## MTN-020 Protocol Safety Review Team Query Form

**IMPORTANT: Complete all required fields so the PSRT has all information needed to respond to your query.**

**Site:**  **Query Date (dd-MMM-yy):**

**Completed by:**  **Email address:**

**PTID:** **Participant Age** (in years):

**Reason for query:**  Consultation on AE assessment/management/reporting

Consultation on product use management

Consultation on participant eligibility and/or evaluability

Other, specify:

**Is this query a request for the PSRT to consult on an adverse event (AE)?**

Yes → continue completing this page

No → skip to Comments on page 2

**AE of concern (include onset date and severity grade):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Relatedness to study product: Current study product administration:**

Related  No change

Not related  On hold

Permanently discontinued

Not applicable

**Has this AE been reported on a SCHARP Has this AE been assessed more than once?**

**AE Log form?**

Yes  Yes

No  No 🡪 skip to Comments on page 2

**Has this AE been reported as an SAE/EAE?**

Yes

No

**Date of most recent assessment (dd-MMM-yy):\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Status of AE at most recent assessment:**

Continuing, stabilized (severity grade unchanged)

Continuing, improving → severity grade decreased to

Continuing, worsening → severity grade increased to

Resolved

**Comments:** Provide additional details relevant to this query. *If product use has been held, include date of last reported product use prior to the hold (per participant report).*

**End of Form for Site Staff.** Email completed form to the MTN-020 Protocol Safety Physicians, [mtn020safetymd@mtnstopshiv.org](mailto:mtn020safetymd@mtnstopshiv.org). If an email response is not received from the PSRT within 3 business days, re-contact the Protocol Safety Physicians, copying the following distribution list ([mtn020mgmt@mtnstopshiv.org](mailto:mtn020mgmt@mtnstopshiv.org)) for assistance as soon as possible.

For PSRT use only — provide response to query here

**PSRT Responding Member:**

**PSRT Response Date (dd-MMM-yy):**

PSRT Comments: