



MTN-034/REACH Operational Guidance #1: Eligibility Criteria for HIV-Related Screen-outs

The purpose of this Operational Guidance document is to clarify eligibility criteria categorization for HIV-related screen-outs in MTN-034/REACH.

- A participant with at least 1 positive HIV rapid test, no matter the outcome should be deemed ineligible per Exclusion Criteria 2 (E-2): *At Screening or Enrollment, has a positive HIV test.*
- A participant confirmed HIV-infected (i.e. has 2 positive rapids or discordant rapids with a positive confirmation) should be deemed ineligible per E-2 and Inclusion Criteria 6 (I-6): *HIV-uninfected based on testing performed at Screening and Enrollment.*
- Per SSP section 5.3.2, site staff should record all reasons for in which a potential participant screens out/screen fails. The table below further clarifies the use of the applicable HIV testing and status-related eligibility codes:

Screening HIV Rapid Test Results	Final HIV Diagnosis (confirmation)	Eligibility Criteria	
		I-6	E-2
Dual Negative	NA	No	No
Discordant	Infected	Yes	Yes
	Uninfected	No	Yes
Dual Positive	NA	Yes	Yes


The Screening and Enrollment Log has been revised to Version 3.0 to correct the omission of code I-6 on previous versions and to add guidance for use of these codes. Sites should immediately begin using the updated Screening and Enrollment Log template, Version 3.0 dated 20 May 2019.

For any participants still in screening or that require code 'I-6' be marked on the previous log, the PTID entry rows should be completed or corrected per GCP on the existing log. The previous log should then be closed out by lining through all unused entries/blank lines, with initials and date. All Screening and Enrollment Logs should be filed together for reference.

Please ensure that the Screening and Enrollment Log and Eligibility Criteria CRF align for any corrected codes.

All Operational Guidance documents must be printed and filed with regulatory documentation.

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