

WOMEN'S INTERAGENCY HIV STUDY
FOLLOW UP VISIT
QUESTION BY QUESTION SPECIFICATIONS
CONS FORM: CONSENT TRACKING

Guidelines for completing CONS, "Consent Tracking." This form will be used to document participant consent for genetics studies, B-cell immortalization, commercial use of immortalized B-cell lines, and GWAS. 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 four types of consents; questions A2, A5, A7, and A10 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 A3 and A4. If no, skip to 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 A6. If no, skip to 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 A8 and A9. If no, skip to A10. 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.
- A10. Indicate if GWAS Consent is to be updated using this form. If yes, complete A11. If no, then the form is finished. At least one question from A2, A5, A7, or A10 should have "yes" as a response.
- A11. Record the most recent status of GWAS Consent for this participant.