



HPTN 052 (096)

IPO-1 (441)

Visit Code [][][] . []

Note: Visit at which the pregnancy was reported.

Index ID

Index ID [][][] - [][][] - 00 - []

Index Pregnancy Outcome

Outcome unknown at end of study. Staff Initials/Date. End of form. Fax to SCHARP DataFax.

1. How many pregnancy outcomes resulted from the reported pregnancy? []

2. OUTCOME #1

2a. Outcome Date dd MMM yy [][] [][][] [][]

2b. Specify Outcome: Mark only one.

- full term live birth (>= 37 weeks)
premature live birth (< 37 weeks)
spontaneous fetal death and/or still birth (>= 20 weeks)
spontaneous abortion (< 20 weeks)
ectopic pregnancy
therapeutic/elective abortion

2b1. Method: C-section [] vaginal []

Complete AE Log. Refer to the protocol and SSP to determine whether an EAE is submitted.

2c. Were any fetal/infant congenital anomalies identified? yes [] no [] not assessed []

If only one outcome, end of form.

If yes, complete AE Log and EAE form.

3. OUTCOME #2

3a. Outcome Date dd MMM yy [][] [][][] [][]

3b. Specify Outcome: Mark only one.

- full term live birth (>= 37 weeks)
premature live birth (< 37 weeks)
spontaneous fetal death and/or still birth (>= 20 weeks)
spontaneous abortion (< 20 weeks)
ectopic pregnancy
therapeutic/elective abortion

3b1. Method: C-section [] vaginal []

Complete AE Log. Refer to the protocol and SSP to determine whether an EAE is submitted.

3c. Were any fetal/infant congenital anomalies identified? yes [] no [] not assessed []

If yes, complete AE Log and EAE form.

Comments: _____

Index Pregnancy Outcome (IPO-1)

This form is used to report the pregnancy outcome(s) of a pregnancy reported post enrollment through termination. A Pregnancy Outcome form is required for each Pregnancy Report and History form completed for a participant. This form is completed when information about a pregnancy outcome becomes available to study staff. If an outcome is unknown at study end, mark the “Outcome unknown at end of study” box at the top of the page and fax to DataFax. When the outcome is known, draw a line through this box, record the outcome, and refax. A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SCHARP for guidance on how to complete this form.

Item-specific Instructions:

- **Visit Code:** Record the visit code of the participant’s corresponding Index Enrollment Pregnancy Report and History form or the Index Follow-up form.
- **Specify Outcome:** If the outcome is therapeutic/elective abortion, note that while the abortion itself is not an adverse experience, if the abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Index Adverse Experience (AE) Log, with “procedure/surgery” marked under “Treatment.”
- **Congenital anomalies:** This item should be updated if information becomes available during the mother’s (the index participant’s) study follow-up period regarding a congenital anomaly. If a congenital anomaly is identified, complete an AE Log and an EAE form. When completing the AE Log, record the mother’s Participant ID and the event as “congenital anomaly of infant” as the diagnosis.