Appendix 1.

Informed Consent form

Research Title: The social context of prevention of mother-to child transmission of HIV in Mbale District Eastern Uganda

Background and Purpose of the study

The study is being conducted by a team of researchers from Makerere University Uganda (Department of paediatrics and child health and Makerere Institute of social research) and the University of Bergen, Norway. The purpose of the study is to contribute towards improving the delivery of services for the prevention of mother to child transmission of HIV (PMTCT) in Uganda. Information for the study will be collected through interviews with 20 pregnant mothers who recently tested for HIV during antenatal visits at Mbale Hospital and health workers involved in the PMTCT programme in Mbale District.

Confidentiality

The information you provide to us will be kept confidential and your names will not be written anywhere in the research report and will not be made known to anyone. The information from your interview will be used only for research purposes and no reference will be made to your name or other personal identities.

Voluntary participation and withdraw/termination

Your participation in this study is voluntary. You are free to withdraw anytime and you will not be required to give a reason for your decision. Your choice to participate or not to participate in this study will not affect the services you receive at this health unit/agency.

Procedure

If you agree to participate in this study, you will be asked some questions about your life in general, HIV testing, disclosure of HIV status and sources of support/help. You are free to ask any question during or at the end of the interview. We expect that the interview will take 40 minutes- 1 hour.

Potential benefits

The results of this study will help the Ministry of Health, the district and other service providers to improve the programme for prevention of mother to child transmission of HIV. Yourself, your relatives and friends may benefit from the improved services in future. Mothers who will be found not to have disclosed or require additional support to cope with the HIV diagnosis, will be counseled and referred to the attending counselor or nurse for continued support.

Potential risks

There are no major risks anticipated. However, some of the questions we shall ask you like those to deal with HIV testing and disclosure of HIV status may cause some discomfort. If this occurs

we shall provide the necessary counselling and guidance or refer you to the attending counsellor/nurse for further support.

Contact Persons

If you have any problem or questions about the study, please feel free to contact any of the following:

1. Principal investigator: Joseph Rujumba, Department of Paediatrics and child health , College of Health Sciences, Makerere University, Kampala

Mobile: 0772-493078, **Email:** jrujumba@yahoo.com

2. Professor James Tumwine Department of Paediatrics and child health, College of Health Sciences, Makerere University, Kampala

Mobile: 0772-494120

For issues related to your rights and ethics contact:

1. The Chairman Research and ethics Committee, College of Health Sciences, Makerere University, Kampala Tel: 0412-530020

Consent and Signature

The study has been explained to me and my questions/concerns about the study have been answered to my satisfaction. I voluntarily agree to participate in this study.

……	……..	…….
Names of respondent	signature/thumb print	Date
……	……..	…….
Names of researcher (Administering consent)	signature	Date
……	……..	…….
Names of Principal investigator	signature	Date

Appendix 2.

1: Interview guide for pregnant women who have gone through routine HIV testing

Target group: Mothers who have been counseled and tested for HIV during the current pregnancy attending follow up ANC visits.

I am …… we are conducting this study to understand women's experiences and concerns about HIV testing and counseling services provided at this health facility. This is to help improve on the way services are provided. I will ask you some questions about your recent experience with HIV counseling and testing and disclosure of test results. This information will be kept confidential and will not affect the services you receive at this health facility. Your name will not be written in our report. Your views are important in helping to improve services for mothers.

a. General information

1. General identification: age, marital status, type of marriage (monogamy/polygamy), highest level of education, main source of income, number of children ever given birth to.
2. How is your health in general?
3. What services have you come for?
4. Whom have you come with?

b. HIV testing and knowledge of routine HIV testing in ANC

5. Tell me about the last time you were here for health services.
   - What services did you come for?
   - What services did you get? (Probe for HIV testing if not mentioned)
6. Were you aware before you came here last time, that this health unit offers HIV counseling and testing services to pregnant women?
   - If yes what were the sources of information on this?
   - What else did you know about HIV, pregnant women and babies before coming to the health unit?
   - Any new things that you learnt about HIV in your last visit?
   - Why did you test for HIV? *(probe: had symptoms, protect baby, confirm suspicion, husband has many sexual partners, perceived self at risk, was asked by health worker as part of services offered to all mothers*)
   - Had you ever tested before?
   - Did you inform anyone that you were going to test for HIV?
     - If yes who and why?
     - If no why?

c. Experience with HIV testing and counseling

7. **Tell me about your experience with HIV testing**
   - How were you handled in the process of counseling and testing? (probe for conduct of health workers)
   - Did you feel you were forced to test for HIV? (explain)

- Would you recommend another person say, your sister or best friend to go through the same process of HIV testing while pregnant? Why/why not)
- What information was provided during ANC/Testing and counseling?
- How useful was the information to you?
- What is the main message that you went home with that day?

8. Results related issues and disclosure

- Did you receive your HIV test results?
- How did you feel after receiving your test results?
- What do these results mean for you?
- What were the immediate actions following testing?
- Have you told anyone about your test results? If so, to whom? Why? Why not?
- ***Probe for disclosure to husband/sexual partner if not mentioned why disclosed or not disclosed?)***
- What have been the outcomes of disclosure to partner? (Probe for positive and negative outcomes)
- How did you disclose to your sexual partner?
- What helped you to disclose? *(Probe- health worker, post test club, faith in God/prayer, religious leader)*
- What help do you require after you disclosed?
- Would you recommend other fellow women who have not yet disclosed to their partners to do so? (Why?)

9. For those who have not yet disclosed to sexual partner

- What plans do you have on disclosing your HIV status to husband/sexual partner?
- What are the reasons that you have not yet disclosed to your partner? (Any fears?)
- What help do you need with regard to disclosure?

10. Overall issues

- What do you think are the benefits of routine HIV testing for women while pregnant?
- Anything you liked about the entire process of HIV testing and counseling?
- What didn't you like about that process?
- What would you say about satisfaction with the process? (satisfied not satisfied) Why?
- What do you suggest / wish should be changed to make HIV counseling and testing for pregnant women better?

11. Other comments/Concerns

- Do you have any other comment or question you would like us to talk about in relation to HIV testing and counseling?

Thank you

Appendix 3. Interview guide for Health Workers involved in HIV counseling and testing of mothers/PMTCT

1. General information

- General identification: Name of health facility, title/position of respondent, length of time involved in PMTCT and training on PMTCT.

- When PMTCT services started being offered at the health facility, days on which HIV counseling and testing services are provided for pregnant mothers and general public.

2. HIV testing and knowledge of routine HIV testing in ANC by mothers

- What would you say generally about knowledge of RCT by mothers before coming to the health facility? High or low awareness? Why
- What is your comment on acceptability of HIV testing by ANC mothers?

3. Tell me about your experience with routine HIV counselling and testing

- How is the process of HIV counselling and testing in ANC? (How is it done at the health facility?)
- What are the main messages emphasized in the process? (*probe for disclosure and partner testing)*
- Of those who test HIV positive and those who test negative, whom do you think get more support and why?

4. What are the main concerns of clients/mothers with routine HIV counselling and testing?

- Do they disclose their status or not? Why?
- To whom do clients disclose their status and why? ***(Probe for disclosure to husband/Sexual partner, is it common?) Why? Why not?***
- In general terms what are the outcomes of disclosure to sexual partners that your clients have shared with you? (*Probe-positive Vs negative outcomes*)
- What help do women require before and after disclosure? *(Probe for HIV positive and HIV negative women)*
- What help is available for HIV positive mothers who experience negative outcomes after disclosure? *(Probe for help at the unit and within the setting).*
- Are there any concerns for HIV positive mothers attending ANC not currently being met? What?
- Any concerns for women who test HIV negative?
- What do you think should be done to improve routine HIV counseling and testing in ANC setting?
- What should be done to support mothers who test positive/ Negative?
- What is your view on the performance of the PMTCT programme? *(Probe: doing well/not well and why?)*
- What should be done to improve the PMTCT programme at your health facility?

5. Other comments/Concerns

- Do you have any other thing you would like us to talk about?

THANK YOU

Appendix 4: Key informant interview guide

Introduction

We would like to learn about the PMTCT programme in your area and the setting in which it operates especially with regard to routine HIV counselling and testing, HIV status disclosure, major constraints affecting the programme and what in your view should be done to strengthen the programme.

A. Background information of respondent

Place of work, title, length of time in current position and roles in relation to the PMTCT programme.

B. Information about PMTCT

1. Can you tell me about the PMTCT programme in this area/at this health facility? When was it initiated? Services offered and the status of key supplies, sources of funding) (Probe: ARVs, HIV test kits, staff, training…)

2. What are the key achievements of the programme? What is your view on the performance of the PMTCT programme?

3. What are the main constraints facing the programme?
- (**Probe:** at family, community and health facility- Staffing, stigma, beliefs…)

4. From your experience of implementing the PMTCT programme, what should be done to strengthen the programme in your area?

5. Do you have any other question or comment you would like us to talk about?

Thank you very much for your time and participation in this study.

Uganda National Council For Science and Technology

(Established by Act of Parliament of the Republic of Uganda)

UNCST

Your Ref:.....

Our Ref:.....SS.2284 *Date:*.....19/10/09.....

Dr. Joseph Rujumba
Department of Paediatrics and Child Health
Makerere University
P.O Box 7072
Kampala

Dear Dr. Rujumba,

RE: RESEARCH PROJECT, "THE SOCIAL CONTEXT OF PREVENTION OF MOTHER-TO-CHILD TRANSMISSION OF HIV IN MBALE DISTRICT, EASTERN UGANDA"

This is to inform you that the Uganda National Council for Science and Technology (UNCST) approved the above research proposal on **October 07, 2009.** The approval will expire on **October 07, 2010.** If it is necessary to continue with the research beyond the expiry date, a request for continuation should be made in writing to the Executive Secretary, UNCST.

Any problems of a serious nature related to the execution of your research project should be brought to the attention of the UNCST, and any changes to the research protocol should not be implemented without UNCST's approval except when necessary to eliminate apparent immediate hazards to the research participant(s).

This letter also serves as proof of UNCST approval and as a reminder for you to submit to UNCST timely progress reports and a final report on completion of the research project.

Yours sincerely,

Leah Nawegulo
for: Executive Secretary
UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY

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FACULTY OF MEDICINE
OFFICE OF THE DEAN

September 25, 2009

Dr. Joseph Rujumba
Department of Paediatrics

Dear Dr. Rujumba,

Re: Approval of Protocol #REC REF 2009- 147
"The social context of Prevention of Mother to Child Transmission (PMTCT) HIV in Mbale District Eastern Uganda"

Thank you for submitting an application for approval of the above – referenced protocol. The committee reviewed it and granted approval for one year, effective September 25, 2009. Approval will expire on September 24, 2010.

Continuing Review
In order to continue work on this study (including data analysis) beyond the expiration date, the Faculty of Medicine Research and Ethics Committee must reapprove the protocol after conducting a substantive, meaningful, continuing review.
This means that you must submit a continuing report form as a request for continuing review. To best avoid a lapse, you should submit the request six (6) to eight (8) weeks before the lapse date. Please use the forms supplied by our office.

Amendments
During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek Faculty of Medicine Research and Ethics Committee approval before implementing it.
Please summarize the proposed change and the rationale for it in a letter to the Faculty of Medicine Research and Ethics Committee. In addition, submit three (3) copies of an updated version of your original protocol application- one showing all proposed changes in bold or 'track changes,' and the other without bold or track changes.

Reporting
Other events which must be reported promptly in writing to the Faculty of Medicine Research and Ethics Committee include:

Suspension or termination of the protocol by you or the grantor

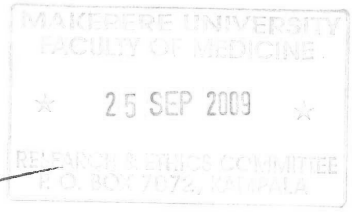
Unexpected problems involving risk to participants or others

Adverse events, including unanticipated or anticipated but severe physical harm to participants.

Do not hesitate to contact us if you have any questions. Thank you for your cooperation and commitment to the protection of human subjects in research.

Final approval is to be granted by Uganda National Council of Science and Technology.

Yours sincerely



Dr. Charles Ningira
Chairperson Faculty of Medicine Research and Ethics Committee

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MINISTRY OF HEALTH
MBALE REGIONAL HOSPITAL
P.O. BOX 921
Mbale – Uganda

THE REPUBLIC OF UGANDA

In any correspondence on this
Subject, please quote: **REIRC 003/2009**

Date 11TH NOVEMBER, 2009

MRHIRC ACCREDITED BY THE UNCST. REGISTRATION NUMBER IRC 019

Att. Joseph Rujumba
Principal Investigator
Makerere University
Department of Paediatrics and Child Health, Makerere University

Dear Rujumba,

RE: APPROVAL OF THE STUDY

The Mbale Regional Referral Hospital Institutional Review Committee (MRHIRC) reviewed the study ***'The social context of prevention of mother-to-child transmission of HIV in Mbale District Eastern Uganda, dated September 2009'*** and resolved under ***minute 6.4*** on ***6th November 2009*** that your study met the minimum standard for execution notably, the scientific content, usefulness, ethics and informed consent, community safety, and public health relevance.

The study may proceed.

You are required to submit study progress reports to the MRHIRC on 3 monthly (quarterly) basis from the start of the study. You are also reminded that the MRHIRC will from time to time visit the study sites and carry out routine study monitoring of this study to assess compliance with the ethical conduct of the study.

This institutional review clearance is for the period November 11th 2009 – October 10th 2010, should need arise to continue the study beyond this period, you are obliged to renew the clearance for another one year.

On behalf of the MRHIRC we wish you well in your study.

Thank you,

Sincerely,

MBALE REGIONAL HOSPITAL INSTITUTION REVIEW COMMITTEE P O BOX 921, MBALE APPROVED Date: 11/11/2009

Dr. Crispus O. Tegu
Chairman MRHIRC

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14th/01/2010

Joseph Rujumba
Principal Investigator
Makerere University
Department of Paediatrics and Child Health Makerere University.

Dear Sir,

RE: APPROVAL OF REQUEST TO COLLECT DATA FROM TASO MBALE REGARDING , THE SOCIAL CONTEXT OF PREVENTION OF MOTHER TO CHILD TRANSMISSION OF HIV IN MBALE DISTRICT

This is to follow-up on the meetings and discussions we have had with your team regarding your request to collect data from TASO Mbale on the social context of mother to child transmission of HIV. We have carefully considered your request and it is acceptable. We hereby grant your request to carry out your research into the planned study. You will need to liaise with the TASO Mbale branch team and the TASO Headquarter Research Unit to coordinate activities and to facilitate effective patient referral to the study clinic. You will also need to work all the logistical issues with the TASO team and ensure smooth transition of care from the TASO Mbale clinic to the study clinic and back into TASO care upon completion of the study.

There will also need to be close collaboration between TASO Mbale and TASO Head quarter research unit to ensure that the study results and progress is shared on either quarterly or biannual basis. Your study will also need to commit to provision of updates and sharing of data with the TASO team.
We are happy to work with you on this research activity and look forward to a fruitful collaboration with your research team.

For any correspondences contact the programme officer in charge of research.

Yours sincerely

Mwesigwa Robert
Chairman TASO IRB
TASO Uganda