

MTN-042/MTN-043 Study Enrollment Decision Tool

INSTRUCTIONS

This is a decision aid tool to help potential participants think through whether to enroll in DELIVER or B-PROTECTED. We expect this conversation to take 10-15 minutes, although for some participants who are very uncertain about entering the study, it might take a bit longer. However, we want to ensure that women who decide to enroll are comfortable with that decision as it will make it more likely that they will use the study products. The role of the staff person is to help the participant think through what the Positives and Negatives of participating might be for them, while remaining neutral, curious, and respectful of participant's decisions. At no time should the staff person try to encourage or persuade the potential participant to reach a certain decision.

The staff person can introduce the exercise as described below. Ask the individual to begin with either column, and once that column is complete, move to the other. It is fine for the participant to add to each category when the other category is being discussed (i.e., when discussing the Negatives, they remember another Positive). When not much else is being evoked from the potential participant, summarize the discussion thus far and add what other Positives and Negatives they think need to be added. Once this discussion is complete, the individual is asked what their decision is on enrolling in the study, should they be eligible.

INTRODUCING THE EXERCISE

In describing the exercise to potential participants, it is important that the staff member highlight that:

- This exercise is to help the individual decide whether or not to enter the study;
- The staff person will remain neutral and not push the individual towards a certain decision;
- If the individual is unable to make a decision during this visit, she can return to continue the conversation

Below is an example of how the exercise can be introduced to participants. Note, however, that this example is not intended as a script that staff should read to potential participants.

To help participants decide whether to join the study, we are spending some time helping them think through the positives and negatives of participating for themselves, and for their baby. My role is to help you think through this, without judging you or pushing you to make a specific decision. At the end, I will ask you what you have decided and if you have still not reached a

decision that is okay, you can go home, think about it, and return to discuss further. How does that sound?

Here we have two columns, one for the Positives and the other for the Negatives aspects of participating in the study. With which column would you like to start? Okay, so what are some of the _____ (Positive or Negatives; whichever the individual selected first) aspects of participating in the study. What are some other ones? Now let's work on the other column, what are some of the _____ (the other column) aspects. What are some other ones? We have a bit of a list here, let me just review them with you. Aside from these, what other Positive or Negative aspects are there about participating in the study?

[Once there are no other Positives or Negatives added....] So, as you look through this list of Positive and Negative aspects about participant in the study, to what decision does it lead you?

[If the participant does not respond after being provided time...] Remember that this is your decision to make and if you are still unsure, it is okay to go home and come back if you want to decide to enter the study or want to discuss this further. I am wondering, what would help you make a decision?