listed on the OHR-1 for the purposes of IRB oversight:

Activities considered research	Activities not considered research
1. Administering non-FDA approved study drugs not provided by the Investigational Drug Service (IDS) 2. Performing study-mandated, research-specific assessments 3. Collecting PHI for research purposes and that is not otherwise routinely collected for clinical care **4.** Reporting SAEs &UAPs **5.** Making independent, protocol-related decisions **6.** Consenting subjects **7.** Independently interacting with subjects to collect research data	1. Administering study drugs provided by the IDS, and as per order of the principal or co-investigator. 2. Performing study-related procedures that are within standard scope of clinical practice, e.g., blood draws 3. Preparing & submitting IRB paperwork 4. Handling de-identified patient data 5. Interacting with a patient on a clinical basis 6. Informing patients about a study or providing them with recruitment materials 7. Following direct orders of principal investigator or co-investigator

Personnel that are conducting **activities considered research** fall under IRB oversight and thus must be listed as research personnel on the OHR-1 and must complete appropriate CITI training and submit conflict of interest disclosure to the Office of University Counsel prior to involvement in the research.

For further guidance, please contact the Office of Human Research at 215-503-8966.

11/3/2015