variety of sources (such as government entities, non-profit institutions, professional organizations, and commercial businesses). WIRB has a recorded webinar that satisfies the training requirements. This webinar takes about an hour to complete.

Examples of courses are listed below. You are not limited to these training resources. Additional opportunities are available through other sources. External links are provided for user convenience and do not represent an endorsement by WIRB.

Online:

- WIRB's webinar entitled, *Protecting People in Clinical Research,* can be accessed at http://www.wirb.com/Pages/EducationServices.aspx.
- WIRB is a participating organization in the Collaborative Institutional Training Initiative (CITI). Investigators submitting research to WIRB can meet the training requirement through CITI or CITI International. CITI training for U.S. research is available at: https://www.citiprogram.org. CITI International training for non-U.S. or international research is available at: www.irbtraining.org. (The international course is available in English, Spanish, and Chinese. Additional languages may be available in the future.)
- The NIH Office of Extramural Research provides an online tutorial called "Protecting Human Research Participants" http://phrp.nihtraining.com/users/login.php.
- Canadian researchers may obtain training through the Tri-Council Policy Statement (TCPS). Training is available in English http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/.

Self-study text offering CME credits:

- Protecting Study Volunteers in Research - A Manual for Investigative Sites by Drs. Dunn and Chadwick (ISBN 1-930624-44-1). Readers can apply for CME credits or nursing contact hours. The book can be purchased through the publisher, Thomson-Centerwatch.

Physicians and their teams who request approval of use of a humanitarian use device or single patient treatment use of an investigational product are not required to complete human subject protection training.

D. Suggested Guidelines for Evaluating Staff Levels at the Site

WIRB's **initial review submission forms** ask for information about staffing levels at the site. WIRB evaluates site staffing levels based on a variety of criteria.

At a minimum, all clinical sites should have the following:

- Enough trained investigators and staff to administer the protocol without deviations that impact subject safety or data integrity.
- Enough trained investigators and staff to ensure there is sufficient time available for staff to interact with the subjects as much as is necessary for good clinical care.

- Enough trained investigators and staff to provide coverage for emergencies.

In addition, the Board considers what level of staffing would be required to execute the protocol. For example:

- How many subjects are already enrolled and what is the predicted rate of accrual?
- How many visits are required by the protocol?
- What type of visits are required and will the subject need to see the investigator at each visit?
- Are the required procedures complex or lengthy?
- Does the administration of the study drug require supervision or extensive instruction?
- Are the subjects generally healthy, seriously ill, or suffering from multiple conditions?
- Is the disease involved acute or unpredictable?
- Are the side effects of the intervention expected to be numerous or serious?
- Are the subjects considered vulnerable?

The particular composition and expertise of the study staff also is a consideration:

- Does the investigator have experience in conducting research? (This variable can affect overall management of the research staff and functions.)
- Are the staff members experienced in conducting research? Are they skilled at maintaining accurate and complete study records?
- Do the investigator and staff have experience with the type of treatment in the protocol?
- Does the site have other ongoing protocols?

For example, the Board might determine that an experienced research coordinator can administer 3 to 5 drug protocols that require weekly or biweekly visits of ½ hour to 2 hours and enrollment of 5 to 15 subjects. However, if the site's ratio amounted to 7-10 of these studies per experienced coordinator, the Board might table the research and recommend the site adjust the staffing levels. The Board would also expect to see at least one physician sub-investigator appointed to provide back-up for the PI.

Different types of protocols, however, require different levels of staff time and expertise. Because of their narrow inclusion criteria, oncology protocols normally don't rapidly accrue subjects, and because they are often carried out by groups of oncology specialists, the Board might tolerate a high protocol-to-staff ratio. In these cases, the Board's focus might shift from the number of staff, to the ability of a large staff to successfully coordinate a subject's care and execute the study plan.

In the case of a non-treatment protocol, the question of staff levels may not be important.