# Lesson 7 Work Assignment\_Track B

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

# Purpose

In Lessons 5, 6 and 7, you learned about the importance of proactively communicating with stakeholders and outlined some of the complexities and benefits of meaningful involvement of stakeholders in aspects of the research, such as the design of trial protocols, informed consent, and the standards of HIV prevention and treatment. This assignment offers an opportunity to apply some of these concepts to hypothetical scenarios.

# Instructions

Read each hypothetical scenario and answer the questions that follow.

Scenario: A research team is designing a multi-country PrEP demonstration project that will enrol young women in three West and East African countries. During the early trial planning stage, there is some local newspaper coverage in one of the countries that highlights community concerns about the proposed research, such as arrangements for treatment access for those who seroconvert and the use of a drug regimen that is not readily available to the general population. In another country, a local non-governmental organisation claims that participants in the trial will not adequately be informed about the risks of the trial product, because the informed consent information will be provided in English to mostly non-English speaking participants.

In response, how can the research team apply GPP to this situation and incorporate key stakeholder input into trial design in a transparent way?

Scenario: A research team plans to conduct a vaccine efficacy trial among ‘key populations’ of MSM and injection drug users in the US, Kenya, Thailand, and Brazil. At the time of protocol development, PrEP is a licensed intervention in the US; in several other trial countries, PrEP policies are moving forward and informed advocates are pushing for PrEP access and licensure. Also during this time, IDU advocacy organizations in Thailand raise concerns about policies that criminalize the purchase and possession of injecting equipment for illegal drug use. Community leaders in Kenya highlight the lack of availability of harm reduction or substance treatment services in their area, which they feel should be part of the HIV prevention package.

How could the sponsor and research team apply GPP at local and national levels to negotiate and decide on the components of the HIV prevention package with different stakeholder groups?