Unit 11

How to Review a Protocol

## 1. What are the main research questions?

Look at the Background and Objectives sections. Are these questions important? Are they a high priority in the community? Will they provide information that will have lasting impact, even if they are not immediately useful?

## 2. What is the length of the study?

How long will the study participant be involved? When will study results be available to the participant? What information will be available to the participant during the trial?

## 3. What is the control group?

What product(s) will people in the control group receive? Are there risks related to getting the control product(s) different than those related to getting the vaccine?

## 4. What are the inclusion/exclusion criteria?

Do they make sense? Do they serve the purpose of the study? Are there groups excluded unnecessarily? Do they create barriers that would make it difficult to enroll participants?

## 5. How often are clinic visits?

What is included in the visits? How long will they take? Are the descriptions of procedures clear? Will the participant also have to give information to the clinic by phone? Are the visits, telephone reports, etc., too complicated? How are they explained to the participant?

## 6. Are there barriers to participation?

Are there aspects of this trial which will make participation difficult? What could be done to minimize the barriers?

## 7. How is the participant protected from undue risk?

Does the participant understand his/her legal rights? Is it easy for study participants to reach out to study staff in case of problems associated with study procedures? Are there adequate compensation mechanisms in case of side effects?

## 8. How will amendments to the trial be handled?

Is the possibility of amendments discussed during the informed consent process?