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

ADULT 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 have read (or had read to me) and understand the Participant Information Leaflet. I have been able to think about the information and ask questions. Any questions have been answered so that I understand the study.

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

3. Access to study data about me: I give permission for parts of my 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 done correctly.

4. Data stored on computer: I understand that information about my 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. Samples: I am aware that blood samples (that are collected to diagnose Ebola Disease) may be stored at a central laboratory in this country for measurement of virus.

6. 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 I start treatment to collect follow-up information. If I am pregnant when I join the study, the study team will also contact me or my healthcare provider after discharge to collect information about my baby's health.

7. Future contact: I agree that the study team may contact me about additional follow-up or future research studies related to Ebola Disease. I understand that agreeing to be contacted does not mean that I am 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

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

A new copy of this form will be given to you after you leave the confirmed ward (we cannot take this copy out of the confirmed ward).

Sign here if the patient can consent for themselves.

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

**1copy 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

ADULT 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 adult has capacity to give consent, but cannot read the text, or sign for themselves.

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and got satisfactory replies. I confirm that they gave their consent freely.

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

Or sign here if the adult lacks capacity to give consent due to the severity of their medical condition (e.g., altered level of consciousness) or for other reasons:

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 Treatment trial. I understand that the patient 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 their 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 receiving consent	Signature	Today's date
……	…….	……/……/……
PRINTED name of witness (if occurring byphone)	Signature	Today's date

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

ADULT PARTICIPANT INFORMATION LEAFLET

Invitation to take part in a research study

We are inviting you to consider 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 medical care will not be affected.

1) Why is this research being done?

You 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 Mapp)

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.

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

You and all patients will be given the same medical care.

If you choose to take part in the study:

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

ii. A computer will randomly assign you (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 you will be allocated.

iii. If you receive 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.

You will be monitored for side effects.

iv. You may have extra blood tests taken. These will be on the day you start the study, and on day 3,5,7,10,13 and 16 following (if you are still in the treatment unit on these days). The blood volume will be about the same amount of blood that you already had taken for your Ebola test. These will also be used to study the virus that is causing your sickness and its effect on your body, and to check if your kidney and liver function (if this has not already been checked).

v. After discharge:
   - You will be invited for a phone or follow-up visit approximately 28 days after starting treatment.
   - We may contact you by telephone approximately 60 days after treatment.
   - If you are pregnant when you join the study, we would like to collect information about your pregnancy and your baby's health after delivery. This information is important for understanding how these treatments affect pregnant women and their babies. We will usually collect this information through telephone calls with you or your 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 you will benefit from taking study treatments. It is possible that one or more of the study treatments may help treat Ebola, and they have been chosen by experts based on 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 symptoms, it is also possible you 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 you closely and treat any reaction immediately.

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

8) Pregnancy and breastfeeding

Pregnant and breastfeeding women 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 evidence and concluded that the 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 participation early?

You can stop being part of the study at any time, even if you have not finished the treatment course. If you decide that you do not wish for more information to be collected about you, you are free to say so (although anonymized information that has been collected up to that point will be used by the research team).

10) What will happen with my blood samples?

We will take a small amount of blood (like a routine blood test). Your blood samples will be tested for the presence of the virus and the response of your body to the infection.

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 private?

All information about you and your health will be kept private. The only people allowed to look at the information will be the trial team, authorised staff at your 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) Do I have to take part?

Joining the study is voluntary. Your decision whether to take part will not affect the care you receive.

14) Are there any financial costs or payments?

All trial treatments will be free. You and your doctors will not be paid for your participation in this study. If you incur costs due to 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 including any information which identifies you will not be shared. We will publish the results so that interested people may learn from our results.

16) 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 study 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 suffer any harm as a direct consequence of your 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: Placide Mbala, [redacted]

Ethics committee: [redacted]