Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

Informed Consent Forms

SMART
DISCHARGES
MOM & BABY

MAKERERE UNIVERSITY SCHOOL OF PUBLIC HEALTH HIGHER DEGREES RESEARCH AND ETHICS COMMITTEE (SPH-REC)

INFORMED CONSENT FORM FOR ADULT MOTHERS PARTICIPATING IN THE CLINICAL STUDY

Title of the proposed study:

Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

Investigators
Dr. Joseph Ngonzi
[redacted]
Obstetrician, Mbarara Regional Referral Hospital
Mbarara University of Science and Technology, Uganda

Dr. Matthew Wiens
[redacted]
University of British Columbia, Canada

Background and rational for the study:

You are being invited to take part in this research study because you are 18 years old or greater and have been admitted to the hospital for delivery of a baby. Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this consent form. This consent form explains the research study and your role in the study. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision and there will be no penalty if you decide to quit the study. If you choose not to participate or to withdraw your consent you will not lose the benefit of any medical care that you are entitled to. The study is being conducted in partnership by Mbarara University of Science and Technology (MUST), the Maternal, Newborn and Child Health Institute, the Centre for International Child Health at the British Columbia Children's Hospital (in Canada), WALIMU and the University of British Columbia (in Canada).

It is a sad fact that many women and their new babies get severely ill and some will die when they leave the hospital after the baby is born. Severe illnesses can cause the death of mothers and their children both during and after hospitalization for delivery care. Our focus in this study is what occurs after hospitalization. We want to be able to better predict who is at risk of severe

illness or death after discharge so that we can protect them better. In order to do this, we need to observe both mothers and their newborn children right from hospital admission for delivery until six weeks after discharge from hospital. We will be collecting simple information from all mother and baby pairs and will also monitor the health of both you and your new baby for six weeks. We will use this information to help the doctors make sure that in the future mothers and newborn babies who are at a high risk of problems after discharge are properly cared for to prevent these unwanted things from happening.

A description of sponsors of the research project and the organizational affiliation of the researchers:

This study is conducted by researchers at Mbarara University of Science and Technology (MUST), a Ugandan university focused on the provision of higher education, promotion of research, and advancement of learning, WALIMU, a non-profit organization whose overall goal is to improve the care of severely ill patients in Uganda, and the University of British Columbia (UBC), a Canadian university and global centre for research and teaching. This study is being funded by the Canadian Institutes of Health Research, a federal agency responsible for funding health and medical research in Canada.

Purpose:

We will use the information we collect in the future to make sure that doctors can find those high-risk mothers and babies who need more care and advice upon being discharged from the hospital. This will be done in order to protect them with better care and help prevent them from severe illness or death after leaving the hospital.

Procedures:

This study will be conducted at Mbarara Regional Referral Hospital (MRRH) and Jinja Regional Referral Hospital. We will enroll about 7,000 mother and infant pairs over the course of about 8-12 months. We will look at your medical notes to get information on your delivery and your pregnancy care. We will also ask you questions about these things and about your medical history, family and home situation, for example who you live with and how much education you have completed. We will also require that both you and your infant give a small amount of blood for analysis before you leave the hospital. This will include a test for blood sugar and anemia. This test will be done through a finger prick and requires only a few drops of blood measuring 200 microlitres. The blood sample will not be kept after the tests are completed.

We will also put a small device on your finger to measure oxygen levels in your blood. We will measure heart speed, breathing speed, blood pressure, body temperature, height, weight, and general health symptoms for you and your baby.

This study involves collecting health-related information both in the hospital and following discharge. We will call you by phone at 72 hours, six weeks and six months following discharge to see how you and your baby are doing. At this time point we will ask if either of you has been taken to a healer or a clinic or has visited a hospital. If either of you has died, we will ask when this occurred and whether it occurred in a hospital or at home. If it is more convenient to you or your loved ones, we will arrange to meet at the health facility to ask you these questions.

The estimated duration the research participant will take to in the research project:

The interview and examination before you leave the hospital should take no more than 30 minutes and the interview at six weeks after you have delivered your baby should take no more than 15 minutes.

Who will participate in the study:

We are enrolling women aged 18 years and above who are admitted for delivery to a participating study site.

Risks / discomforts:

Taking part in this study is safe and you and your baby will be assessed and treated in the usual way. You will be required to spend some time answering questions about your health. Also, the small amount of extra blood we will take through a finger prick may cause some discomfort to you and your baby.

Benefits:

This study offers no direct benefits to you or your baby. By participating in the study you will help us learn how to better treat mothers and babies who deliver in the hospital and protect them from getting very sick or dying after leaving the hospital.

Confidentiality:

Our researchers are trained on how to keep data secure and confidential and will ensure that your rights and confidentiality of data are protected and respected. No information that discloses your identity will be stored, released or published without your consent. If you choose to participate, we will assign a unique identifier number to you that keeps your identity confidential. With your permission, we will use an electronic survey to capture your responses and all this information will be stored on password-protected computers and accessed only by the project members. We will securely keep this data that includes your information on computers and destroy it after ten years.

Some groups working with MUST, WALIMU, and UBC may have access to this information including Makerere University School of Public Health Higher Degrees Research Ethics Committee. Others may include ethical review boards, government agencies (such as the Uganda National Council for Science and Technology), and other groups that supervise research projects.

We will not use your name in any reports or presentations about this project. We will remove your name, address, and any other information that could identify you from our data. This de-identified data will be stored on a secure virtual library hosted in Canada. In the future, we may share the de-identified data from this study with other researchers who are also working to improve care. Any information that is shared with the public will be a summary of all of these data and will not include any information that could identify you.

Alternatives:

Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision.

Costs:

You will not incur any costs to participate in the study. Any study costs related to your participation will be incurred by the study.

Compensation for participation in the study:

You will not be paid but you will receive a bar of soap from our research team to thank you for your participation in this study.

Questions about the study:

If you have any questions about this study, you can contact the Principal Investigator, Dr. Joseph Ngonzi at [redacted]

Questions about participants' rights:
Only in the case of inquiries on your rights as a study participant, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC) (Dr. Suzanne Kiwanuka on [redacted]).

Statement of voluntariness:
Your participation in this study is entirely voluntary and you may join on your own free will. You have a right not to answer questions you make you feel uncomfortable. If you choose not to participate or to withdraw your consent you will not lose the benefit of any medical care that either you or your baby are entitled to.

Dissemination of results:
Findings from this study will be made available to research participants and their health care providers through an open access journal publication.

Ethical approval:
This study has been approved by Makerere University College of Health Sciences Institutional Review Board, the Uganda National Council of Science and Technology in Uganda and the University of British Columbia Ethics Committee in Canada.

Please check the box below if you would be willing to be contacted at a later date for future research and provide your contact details:

☐ **Yes, I wish to be contacted for future research**

Phone number: _____

Consent:

STATEMENT OF CONSENT/ASSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name/thumbprint of participant ……

Signature/thumb print of participant ……Date ……..

Name of witness…….

Signature of witness (if applicable)…….....Date……

Name of person obtaining informed consent…….

Signature of Person obtaining informed consent …….....Date……

MAKERERE UNIVERSITY

SCHOOL OF PUBLIC HEALTH HIGHER DEGREES RESEARCH AND ETHICS COMMITTEE (SPH-REC)

INFORMED CONSENT FORM FOR EMANCIPATED MINORS PARTICIPATING IN THE CLINICAL STUDY

Title of the proposed study:

Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

Investigators
Dr. Joseph Ngonzi
[redacted]
Obstetrician, Mbarara Regional Referral Hospital
Mbarara University of Science and Technology, Uganda

Dr. Matthew Wiens
[redacted]
University of British Columbia, Canada

Background and rational for the study:

You are being invited to take part in this research study because you are 17 years old or younger and have been admitted to the hospital for delivery of a baby. Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this consent form. This consent form explains the research study and your role in the study. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision and there will be no penalty if you decide to quit the study. If you choose not to participate or to withdraw your consent you will not lose the benefit of any medical care that you are entitled to. The study is being conducted in partnership by Mbarara University of Science and Technology (MUST), the Maternal, Newborn and Child Health Institute, the Centre for International Child Health at the British Columbia Children's Hospital (in Canada), and the University of British Columbia (in Canada).

It is a sad fact that many women and their new babies get severely ill and some will die when they leave the hospital after the baby is born. Severe illnesses can cause the death of mothers and their children both during and after hospitalization for delivery care. Our focus in this study is what occurs after hospitalization. We want to be able to better predict who is at risk of severe illness or death after discharge so that we can protect them better. In order to do this, we need to observe both mothers and their newborn children right from hospital admission for delivery until six weeks after discharge from hospital. We will be collecting simple information from all mother and baby pairs and will also monitor the health of both you and your new baby for six weeks. We will use this information to help the doctors make sure that in the future mothers and newborn babies who are at a high risk of problems after discharge are properly cared for to prevent these unwanted things from happening.

A description of sponsors of the research project and the organizational affiliation of the researchers:

This study is conducted by researchers at Mbarara University of Science and Technology (MUST), a Ugandan university focused on the provision of higher education, promotion of research, and advancement of learning, WALIMU, a non-profit organization whose overall goal is to improve the care of severely ill patients in Uganda, and the University of British Columbia (UBC), a Canadian university and global centre for research and teaching. This study is being funded by the Canadian Institutes of Health Research, a federal agency responsible for funding health and medical research in Canada.

Purpose:

We will use the information we collect in the future to make sure that doctors can find those high-risk mothers and babies who need more care and advice upon being discharged from the hospital. This will be done in order to protect them with better care and help prevent them from severe illness or death after leaving the hospital.

Procedures:

This study will be conducted at Mbarara Regional Referral Hospital (MRRH) and Jinja Regional Referral Hospital. We will enroll about 7,000 mother and infant pairs over the course of about 8-12 months. We will look at your medical notes to get information on your delivery and your pregnancy care. We will also ask you questions about these things and about your medical history, family and home situation, for example who you live with and how much education you have completed. We will also require that both you and your infant give a small amount of blood for analysis before you leave the hospital. This will include a test for blood sugar and anemia. This test will be done through a finger prick and requires only a few drops of blood measuring 200 microlitres. The blood sample will not be kept after the tests are completed.

We will also put a small device on your finger to measure oxygen levels in your blood. We will measure heart speed, breathing speed, blood pressure, body temperature, height, weight, and general health symptoms for you and your baby.

This study involves collecting health-related information both in the hospital and following discharge. We will call you by phone at 72 hours, six weeks and six months following discharge to see how you and your baby are doing. At this time point we will ask if either of you has been taken to a healer or a clinic or has visited a hospital. If either of you has died, we will ask when this occurred and whether it occurred in a hospital or at home. If it is more convenient to you or your loved ones, we will arrange to meet at the health facility to ask you these questions.

The estimated duration the research participant will take to in the research project:

The interview and examination before you leave the hospital should take no more than 30 minutes and the interview at six weeks after you have delivered your baby should take no more than 15 minutes.

Who will participate in the study:

We are enrolling women or adolescent girls aged between 12 and 17 years who are admitted for delivery to a participating study site.

Risks / discomforts:

Taking part in this study is safe and you and your baby will be assessed and treated in the usual way. You will be required to spend some time answering questions about your health. Also, the small amount of extra blood we will take through a finger prick may cause some discomfort to you and your baby.

Benefits:

This study offers no direct benefits to you or your baby. By participating in the study you will help us learn how to better treat mothers and babies who deliver in the hospital and protect them from getting very sick or dying after leaving the hospital.

Confidentiality:

Our researchers are trained on how to keep data secure and confidential and will ensure that your rights and confidentiality of data are protected and respected. No information that discloses your identity will be stored, released or published without your consent. If you choose to participate,

we will assign a unique identifier number to you that keeps your identity confidential. With your permission, we will use an electronic survey to capture your responses and all this information will be stored on password-protected computers and accessed only by the project members. We will securely keep this data that includes your information on computers and destroy it after ten years.

Some groups working with MUST, WALIMU, and UBC may have access to this information including Makerere University College of Health Science Research Ethics Committee. Others may include ethical review boards, government agencies (such as the Uganda National Council for Science and Technology), and other groups that supervise research projects.

We will not use your name in any reports or presentations about this project. We will remove your name, address, and any other information that could identify you from our data. This de-identified data will be stored on a secure virtual library hosted in Canada. In the future, we may share the de-identified data from this study with other researchers who are also working to improve care. Any information that is shared with the public will be a summary of all of these data and will not include any information that could identify you.

Alternatives:

Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision.

Costs:

You will not incur any costs to participate in the study. Any study costs related to your participation will be incurred by the study.

Compensation for participation in the study:

You will not be paid but you will receive a bar of soap from our research team to thank you for your participation in this study.

Questions about the study:

If you have any questions about this study, you can contact the Principal Investigator, Dr. Joseph Ngonzi at [redacted]

Questions about participants' rights:
Only in the case of inquiries on your rights as a study participant, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC) (Dr. Suzanne Kiwanuka on [redacted]).

Statement of voluntariness:
Your participation in this study is entirely voluntary and you may join on your own free will. You have a right not to answer questions you make you feel uncomfortable. If you choose not to participate or to withdraw your consent you will not lose the benefit of any medical care that either you or your baby are entitled to.

Dissemination of results:
Findings from this study will be made available to research participants and their health care providers through an open access journal publication.

Ethical approval:
This study has been approved by Makerere University College of Health Sciences Institutional Review Board, the Uganda National Council of Science and Technology in Uganda and the University of British Columbia Ethics Committee in Canada.

Please check the box below if you would be willing to be contacted at a later date for future research and provide your contact details:

☐ **Yes, I wish to be contacted for future research**

Phone number: _____

Consent:

STATEMENT OF CONSENT/ASSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name/thumbprint of participant ……

Signature/thumb print of participant ……..Date ……...

Name of witness…….

Signature of witness (if applicable)……..Date……

Name of person obtaining informed consent…….

Signature of Person obtaining informed consent …….....Date……

MAKERERE UNIVERSITY

SCHOOL OF PUBLIC HEALTH HIGHER DEGREES RESEARCH AND ETHICS COMMITTEE (SPH-REC)

INFORMED CONSENT FORM FOR ADULT FAMILY MEMBERS PARTICIPATING IN THE FOCUS GROUP DISCUSSIONS

Title of the proposed study:
Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

Investigators:

Dr. Joseph Ngonzi
[redacted]
Mbarara University of Science and Technology, Uganda

Dr. Matthew Wiens
[redacted]
University of British Columbia, Canada

Background and rationale for the study:
You are being contacted today because you or your family member gave birth at .....Hospital where we have been making post-discharge follow up of postnatal mothers as part of ensuring good outcomes. We are now inviting some of the mothers, fathers, and grandmothers to participate in a group discussion about their child's postnatal discharge process. First, I am going to explain what this study is about and then answer any questions that you may have. Afterwards, you can decide if you want to participate in the study or not.

Although the point of discharge represents the second most critical period in the postnatal period (after triage and hospital care), very little is known about the processes and pathways experienced by the mother, the baby, the healthcare workers, and the health system, as the mother and baby transition from hospital care to home care. A better understanding of this

process is needed for future quality improvement interventions targeting the discharge process for mothers and babies.

A description of sponsors of the research project and the organizational affiliation of the researchers:

This study is conducted by researchers at Mbarara University of Science and Technology (MUST), a Ugandan University focused on the provision of higher education, promotion of research, and advancement of learning, WALIMU, a non-profit organization whose overall goal is to improve the care of severely ill patients in Uganda and the University of British Columbia (UBC), a Canadian University and global centre for research and teaching. This study is being funded by Canadian Institutes of Health Research, a federal agency responsible for funding health and medical research in Canada.

Purpose:

The purpose of this study is to understand the postnatal discharge pathways, from the time of admission until post-discharge follow-up.

The estimated duration the research participant will take to in the research project:

If you choose to do so, your participation in this study is likely to take approximately 90 minutes.

Procedures:

We are inviting caregivers of children who were recently born and discharged from either the Mbarara Regional Referral Hospital (MRRH) or Jinja Regional Referral Hospital to participate in a focus group discussion at the health facility. During this focus group discussion, a study member will ask you and other caregivers about your child's recent discharge experience.

First, we will ask you to sign this paper to show that you have been given information about this study and you have agreed to voluntarily participate. After signing, you will be asked several questions about perception and how you felt about the process. Your responses will be audio recorded.

Who will participate in the study:

We are enrolling caregivers aged 18 years and over of children who were recently born and have been discharged from a participating health facility. We will aim to enrol 96 family members (24 adult mothers, 24 teenage mothers, 24 fathers, 24 grandmothers) to participate in a 90-minute discussion. Each focus group discussion will include 12 participants.

Risks/Discomforts:

If you participate in this study, there is a possibility of a breach of confidentiality especially if one of the participants decides to share what you will have discussed in the focus group discussion. However, all efforts will be made by the study team to reduce the risk of a breach of confidentiality by asking participants not to share what they discussed outside of the group discussion. Remembering yourchild's previous condition may cause negative feelings during the discussion. If this happens, you will be free to stop answering any more questions. You may also be referred to the social worker at the hospital to counsel you.

Benefits:

Although there is no direct or immediate benefit to you or your child, participants will have an opportunity to provide input on the postnatal discharge pathway that will help to inform future quality improvement interventions at this facility which potentially could benefit other children and mothers in the future.

It is expected that society will benefit from the participants' responses by providing evidence that could improve the processes that influence postnatal discharge in Uganda as the program is scaled up at a national level.

Confidentiality:

Our researchers are trained on how to keep data secure and confidential and will ensure that your rights and confidentiality of data are protected and respected. No information that discloses your identity will be stored, released or published without your consent. If you choose to participate, we will assign a unique identifier number to you that keeps your identity confidential. With your permission, we will use audio recorders to capture your responses and all this information will be stored on password-protected computers and accessed only by the project members. We will securely keep this data that includes your information on computers and destroy it after ten years.

Some groups working with MUST, WALIMU and UBC may have access to information including Makerere University College of Health Science Research Ethics Committee. Others may include ethical review boards, government agencies (such as the Uganda National Council for Science and Technology), and other groups that supervise research projects.

We will not use your name in any reports or presentations about this project. We will remove your name, address, and any other information that could identify you from our data. This de-identified data will be stored on a secure virtual library hosted in Canada. In the future, we may share the de-identified data from this study with other researchers who are also working to improve care. Any information that is shared with the public will be a summary of all of these data and will not include any information that could identify you.

Alternatives:

Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this form. If you do

decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision.

Cost:
You will not incur any costs to participate in the study. Any study costs related to your participation will be incurred by the study

Compensation for participation in the study:

You will not be paid but you will receive 30,000 UGX from our research team to thank you for your participation in this study. During the discussion, you will also receive a drink and a snack.

Questions about the study:
If you have any questions about this study, you can contact the Principal Investigator, Dr. Joseph Ngonzi at [redacted]

Questions about participants' rights:
Only in the case of inquiries on your rights as a study participant, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC) (Dr. Suzanne Kiwanuka on [redacted]

Statement of voluntariness:
Your participation in this study is entirely voluntary and you may join on your own free will. You have a right not to answer questions that may make you feel uncomfortable. You also have a right to withdraw from the study at any time without penalty.

Dissemination of results:
Findings from this study will be made available to research participants and their health care providers through an open access journal publication.

Ethical approval:
This study has been approved by Makerere University College of Health Sciences Institutional Review Board, the Uganda National Council of Science and Technology in Uganda and the University of British Columbia Ethics Committee in Canada.

Consent:

STATEMENT OF CONSENT/ASSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name/thumbprint of participant .....

Signature/thumb print of participant .....Date .....

Name of witness.....

Signature of witness (if applicable).....Date.....

Name of person obtaining informed consent.....

Signature of Person obtaining informed consent .....Date.....

MAKERERE UNIVERSITY

SCHOOL OF PUBLIC HEALTH HIGHER DEGREES RESEARCH AND ETHICS COMMITTEE (SPH-REC)

INFORMED CONSENT FORM FOR FAMILY MEMBERS UNDER THE AGE OF 18 YEARS PARTICIPATING IN THE FOCUS GROUP DISCUSSIONS

Title of the proposed study:
Smart Discharges for Mom & Baby: A cohort study to develop prognostic algorithms for post-discharge readmission and mortality among mother-infant dyads

Investigators:

Dr. Joseph Ngonzi
[redacted]
Mbarara University of Science and Technology, Uganda

Dr. Matthew Wiens
[redacted]
University of British Columbia, Canada

Background and rationale for the study:
You are being contacted today because you or your family member gave birth at .....Hospital where we have been making post-discharge follow up of postnatal mothers as part of ensuring good outcomes. We are now inviting some of the mothers, fathers, and grandmothers to participate in a group discussion about their child's postnatal discharge process. First, I am going to explain what this study is about and then answer any questions that you may have. Afterwards, you can decide if you want to participate in the study or not.

Although the point of discharge represents the second most critical period in the postnatal period (after triage and hospital care), very little is known about the processes and pathways experienced by the mother, the baby, the healthcare workers, and the health system, as the mother and baby transition from hospital care to home care. A better understanding of this process is needed for future quality improvement interventions targeting the discharge process for mothers and babies.

A description of sponsors of the research project and the organizational affiliation of the researchers:

This study is conducted by researchers at Mbarara University of Science and Technology (MUST), a Ugandan university focused on the provision of higher education, promotion of research, and advancement of learning, WALIMU, a non-profit organization whose overall goal is to improve the care of severely ill patients in Uganda and the University of British Columbia (UBC), a Canadian University and global centre for research and teaching. This study is being funded by Canadian Institutes of Health Research, a federal agency responsible for funding health and medical research in Canada.

Purpose:

The purpose of this study is to understand the postnatal discharge pathways, from the time of admission until post-discharge follow-up.

The estimated duration the research participant will take to in the research project:

If you choose to do so, your participation in this study is likely to take approximately 90 minutes.

Procedures:

We are inviting caregivers of children who were recently born and discharged from either the Mbarara Regional Referral Hospital (MRRH) or Jinja Regional Referral Hospital to participate in a focus group discussion at the health facility. During this focus group discussion, a study member will ask you and other caregivers about your child's recent discharge experience.

First, we will ask you to sign this paper to show that you have been given information about this study and you have agreed to voluntarily participate. After signing, you will be asked several questions about perception and how you felt about the process. Your responses will be audio recorded.

Who will participate in the study:

We are enrolling caregivers aged between 12 and 17 years of children who were recently born and have been discharged from a participating health facility. We will aim to enrol 96 family members (24 adult mothers, 24 teenage mothers, 24 fathers, 24 grandmothers) to participate in a 90-minute discussion. Each focus group will include 12 participants.

Risks/Discomforts:

If you participate in this study, there is a possibility of a breach of confidentiality especially if one of the participants decides to share what you will have discussed in the focus group discussion. However, all efforts will be made by the study team to reduce the risk of a breach of

confidentiality by asking participants not to share what they discussed outside of the group discussion. Remembering your child's previous condition may cause negative feelings during the discussion. If this happens, you will be free to stop answering any more questions. You may also be referred to the social worker at the hospital to counsel you.

Benefits:

Although there is no direct or immediate benefit to you or your child, participants will have an opportunity to provide input on the postnatal discharge pathway that will help to inform future quality improvement interventions at this facility which potentially could benefit other children and mothers in the future.

It is expected that society will benefit from the participants' responses by providing evidence that could improve the processes that influence postnatal discharge in Uganda as the program is scaled up at a national level.

Confidentiality:

Our researchers are trained on how to keep data secure and confidential and will ensure that your rights and confidentiality of data are protected and respected. No information that discloses your identity will be stored, released or published without your consent. If you choose to participate, we will assign a unique identifier number to you that keeps your identity confidential. With your permission, we will use audio recorders to capture your responses and all this information will be stored on password-protected computers and accessed only by the project members. We will securely keep this data that includes your information on computers and destroy it after ten years.

Some groups working with MUST, WALIMU and UBC may have access to information including Makerere University College of Health Science Research Ethics Committee. Others may include ethical review boards, government agencies (such as the Uganda National Council for Science and Technology), and other groups that supervise research projects.

We will not use your name in any reports or presentations about this project. We will remove your name, address, and any other information that could identify you from our data. This de-identified data will be stored on a secure virtual library hosted in Canada. In the future, we may share the de-identified data from this study with other researchers who are also working to improve care. Any information that is shared with the public will be a summary of all of these data and will not include any information that could identify you.

Alternatives:

Your participation is entirely voluntary, so it is up to you to decide whether or not you wish to take part in this study. If you wish to participate, you will be asked to sign this form. If you do decide to take part in this study, you are still free to withdraw at any time without giving any reasons for your decision.

Cost:
You will not incur any costs to participate in the study. Any study costs related to your participation will be incurred by the study

Compensation for participation in the study:

You will not be paid but you will receive 30,000 UGX from our research team to thank you for your participation in this study. During the discussion, you will also receive a drink and a snack.

Questions about the study:
If you have any questions about this study, you can contact the Principal Investigator, Dr. Joseph Ngonzi at [redacted]

Questions about participants' rights:
Only in the case of inquiries on your rights as a study participant, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC) (Dr. Suzanne Kiwanuka on [redacted]

Statement of voluntariness:
Your participation in this study is entirely voluntary and you may join on your own free will. You have a right not to answer questions that may make you feel uncomfortable. You also have a right to withdraw from the study at any time without penalty.

Dissemination of results:
Findings from this study will be made available to research participants and their health care providers through an open access journal publication.

Ethical approval:
This study has been approved by Makerere University College of Health Sciences Institutional Review Board, the Uganda National Council of Science and Technology in Uganda and the University of British Columbia Ethics Committee in Canada.

Consent:

STATEMENT OF CONSENT/ASSENT

..... has described to me what is going to be done, the risks, the benefits involved and my rights regarding this study. I understand that my decision to participate in this study will not alter my usual medical care. In the use of this information, my identity will be concealed. I am aware that I may withdraw at anytime. I understand that by signing this form, I do not waive any of my legal rights but merely indicate that I have been informed about the research study in which I am voluntarily agreeing to participate. A copy of this form will be provided to me.

Name/thumbprint of participant .....

Signature/thumb print of participant .....Date .....

Name of witness.....

Signature of witness (if applicable).....Date.....

Name of person obtaining informed consent.....

Signature of Person obtaining informed consent .....Date.....

MAKERERE UNIVERSITY

SCHOOL OF PUBLIC HEALTH HIGHER DEGREES RESEARCH AND ETHICS COMMITTEE (SPH-REC)

INFORMED CONSENT FORM FOR HEALTH WORKERS AND ADMINISTRATORS PARTICIPATING IN PROCESS MAPPING

Title of the proposed study:
Targeted follow-up after facility delivery with accurate predictions of neonatal and maternal morbidity or mortality.

Investigators:

Dr. Joseph Ngonzi
[redacted]
Mbarara University of Science and Technology, Uganda

Dr. Matthew Wiens
[redacted]
University of British Columbia, Canada

Background and rationale for the study:
You have been identified as a potential participant for a process mapping exercise analyzing the postnatal discharge processes at your facility. First, I am going to explain what this study is about and then answer any questions you have. Afterwards, you can decide if you want to participate in the study or not.

Although the point of discharge represents the second most critical period in the postnatal period (after triage and hospital care), very little is known about the processes and pathways experienced by the mother, the baby, the healthcare workers, and the health system, as the mother and baby transition from hospital care to home care. An improved understanding of this process is needed for future quality improvement interventions targeting the discharge process for mothers and babies.

A description of sponsors of the research project and the organizational affiliation of the researchers:

This study is conducted by researchers at Mbarara University of Science and Technology (MUST), a Ugandan university focused on the provision of higher education, promotion of research, and advancement of learning, WALIMU, a non-profit organization whose overall goal is to improve the care of severely ill patients in Uganda and the University of British Columbia (UBC), a Canadian university and global centre for research and teaching. This study is being funded by Canadian Institutes of Health Research, a federal agency responsible for funding health and medical research in Canada.

Purpose:
The purpose of this study is to understand the postnatal discharge pathways, from the time of admission until arrival home, with an emphasis on understanding both human factors (health workers and patient/caretaker) as well as system factors which influence this process.

The estimated duration the research participant will take to in the research project:
If you choose to do so, your participation in this study is estimated at 90minutes.

Procedures:
You will participate in a process mapping exercise facilitated by a research staff member. You will be part of a working group who will be engaged in a brainstorming activity to gain an understanding of the postnatal discharge process at your facility as it currently operates and to identify inefficiencies to care and potential solutions. Your responses will be audio recorded.

Who will participate in the study:
Health workers, including physicians, nurses, medical students, and residents, who have been working in the maternity ward at participating health facilities for at least 2 months and hospital administrators who have some oversight on maternity ward operations will be invited to participate. We will aim to enrol 12 health workers and 4 hospital administrators for this activity.

Risks/Discomforts:
Health workers and administrators may feel discomfort sharing the gaps in the discharge process at their facility for fear of repercussions for sharing their perspectives about their place of work. However, we will not identify participants by name and will assign a unique identification number to each participant to protect their identity. No identifying information will be released to your employers.

Although there are no direct or immediate benefit to you, we hope that this study will help to inform future quality improvement interventions at your facility which may lead to improved work environments.

It is expected that society will benefit from your responses by providing evidence that could improve the processes that influence postnatal discharge in Uganda as the program is scaled up at a national level.

Confidentiality:

Our researchers are trained on how to keep data secure and confidential and will ensure that your rights and confidentiality of data are protected and respected. No information that discloses your identity will be released or published to anyone, including your superiors. If you choose to participate, the study will be conducted in private and we will assign a unique personal identifier number to you that keeps your identity confidential. We will use paper and audio recorders to record your responses and all this information will be stored on password-protected computers. We will securely keep this data that includes your information on computers and destroy it after ten years.

No study staff members not directly involved in process mapping exercises will have access to data that is linked to your name. Information that contains your identity will remain only with the Principal Investigators. Some groups working with WALIMU may have access to private information including the Makerere University College of Health Science Research Ethics Committee and the Uganda National council for Science and Technology (UNCST). Others may include ethical review boards, government agencies (such as the Uganda National Council for Science and Technology), and other groups that supervise evaluation studies.

We will not use your name in any reports or presentations about this project. We will remove your name, address, and any other information that could identify you from our data. This de-identified data will be stored on a secure virtual library hosted in Canada. In the future, we may share the de-identified data from this study with other researchers who are also working to improve care. Any information that is shared with the public will be a summary of all of these data and will not include any information that could identify you.

Alternatives:

Your participation in this study is entirely voluntary. If you choose not to participate, or if later you decide to stop participating in this study, there will be no penalties to you or your employment at this facility.

Cost:

There will be no costs to you for your participation in this study.

Compensation for participation in the study:
You will not be paid for participating in this study. The study will give you 25,000 UGX as a token of appreciation for your time and inconveniences. During the discussion, you will also receive a drink and a snack.

Questions about the study:
If you have any questions about this study, you can contact the Principal Investigator, Principal Investigator, Dr. Joseph Ngonzi at [redacted]

Questions about participants' rights:
Only in the case of inquiries on the rights of participants, you can call the Chair of the Higher Degrees, Research and Ethics Committee (HDREC) (Dr: Suzanne Kiwanuka on [redacted]

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