How to Critically (and Quickly) Read a Protocol
Office of HIV/AIDS Network Coordination
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It is important for CAB members to critically review protocols from a community perspective. Some of the key questions to consider when reviewing a protocol are outlined below to help CAB members focus their review on the most critical areas of the protocol. Each of the sections/topics listed below is addressed in protocols across all the NIAID-funded networks though they may be labeled differently or listed in a different order.

Cover Sheet and Protocol Team Membership:

The protocol cover sheet notes which Network Committee developed the protocol and is typically followed by a list of the members of the protocol team, which should always include the CAB representative/s.

Study Objectives

Study objectives are typically provided early in the protocol, possibly after the background and rationale for the study. The objectives often include a list of sub-studies.

Quickly review the number of sub-studies, and ask if it is feasible to try to do so many studies under one main study? What conversations have taken place to make sure that community members are involved in the review process where the study is being developed and conducted? If the study is being conducted by more than one network, consider whether all the communities have been consulted.

Protocol Summary

Schema

The schema is a general outline of the study including randomization (if any), number of participants, treatment arms, criteria for treatment response or efficacy and/or failure, and secondary steps, etc. The schema will give you a good idea of the study design and target population, including eligibility criteria, which you should review carefully to determine how inclusive the study is and how clearly and accurately the study population is described. Is the rationale for the control group included? There may be times when a study is prematurely terminated, and it's important to know under what circumstances that could happen.

Study Design

What are the main research questions? Are these questions a high priority in the community? Will the study provide information that will impact future research even if the results are not immediately useful?

[1] This document was initially developed in 1997 for the AIDS Clinical Trials Group (ACTG) to help CAB members review a treatment protocol. However, this document has evolved and been updated. The general approach for reviewing a protocol is the same for CAB members working with treatment, cure, and/or prevention networks, though each protocol is unique and may have additional questions to consider.

Duration of Study
How long will the study participant be involved? When will study results be available to participants? What information will be available to the participant during the trial? What information will be available to the participant at the end of the study? Does the study address access to the study product(s) when the trial is complete?

Study Procedures and Clinic Visits (Schedule of Evaluations/Events)
What is included in each clinic visit? How long does each clinic visit take? Are the descriptions of procedures clear? Will the participant also have to provide information to the clinic by phone or electronically? Are the visits, telephone reports, etc., too complicated? How are they explained to the participant? Think about the various tests that are being done and if there are too many or too few. For example, are there too many blood tests? Are there enough viral load assessments? Look for information about whether study participants will get their test results in in "real time". Will the test results be available immediately, or will the test results of participants be "batched" together with results coming later, and often not shared with the participant?

Study Population

Who will be recruited for this study? How many individuals is the study seeking to recruit? Are there specific targets for certain populations? What language is used to describe the study population—is it inclusive, accurate, and non-stigmatizing? Is the study population described correctly in terms of gender identity and sex assigned at birth?

Eligibility Criteria
The eligibility criteria are important to review because they dictate who can and cannot participate in the study. If the eligibility criteria are based on sex assigned at birth or gender identity, it is important that there is a valid scientific reason. Also, if specific populations are included, it is important it be very clear that they are eligible to participate. Do the eligibility criteria make sense? Do they serve the purpose of the study? Are any groups of people excluded unnecessarily? Do the criteria create barriers that would make it difficult to enroll participants? To help ensure that the study is as inclusive as possible, ask if there are scientific justifications for exclusions and reference the Representative Studies Rubric and ask the protocol team to discuss and complete it.

Informed Consent

Does the informed consent explain the study in simple, clear language? Are all the medical terms explained? Is there a plan for publication? How and when will participants be informed of the results? Are all the major risks and benefits explained? How is participant confidentiality maintained? Are participants adequately compensated for participation? How will research-related harm be compensated? Is emergency contact information included? Will participants understand their legal rights after reading the informed consent?

Keep in mind that the informed consent is only a "template'; each individual institution's Institutional Review Board (IRB) or Ethics Committee has their own requirements for the content and format of the informed consent.

Other

Barriers to Participation

Are there aspects of this trial that will make it difficult to participate in? What could be done to minimize the barriers?

Review for Stigmatizing language

Is non-stigmatizing language being used throughout the protocol and all study related documents? Is the NIAID HIV Language Guide being used as a reference to check for stigmatizing language?

Resources

There are a number or resources to support CABs available on the Office of HIV/AIDS Network Coordination public portal. Under Coordination Areas, go to Community and then Community Partners and then Resources for a listing of available resources.

Training materials are available to support your knowledge of clinical research and protocol development on the DAIDS Learning Portal (DLP), including ***Understanding Clinical Research*** and ***Research Ethics and Informed Consent.***

These e-learning modules can be found on the Resources Page of the DLP under Community Engagement, along with other resources, publications, and training tools that you may be valuable to you and your CABs. Please feel free to share this broadly with your communities.

The DLP is available to staff, stakeholders, and others working with the Division of AIDS. If you do not already have an account, click on “request an account” to get access; you will need your site number to complete the request form. If you are affiliated with you a site, you can simply ask the study coordinator or site PI for the site ID. However, even if you’re not affiliated with a site, you can request an account by using 99999 as your site ID. You will receive an automated email with instructions on how to create a password. If you have any problems accessing the materials, please contact support-daidslearningportal@niaid.nih.gov/.