**Who MUST be listed as “Study Staff” on the HS-1A form and what are their training requirements?**

**Why is the HS-1A form important?**
A completed HS-1A form is required for all new and continuing projects. The form is used as an institutional tool to track all currently approved projects. It provides valuable information to the IRB regarding your study including: research sites, contact information, study staff, and current repository for your study documents, etc. In addition, it helps the IRB to ensure that educational requirements and conflict of interest determinations are completed. If the information is incomplete or incorrect, approval delays may occur.

**Page 2 of the HS-1A asks me to list “Study Staff.” What members of the research staff does the term refer to?**
“Study Staff” includes:
- Principal Investigator (PI)
- Co-PI(s)
- ALL individuals who obtain consent—these individuals MUST be identified
- Study/research coordinator
- Study/research manager
- Data collectors
- Recruiters
- Interviewers
- Statisticians

(NOTE: An example of individuals who are NOT considered to be “Study Staff” include: lab technicians at outside laboratories who process/analyze blood samples for the study.)

**Who requires that education/training be completed?**
Federal regulation and UB policy requires that all “Study Staff” complete training to ensure the protection and rights of human subjects.

**What is the minimum required training for all “Study Staff”?**
- Read the “Belmont Report: Ethical Principles and Guidelines for the Protection of Human Research Subjects.”
- Read the “Protection of Human Research Subjects Policy and Procedures Manual” (UBSOP).
- Complete the NIH online tutorial on human research subjects protection. (A copy of the completion certificate must be submitted to IRB.)

(NOTE: Links to training sites are accessible from the IRB websites.)

**My current list of “Study Staff” on the HS-1A is not complete. What should I do?**
The IRB MUST be informed of all “Study Staff” changes as they occur. If your current list is not up to date, you should submit an amendment to your protocol, as soon as possible, that requests the addition of missing study staff. A copy of the NIH tutorial completion certificate must be provided for each person added (unless a copy of the document is already on file with the IRB) before the amendment will be approved. By submitting a protocol amendment to the IRB to add “Study Staff,” the PI is attesting that the “Study Staff” listed have completed the minimum required training.

**What will happen if my HS-1A is incomplete or incorrect?**
Whether you are submitting a new protocol or submitting a Renewal for Continuing Review, information provided on the HS-1A is considered in the IRB approval process. If the information is incomplete or incorrect, approval delays may occur.

**Not required but highly recommended: “Researcher 101” Training**
This training is designed for new researchers and/or new research staff. A similar but modified version is offered as refresher training for those who already have research experience. This training is available through UB’s Human Research Protection Program (HRPP).

For more information on this and other available training, contact Dorothy Wright at: dswright@research.buffalo.edu

Comments and suggestions for future “HRPP Topics” are welcome and should be submitted to: Dorothy Wright at: dswright@research.buffalo.edu