HOPE Hair Collection Counseling Messages

- As part of HOPE, we are asking for your permission to cut a small sample of hair from your head to check the amount of dapivirine in this hair sample.
 - Note: For participants who have never had exposure to dapivirine, e.g. those who have always declined the ring, hair samples will be used as negative controls (samples known not to contain dapivirine so we can compare to samples which contain dapivirine)
- Hair sample testing has been part of many other studies throughout Africa and the world, and is being done in HOPE as another possible way to help researchers understand how much dapivirine is needed to prevent HIV infection.
- Medicines go into many places in the body, for example into your blood, tissue, and your hair. Medicine remains in hair for longer than it remains in the blood or in tissue. Because of this, the amount of dapivirine found inside the hair sample may provide a better idea of how much dapivirine was released over a long period of time.
 - Note: Collecting blood and vaginal swab samples is still important for the HOPE study, so that we can understand more fully how dapivirine is working in the body and how well different levels prevent HIV.
- We will collect about 50 hairs from your head. Of note, we all lose about 100 strands from our scalp daily (that amount of hair falls out or is brushed out).
- Cutting this small amount of hair from your head will not disrupt your hairstyle and will not affect the normal new growth of your hair.

PAUSE AND SHOW IMAGES OF HAIR COLLECTION PROCESS AND AMOUNT OF HAIR COLLECTED

- Hair sample testing requires specialized equipment that is not available in many local research sites. For that reason, the samples are shipped to the US laboratory for processing. All shipping is secure, and information that identifies participants is not linked to the shipped samples.
- Once hair samples reach the lab, they are stored safely, cut up into small pieces and entirely dissolved into a liquid. That liquid is then injected into a machine to measure the amount of study medication. The hair sample is completely dissolved so there is none remaining.

- If there is hair collected that is not analyzed, those hair samples will be completely destroyed at the end of the study by dissolving the hair into a liquid and then disposing of the liquid.
- No one but study investigators will have access to the hair samples and they will be kept safe at all times in a secured laboratory. The laboratory will not have access to any names or any identifying information for the people from whom hair was collected.

PAUSE AND SHOW IMAGES OF HAIR PROCESSING AND DISPOSAL OF SAMPLES IN THE LAB.

 As with any study procedure, collection of hair samples is voluntary. If you choose not to provide a hair sample, this will not affect your participation in HOPE.