RESEARCH ON POTENTIAL TREATMENTS FOR EBOLA (BUNDIBUGYO) DISEASE – PARTNERS TRIAL

PARENT AND GUARDIAN CONSENT FORM

Hospital Name: (use CAPITALS)		
Patient Name: (use CAPITALS)		
Study ID: (enter after randomisation)		**Confirmed** or **Suspected** (circle one category)

1. Information about the study has been provided to me: I confirm that I have read (or had read to me) and understood the Participant Information Leaflet and I have had the opportunity to consider the information and ask questions. These questions have been answered.

2. Voluntary participation: I understand that my child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, and without his/her medical care or legal rights being affected.

3. Access to study data about my child: I give permission for relevant sections of my child's medical notes and information collected during the study to be looked at, in confidence, by the study team, authorised staff from this hospital, and regulatory authorities to check that the study is being carried out correctly.

4. Data stored on computer: I understand that information about my child's progress in the study will be recorded on a computer database, and that this data will be stored on computers supervised by the World Health Organization. I understand that this information will be kept securely and confidentially.

5. Follow-up after discharge: I understand that, as part of this study, the study team will contact me about 28 days and 60 days after my child starts treatment to collect follow-up information. If my child is pregnant when they join the study, the study team may also contact me, my child, or my child's healthcare provider after discharge to collect information about the baby's health.

6. Future contact: I agree that the study team may contact me and/or my child in the future about other research studies related to Ebola Disease or possible longer-term follow-up beyond this study. I understand that agreeing to be contacted does not mean that my child or I are agreeing to take part in any future study.

□ YES, I agree to be contacted in the future

□ NO, I do not wish to be contacted in the future

7. Samples: I am aware that blood samples (that are collected to diagnose Ebola Disease) may be sent to a central laboratory in this country for measurements.

8. Agreement to take part: I have read the information (or had it read to me), had an opportunity to ask questions and agree for my child to take part in the above study.

Sign here if a parent/guardian can provide written consent.

……	…….	……/……/……
PRINTED name of parent/guardian	Signature	Today's date
……	…….	……/……/……
PRINTED name of person receiving consent	Signature	Today's date

**1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes (if infection control guidance permits)*

RESEARCH ON POTENTIAL TREATMENTS FOR EBOLA (BUNDIBUGYO) DISEASE –PARTNERS TRIAL
PARENT AND GUARDIAN CONSENT FORM (Continued)

Hospital Name: (use CAPITALS)		
Patient Name: (use CAPITALS)		
Study ID: (enter after randomisation)		**Confirmed** or **Suspected** (circle one category)

Or sign here if the parent/guardian is not able to be physically present or is unable to read or sign this form themselves, but has capacity to give consent.

I witnessed accurate reading of the consent form to the potential participant's parent/guardian, who could ask any questions and received satisfactory replies. I confirm that they gave their consent freely.

……	…….	……/……/…….
PRINTED name of witness	Signature	Today's date
……	…….	……/……/…….
PRINTED name of person taking consent	Signature	Today's date

Or sign here if a parent or guardian cannot be found.

I have read the information (or had it read to me) and had an opportunity to ask questions.

I have no other involvement in the PARTNERS trial. I understand that the patient's family will be informed about the trial as soon as they have the capacity to do so and that if they wish, they will be able to withdraw from the study without it affecting the patient's medical care. I believe that if they were able to, the patient would wish to take part in this study.

……	…….	……/……/…….
PRINTED name of Legal Representative	Signature	Today's date

……
Relationship to participant *(or state 'professional' if clinician acting as legal representative)*

……	…….	……/……/…….
PRINTED name of person taking consent	Signature	Today's date
……	…….	……/……/…….
PRINTED name of witness (If occurring by phone)	Signature	Today's date

RESEARCH ON POTENTIAL TREATMENTS FOR EBOLA (BUNDIBUGYO) DISEASE – PARTNERS TRIAL

CHILD ASSENT FORM

Hospital Name: (use CAPITALS)		
Patient Name: (use CAPITALS)		
Study ID: (enter after randomisation)		**Confirmed** or **Suspected** (circle one category)

Your doctors have found that you might have a condition called Ebola Disease (Ebola). Patients with this disease are given treatment for the symptoms (such as diarrhoea and vomiting), but there might be treatments for the infection itself. We are doing this study to find out if the medicines that we are testing help people get better more quickly.

The medicines are listed in the more detailed information sheet given to your parents or guardian. You can have your own copy if you wish. If you and your parents/guardian decide that you want to take part, then:

- The study doctors and nurses will ask you some questions about your medical history and take some blood tests.
- A computer will decide whether you will receive extra treatment(s) as part of the study.
- The medicines are only given in hospital: when you go home the study treatment will be stopped.
- If you and your parents/guardian decide you can and want to take part, then they will sign a consent form and if you want to you can sign below to show you also have understood this information and agree to take part. You have the right to say no to being in the study.

If you have any other questions please ask your parents, your doctors or nurses or the research doctors or nurses. You will be given a copy of this paperwork when you leave the confirmed ward.

……	…….	……/……/…….
PRINTED name of participant	Signature	Today's date
……	…….	……/……/…….
PRINTED name of person receiving assent	Signature	Today's date

Information about the EBOLA (BUNDIBUGYO) PARTNERS Trial for younger children

(to read with parents/guardian)

You have come into hospital because you are sick with Ebola.

At the moment there is no known treatment or vaccine for this type of Ebola.

The doctors and nurses in the hospital will be doing all they can to help you get better.

Your parents (or guardians) have agreed for you to take part in a study to find out whether there are extra medicines that can help children and grown-ups get better faster.

What will happen?

- A computer will decide if you will receive an extra treatment.
- You may have the new medicine as one of your treatments in hospital.
- You won't have to take the medicine after you go home.
- You will have some blood tests while you are in the hospital.
- When enough children and grown-ups have taken part, we will work out whether the new medicines work.
- If you have any other questions, please ask your parents, your doctors or nurses.

Invitation to participate for parents/guardians of children up to 18 years old

Invitation to take part in a research study

We are inviting you to consider your child taking part in a research study for people who may have Ebola Disease. Before you decide, please read the information below or have it read to you. You may ask any questions at any time. Taking part is voluntary. If you decide not to take part, your child's medical care will not be affected.

1) Why is this research being done?

Your child may have Ebola Disease. Although vaccines and treatments exist for some types of Ebola, there is currently no approved treatment specifically for the type causing this outbreak. All patients will receive the best available supportive care. This study aims to find out whether additional treatments can help patients recover.

2) What is the purpose of this study?

This study compares potential treatments for Ebola Disease. The treatments were selected by experts advising the World Health Organization because they may help patients recover, but it is not yet known whether they are effective for this type of Ebola.

The treatments being studied are:

- Remdesivir (made by Gilead)
- MBP134 (made by MappBio)

These treatments have shown promise in laboratory studies, animal studies, and/or other Ebola outbreaks, but they have not been proven to work for Bundibugyo Ebola Disease.

3) Who is doing the study?

The study is sponsored by the World Health Organization (WHO). The Principal Investigator (lead study doctor) for Uganda is Professor Pauline Byakika from Mbarara University of Science and Technology.

4) Who can take part?

People of any age may take part if:

- They have Ebola confirmed by a blood test, and
- They are receiving care in hospital or an Ebola treatment unit

People will not be enrolled if their doctor believes a study treatment would be unsafe for them. People can have a vaccine or post-exposure prophylaxis for Ebola and still be included in the study.

5) What happens next if I agree for my child to be included in this study?

All patients will be given the same medical care whether they are in the study or not.

If you choose for your child to take part in the study:

i. Researchers will collect information about how your child is feeling, your child's medications, and blood test results (including virus tests, malaria tests, liver and kidney tests, and pregnancy tests). Researchers may ask you or your child some extra questions about symptoms that the usual doctor has not asked about.

ii. A computer will randomly assign your child (like rolling a dice) to either usual care alone or to usual care plus one (or sometimes more) of the study treatments. Neither you, the study team, nor your doctors can choose which of these options your child will be allocated.

iii. If your child receives a study treatment:
- MBP134 is given once through a drip into a vein.
- Remdesivir is given once daily through a drip for up to 10 days.

They will be monitored for side effects.

iv. They may have extra blood tests taken. These will be on the first day of the study, and on day 3,5,7,10,13 and 16 (if they are still in the treatment unit on these days). The blood volume will be about the same amount that they already had taken for their virus test. These tests will be used to study the virus and its effect on their body, and to check your child's kidney and liver function. If there is extra blood left over, this will be stored for tests later on. These tests may not help your child directly but will help the researchers understand these illnesses and help patients in the future.

v. After discharge:
- You will be invited for a phone or follow-up visit approximately 28 days after your child starts treatment.
- We may contact you by telephone approximately 60 days after treatment.
- If your child is pregnant when they join the study, we would like to collect information about the pregnancy and the baby's health after delivery. This information is important for understanding how these treatments affect pregnant people and their babies. We will usually collect this information through telephone calls with you, your child, or your child's healthcare provider and, where appropriate, by reviewing relevant medical records.

6) What are the possible benefits of being in the study?

We do not know if your child will benefit from taking study treatments in this study. It is possible that one or more of the study treatments may help your child fight this illness and they have been chosen by experts who think there is evidence to suggest this. Information from this study may help improve treatment for future patients.

7) What are the possible risks of being in the study?

All medicines can cause side effects. While the medications given in the trial may improve your child's symptoms, it is also possible your child may become sicker.

- Remdesivir: Its side effects are not common or serious, and last only a few days. These involve digestive discomfort (such as loss of appetite, heartburn, feeling sick or being sick, loose stool or constipation) or general discomfort (such as trembling, itching, headache, dizziness or unusual feelings in the ear). Some patients' blood tests show changes in how well the kidney or liver is functioning, but these stop when the drug is stopped.
- MBP 134: It has been given to a small number of healthy people in the United States and previous patients with Ebola Disease. Side effects were uncommon but included chest pain, shortness of breath, or feeling of warmth in their face during the infusion, but these symptoms were not severe and went away quickly. Like other antibody medicines, MBP134 can rarely cause allergic reactions, including severe allergic reactions. Staff will monitor your child closely and treat any reaction immediately.

Taking blood samples may cause soreness, bleeding or bruising where the needle went in.

8) Pregnancy and breastfeeding

Children and adolescents who are pregnant or breastfeeding may take part in this study. We do not know all possible effects of these treatments during pregnancy or breastfeeding. However, experts have reviewed the available evidence and concluded that the potential benefits of treatment outweigh the risks associated with Ebola Disease. Decisions about infant feeding will be discussed separately from decisions about study treatment and will follow current WHO guidance.

9) Can I stop my child's participation early?

If you want to stop the study treatment for your child before the course has been completed, then you are free to do so. If you decide that you do not wish any more information to be collected about your child, you are free to say so (although anonymized information up to that point will be analysed by the research team).

10) What will happen with my child's blood samples?

We will take a small amount of blood (like a routine blood test). Blood samples will be used for tests related to your child's illness and response to treatment.

11) Linking to other research studies

We would like your permission to contact you about future research studies or longer-term follow-up related to Ebola Disease. Agreeing to future contact does not mean you are agreeing to participate in future studies. Separate consent would always be requested.

12) Is my information kept private?

All information about your child will be kept private. The only people allowed to look at the information will the trial team, authorised staff at the hospital, and the regulatory authorities who check that the study is being carried out correctly. The data may also be shared with the company that makes the study treatment.

13) Does my child have to take part?

Joining the study is voluntary. Your decision whether to take part will not affect the care your child receives.

14) Are there any financial costs or payments?

All study treatments will be free. Neither you nor your medical staff will be paid for your child's participation in this study. If you incur costs due to your child's participation in the trial (e.g., transport to a trial follow up) you will either be reimbursed, or this will be provided free of charge.

15) Sharing the results

The knowledge that we get from this research will be made widely available to the public. Confidential information will not be shared. We will publish the results so that interested people may learn from our results.

16) What is the role of the World Health Organization?

The study is organised by the World Health Organization, not the makers of any of the study treatments (who may provide the treatment free of charge to the trial). If we find out any new information that might affect your decision to stay in the study, we will give it to you. The World Health Organization has appropriate insurance in place in the unlikely event that you / your child suffers any harm as a direct consequence of your child's participation in this study.

17) If I have any questions or problems, who can I call?

Questions related to the study should be addressed to the Principal Investigator (Senior Doctor) while those related to rights and welfare should be addressed to the local Ethics Committee chairperson in this country.

Principal Investigator: Pauline Byakika, [redacted]

MUST Ethics committee: [redacted]