

**WOMEN'S INTERAGENCY HIV STUDY
QUESTION BY QUESTION SPECIFICATIONS
CONS FORM: CONSENT TRACKING**

Guidelines for completing the *Consent Tracking Form* (CONS).

This form will be used to document participant consent for genetics studies, B-cell immortalization, and commercial use of immortalized B-cell lines. Most consents were documented prior to the first use of this form at visit 28 and transferred into the WIHS data entry system for visit 28. Therefore, sites only need to complete this form if a participant has never been asked for her consent and returns to a WIHS visit or if a participant changes her mind about her consent.

There are three types of consents; Questions A2, A5, and A7 allow you to skip over a particular consent if the participant is not changing that consent. Complete questions relating to the consent(s) being changed at the visit. Entering this data into Apollo will enable sites to track consent status and obtain any missing consents as documented by the *Visit Control Sheet* or Apollo reports.

SECTION A: GENERAL INFORMATION

- A1. Record the date that the form was completed.
- A2. Indicate if a Genetics Consent is to be updated using this form. If yes, complete **Questions A3** and **A4**. If no, skip to **Question A5**.
- A3. Record the most recent status of Genetics Consent for this participant.
- A4. Record the visit at which Genetics Consent was obtained.
- A5. Indicate if a B-Cell Consent is to be updated using this form. If yes, complete **Question A6**. If no, skip to **Question A7**.
- A6. Record the most recent status of B-Cell Consent for this participant.
- A7. Indicate if a commercial use of B-cell Consent is to be updated using this form. If yes, complete **Question A8** and **A9**. If no, then the form is finished.

At least one question from A2, A5, or A7 should have “yes” as a response.

NOTE: Commercial use of B-cell consent was not required at all sites.

- A8. Record the most recent status of commercial use of B-cell Consent for this participant.
- A9. Record the visit at which commercial use of B-cell Consent was obtained.