**Lesson 7 Work Assignment**

*Remember to save a personal copy of this completed work assignment for future reference.*

# Purpose

In Module 7, you learned that negotiation with stakeholders is a critical part of determining a trial’s HIV prevention package and procedures for access to HIV care and treatment. This assignment offers an opportunity to think about some issues related to HIV prevention and treatment in your community and to brainstorm about a potential HIV prevention package for trial participants and the community.

# Step 1: Assessment

Complete Section 1.6 of the GPP Blueprint and record your responses in the answer sheet below.

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| SECTION 1.6 **Existing HIV prevention and treatment programs** |
| 1) Is there a robust HIV prevention program in the country where the trial is set? Which prevention strategies does it make available |
| 2) Are there aspects of the proposed research that could conflict with national health care policies or protocols (particularly those related to HIV)? |
| 3) If there is a national HIV program, has it been implemented in the trial-site community? How do prevention services in the trial-site community differ from the national program? Which strategies are made available? e.g. If MTCT is part of the national program how many mothers are accessing services? |
| 4) How equipped are health providers to explain and provide HIV prevention? |
| 5) What kind of non-HIV-related health care services are available to members of the local community? This includes inpatient and outpatient services |
| 6) List any regulatory bodies (e.g., institutional review boards, national ethics committees) that have authority to approve or reject clinical trial proposals, as well as those with the potential to impact trial conduct, product or strategy approval, or rollout. How experienced are they in reviewing research? How well versed are they in the research area of the proposed trial? |

# Step 2: Stakeholder Identification

List some of the key stakeholders you would involve in negotiation of the HIV prevention package for your trial and highlight some of their priorities.

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# Step 3: Description of the HIV Prevention Package

* Think about your target trial population and the surrounding community and review your responses to Module 1 and 2 Work Assignments.
* Describe what the HIV prevention package might look like for your trial. Remember to consider potential interventions that have recently demonstrated efficacy or may demonstrate efficacy during the course of the trial.
* Briefly describe your rationale, including your reasons for not including certain prevention options in the package.

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