



MATRIX-002 Operational Guidance # 02

Operational Guidance Category:

Clinical Procedures Pharmacy Laboratory Other, specify:

Brief Description: Provision of placebo vaginal films for the IDIs

The purpose of this Operational Guidance document is to provide guidance on the process and documentation for providing placebo vaginal films for conducting IDIs at the site.

The following provides instructions on the implementation of the process:

1. The site PoR will receive an email notification of an upcoming IDI, at least 48 hours in advance.
2. The films, one film A and one film B, should be provided from the supply of both Film A and Film B that have been returned unused from the clinic and are located in the quarantine bin.
3. The attached Chain of Custody Form for IDIs should be completed to document provision of the films for the IDI.
4. The films should be returned to quarantine in the pharmacy promptly after the IDI and the bottom portion of the Chain of Custody form is to be completed to document the return of the films.

Operational Guidance memos, once signed, must be distributed to MATRIX sites via email. Sites are responsible for ensuring that appropriate staff review and understand the content of each memo and file the memo with their essential documents. Operational Guidance memos must also be posted to the appropriate MATRIX webpage. As per SSP section 13, the memos are official study documentation and will be considered an official part of the MATRIX SSP Manual. The Operational Memo becomes effective the date it is signed.

Cindy Jacobson

Signer Name: Cindy Jacobson
Signing Reason: I am the author of this document
Signing Time: 3/15/2024 | 1:41:12 PM PDT

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3/15/2024

Date

Title: Protocol Pharmacist