Capturing Participant Information for Mucosal Sampling
An Investigator’s Guide

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1. To comprehend potentially protective humoral and cellular immune responses present at the mucosal site, we need high quality and reliable mucosal specimens.

2. Many factors influence the quality of the mucosal sample, so collective guidance from experienced investigators can save resources and expedite research.
A consolidated resource for organizations and investigators engaging in clinical studies with a mucosal immunology component.
Purpose of the Guide

• To consider individuals’ parameters that may affect the interpretation of mucosal data

• To use in conjunction with Network procedures and policies, protocols, and CRFs

• To supplement and enhance the quality of clinical research conducted with mucosal specimens and promote cross trial data comparison.
Development of the Guide

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Overview

The Guide provides easy to understand, up to date rationales and references for participants’ characteristics to be considered for inclusion in study records.
Guide Content

- **Rationale**
- **Considerations**
- **Selected references**
- **CRF examples**
2. Reproductive History

2.8. Sexually-transmitted and Reproductive Tract Infections (STIs/RTIs)

Points to consider in the RATIONALE

Data support that active GI or GU STI/RTI tract infections that cause local inflammatory responses in the mucosal compartment confound interpretation of mucosal immune responses.

The screening of STIs in asymptomatic study participants is a critical part of obtaining interpretable mucosal specimens.

May consider enrolling participants with STI who are treated and cured.
Points developed in the **CONSIDERATIONS**

Important STI/RTI information to record may include:
- History of STIs
- History of treatment for STIs
- Genital or rectal sores, ulcers, fistulas, fissures
- Genital or rectal discharge
- Genital or rectal pain
- Skin rashes in the genital and rectal areas

Treatment decisions for a lab-diagnosed STI may be limited as local public health standards for diagnosing STI/RTI are empiric or syndromic- so offer diagnostic testing

How to inform the participant?

Post-hoc use of STI test results for protocol eligibility?
- entirely ineligible vs. eligible after treatment; is a test for cure necessary?
- consequences for study size, protocol timing and budget
How to Access and Distribute the Guide:

The Guide is free to access online or in print.

Get **the booklet version** of the Guide for you and your colleagues for multiple copies, please email requests to: timelytopics@vaccineenterprise.org

**The online version**, fully downloadable, with links to resources, can be easily found on the Global HIV Vaccine Enterprise website at: www.vaccineenterprise.org/mucosal-sampling-guide
How to Contribute

Include a link to the Guide on your organization’s website

Be a contributing expert

The field of mucosal immunology is rapidly evolving and the Guide is a living document; consider volunteering to be included in an expert member for future updates.
Thank you!

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