Development of a New Microbicide
Research Core-Science

Case Study 2: Informed Consent

A randomized, placebo-controlled trial of a vaginal microbicide product is under way in a resource-poor country. The purpose of this trial is to look at the effectiveness of a topically applied microbicide on heterosexual acquisition of HIV. Half of the women enrolled will receive the test product and condoms and the other half will receive a placebo and condoms. Both the local Research Ethics Committee (REC) and sponsor's REC have approved this research and the consent process.

During a routine monitoring visit for this trial, the monitor observes the consent process for several study participants. The monitor finds that the study counselors administering the informed consent do not explain all of the information on the consent form, as was planned at the staff training. Most of the consent form is paraphrased and several essential elements are omitted. All participants sign the consent form.

When the counselors are questioned about this, they state that the women at this site are not capable of understanding everything in the consent form, so the site counselors and the study investigator agreed on emphasizing only the most important aspects of the consent form.

The monitor speaks to the investigator about this issue. She is told that investigators are encouraged to review and modify consent forms as necessary to account for local conditions. The investigator feels that the study counselors were correctly following the informed consent process. The monitor reports her findings to the REC.

Question
In this case the REC should:

1. Recommend that the study be terminated (not allowed to continue).

2. Retrain the site investigator and the study staff in the informed consent process.

3. Rely on the site investigator's knowledge of the study population.

4. Take no action. Signed consent forms for each participant are on file.