

1. REQUEST FOR CONSENT TO TESTING

101 LABORATORY TECHNICIAN: IDENTIFY AND REQUEST CONSENT FROM PARENT OR OTHER ADULT RESPONSIBLE FOR CHILD.

102 HIV is one of the leading causes of death in this country. HIV can be found in blood. We want to see how many children in Uganda have HIV. We would also like to store some of the blood that remains and test for other diseases in the future. Your household has been selected purely by chance from your community. As part of this survey we ask parents to consent for us to take a little blood from their children under five years. We will be testing more than 10,000 children from all over the country. You can choose to let your child give blood or not. It is your choice. If you choose not to let your child give blood, there is no problem. If you agree, we would like to take a few drops of blood from your child's finger (heel).

We use only new sterile lancets to collect blood. The tests are simple, fast and accurate. We can do them here in the home. They take about 30 minutes. We can tell you your child's results right away. We will offer to counsel you before and after the test. That way you know what the test and the result means. If your child is less than 18 months' old and if the test is positive, then we will send the blood for further testing to a laboratory in Entebbe. We will give you a card with a unique code which you can take to a health facility nearby [MENTION NAMES] to find out if your child has HIV. The health providers there will advise you on the need for treatment. The result will be ready in about 6 weeks. The results will remain available in the health facility for 6 months. If the result is not picked in that period, your child who tests HIV positive will have to have the tests again in a health facility providing these services. If you agree, we will keep the leftover blood. We may use it for later testing related to health or diseases in a central laboratory. Because we do not keep your child's name, we cannot tell you about any results from future testing. Such testing will help the Government to improve health in Uganda. You can join this study even if you don't want us to keep your child's blood.

You can decide to let your child give blood for the tests or not to give blood. You can decide if you want all, only some or none of the tests done in the home. You can also decide for each test if you want the results given to you. The pinprick may hurt your child a little. If there is bleeding or swelling at the site, please contact our study staff or your health worker. All information you share will be kept secret. We will put a study number, not your child's name, on the blood samples. That way we can make sure nobody can tell to whom the blood belongs. We do not expect major risks from participating in this survey.

1. Your child's name or identifiable information will NOT be used in any survey materials.
2. Only research team members will have access to your child's data and specimens.
3. Skilled interviewers will be trained to protect your privacy.

You may not benefit directly from being part of this survey. As mentioned earlier, we will offer free treatment or advise you what to do. We will provide counseling and results for HIV to all who request for them in the household. We shall refer children who are HIV positive to health facilities for medical care services. We do not offer money for participating in this study.

Everything we talk about will be kept secret to the extent allowed by the law. Your child's test results will be kept secret to the extent allowed by the law. To protect your privacy, we will use a code number to identify your child and all specimens. We will keep these records and specimens locked. Only special staff will be able to look at the records or use the specimens. Your child's name or any other facts that might point to your household will not appear when we present this survey or publish its results.

We would like to answer all your questions. If you have any questions now, please ask us. If you have any questions in the future, there are other persons that you can contact. Ministry of Health:
 Dr. Alex Opio: 0414-256683
 Dr. Joshua Musinguzi: 0414-256683
 Dr. Wilford Kirungi: 0414-256683
 If you have any concerns about this survey, contact Mr. Tom Lutalo Chairman UVRI Science and Ethics Committee 0414-320272.

HIV TEST

103	Would you like to have your child take part in this survey where a sample of (NAME'S) blood is taken for the HIV tests?	AGREED 1 REFUSED 2 (THANK THE PARENT/GUARDIAN AND GO TO NEXT CHILD ELIGIBLE FOR TESTING. IF NO MORE ELIGIBLE CHILDREN, GO TO NEXT HOUSEHOLD). _____ (SIGN)
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STORED BLOOD

104	May we store and use any blood that remains for future testing at the central laboratory?	AGREES 1 REFUSES 2 _____ (SIGN)
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105	CHECK 103 AND 104. INDICATE IF RESPONDENT AGREED TO HIV TEST OR TO STORAGE OF BLOOD. <table style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;"> AGREED TO HIV TEST OR TO STORAGE OF BLOOD <input type="checkbox"/> </td> <td style="width: 50%; text-align: center;"> REFUSED HIV TEST AND STORAGE OF BLOOD (THANK THE PARENT/GUARDIAN AND GO TO NEXT CHILD ELIGIBLE FOR TESTING. IF NO MORE ELIGIBLE CHILDREN, GO TO NEXT HOUSEHOLD). <input type="checkbox"/> </td> </tr> </table> _____ (SIGN)	AGREED TO HIV TEST OR TO STORAGE OF BLOOD <input type="checkbox"/>	REFUSED HIV TEST AND STORAGE OF BLOOD (THANK THE PARENT/GUARDIAN AND GO TO NEXT CHILD ELIGIBLE FOR TESTING. IF NO MORE ELIGIBLE CHILDREN, GO TO NEXT HOUSEHOLD). <input type="checkbox"/>
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106	CHECK 103 AND INDICATE IF PARENT/GUARDIAN AGREED TO HIV TEST FOR THIS CHILD. <table style="width: 100%;"> <tr> <td style="width: 50%; text-align: center;"> AGREED TO HIV TEST <input type="checkbox"/> </td> <td style="width: 50%; text-align: center;"> REFUSED HIV TEST (SKIP TO 201) <input type="checkbox"/> </td> </tr> </table>	AGREED TO HIV TEST <input type="checkbox"/>	REFUSED HIV TEST (SKIP TO 201) <input type="checkbox"/>
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107	COUNSELOR SHOULD PERFORM PRE-RESULTS COUNSELING. COUNSELOR SHOULD VERIFY AT THE END OF THE SESSION THAT THE PARENT/CAREGIVER WANTS THE CHILD TO BE TESTED FOR HIV.	AGREES 1 REFUSES 2 _____ (SIGN)
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2. SPECIMEN COLLECTION AND FIELD TEST RESULT RECORD

201	CHECK THE CONSENT RECORD AND DETERMINE WHETHER OR NOT THE PARENT/GUARDIAN HAS AGREED TO THE HIV TEST. IF YOU CANNOT COLLECT A SAMPLE OR CONDUCT A TEST, CIRCLE CODE 6 (OTHER) IN COLUMN (1) IN Q.204 AND NOTE REASON. PREPARE ALL OF THE MATERIALS THAT YOU WILL NEED TO CONDUCT THE TESTS AND TO COLLECT THE DBS SAMPLE. ASSIGN A UNIQUE BAR CODE NUMBER TO THE CHILD. PASTE A LABEL WITH THAT NUMBER ON THE COVER PAGE. PLACE LABELS WITH THE CHILD'S BAR CODE ON FILTER PAPER CARD, AND OTHER TEST DEVICES AS APPROPRIATE. COLLECT SAMPLES AND PERFORM HOME-BASED HIV TESTS. RECORD OUTCOME OF THE HIV TESTS IN COLUMN (2).		(1)		(2)						
202	What is [NAME]'s month and year of birth? PASTE BAR CODE LABEL ON COVER PAGE.	MONTH <table border="1" style="display:inline-table; vertical-align: middle;"><tr><td style="width:20px; height:20px;"></td><td style="width:20px; height:20px;"></td></tr></table> YEAR <table border="1" style="display:inline-table; vertical-align: middle;"><tr><td style="width:20px; height:20px;"></td><td style="width:20px; height:20px;"></td><td style="width:20px; height:20px;"></td><td style="width:20px; height:20px;"></td></tr></table>									
203	CHECK 106 AND INDICATE WHETHER PARENT/GUARDIAN AGREED TO HIV RAPID TEST AGREED TO HIV RAPID TEST <input type="checkbox"/> REFUSED HIV RAPID TEST <input type="checkbox"/> → 208										
204	HIV DETERMINE TEST	TESTED, WANTS RESULT 1 TESTED, DID NOT WANT 2 RESULTS 3 REFUSED 4 (SKIP TO 208) ← OTHER _____ 6 (SPECIFY)			DETERMINE POSITIVE 1 NEGATIVE 2						
205	POSITIVE DETERMINE TEST AND CHILD IS ≥18 MONTHS <input type="checkbox"/> NEGATIVE DETERMINE TEST REGARDLESS OF AGE <input type="checkbox"/> → 208 POSITIVE DETERMINE TEST AND CHILD <18 MONTHS <input type="checkbox"/> → 208										
206	HIV STATPAK TEST	TESTED 1 OTHER _____ 6 (SPECIFY)			STATPAK POSITIVE 1 (SKIP TO 208) ← NEGATIVE 2						
207	HIV UNIGOLD TEST	TESTED 1 OTHER _____ 6 (SPECIFY)			UNIGOLD POSITIVE 1 NEGATIVE 2						
208	CHECK 104 AND INDICATE WHETHER PARENT/GUARDIAN AGREED TO STORAGE OF BLOOD AGREED TO STORAGE OF BLOOD <input type="checkbox"/> REFUSED STORAGE OF BLOOD <input type="checkbox"/> → 301										
209	DBS ON FILTER PAPER	COLLECTED 1 REFUSED 3 (SKIP TO 301) ← OTHER _____ 6 (SPECIFY)									
210	HIV PCR [ONLY FOR CHILDREN <18 MONTHS WITH POSITIVE DETERMINE TEST] RECORD AGREEMENT AFTER POST-TEST COUNSELING SESSION.	AGREED 1 REFUSED 3 OTHER _____ 6 (SPECIFY)									

3. HIV TEST RESULT NOTIFICATION

301	CHECK 204, 205, 206 AND 207 AND RECORD RESULT OF HIV TEST. POSITIVE DETERMINE HIV TEST (204) AND EITHER STATPAK (206) OR UNIGOLD (207) IS POSITIVE (POSITIVE HIV TEST AND CHILD IS ≥18 MONTHS) <input type="checkbox"/>				POSITIVE DETERMINE TEST CHILD <18 MONTHS <input type="checkbox"/> → 303 NEGATIVE DETERMINE TEST <input type="checkbox"/> → (INFORM RESPONDENT OF THE NEGATIVE RESULT, CONDUCT POST-TEST COUNSELING AND END).
302	FOR CHILDREN ≥18 MONTHS WITH POSITIVE HIV TEST INFORM PARENT/GUARDIAN ABOUT POSITIVE HIV STATUS AND PROVIDE POST-TEST COUNSELING. AS PART OF POST-TEST COUNSELING, PROVIDE A REFERRAL TO THE NEAREST HEALTH FACILITY WHERE HIV CARE AND SUPPORT SERVICES ARE AVAILABLE. END				
303	FOR CHILDREN <18 MONTHS WITH POSITIVE DETERMINE TEST, INFORM PARENT/GUARDIAN ABOUT THE NEED FOR ADDITIONAL (PCR) TEST TO CONFIRM HIV TEST RESULT AND PROVIDE POST-TEST COUNSELING. The test indicates that [NAME] may be having the HIV virus. However, we need to do an additional test to determine whether [NAME] really has the virus or not. We will send the blood for this test to a Central Laboratory at UVRI in Entebbe. We will give you a unique code with which you can get the final HIV result for [NAME] in a health facility nearby [MENTION NAMES]. The clinic staff there will advise you on the test result and need for treatment. The result will be ready in about 6 weeks. The results will remain available in the health facility for a period of 6 months. If the result is not picked in that period, [NAME] will have to have the test again in a health facility providing HIV testing services.				
					AGREES 1 REFUSES 2 _____ (SIGN) (RECORD OUTCOME OF REQUEST FOR CONSENT FOR PCR TEST IN 210).

OBSERVATIONS

COMMENTS ABOUT RESPONDENT:

COMMENTS ON TESTING PROCESS:

ANY OTHER COMMENTS, SUCH AS REACTION TO COARTEM OR OTHER TREATMENT:

SUPERVISOR'S OBSERVATIONS

NAME OF THE SUPERVISOR: _____ DATE: _____