International Studies for AIDS Associated Co-infection
ISAAC 001 002 003 004 (circle)
KCMC/Duke HIV/AIDS Collaborative Project

Name _____
Screen Number _____
Date _____
Day/Month/Year

Consent Form Quality Control Tool
Page 1 of 1

This form serves to confirm the adequacy of the consent process. Check boxes serve to affirm statements. <u>All boxes must be completed and verified prior to randomization or N/A written to the left of the box</u>. Verficiation will be the responsibility of the person obtaining consent, and a second reviewer, i.e., study coordinator, research clinical officer, or research nurse, and must be signed and dated by both. After completion, this tool must be stapled to the front of the consent form and returned to the data management office for filing.

Check to confirm or write N/A next to the box if not applicable.

<u>1st 2nd Reviewer</u>

□ □ The correct version of this consent has been used. List version: _____

□ □ All pages of the consent form are present and correspond to the same version.

□ □ All pages of the consent form are labeled with subject identifer(s) and belong to the same subject.

□ □ All pages have been initialed or marked in dark ink by the subject verifying the information on this page was reviewed.

□ □ Signature page has been signed and dated, or marked (fingerprint or "X") by the participant in dark ink.

□ □ Signature page has been signed and dated by the person obtaining consent in dark ink.

□ □ Signature page has been signed and dated by the witness for illiterate participants in dark ink.

□ □ Signature page has been signed and dated by child 12 years of age or older for written assent in dark ink and parent/guardian signature line and date have been completed as well in dark ink.

□ □ The database repository consent has been obtained in addition to the main study consent.

□ □ All other areas on the consent form requiring initials have been completed in dark ink and have initials, not check mark.

□ □ Documentation of consent form process exists in flow sheet or TELEform, including how onsent was obtained and copy provided to subject.

_____ _____
Person Obtaining Consent/Date 2nd Reviewer Verifying Quality Control/Date