Insert Institution/hospital: **Patient Information and Consent Form**

STUDY TITLE: **Gastroenteritis Rehydration Of children with Severe Acute Malnutrition. (GASTRO-SAM)**

LAY TITLE: **Giving fluids to children admitted with Malnutrition and diarrhoea.**

Institution	**Investigators.**
Insert Institution/hospital	
Imperial college UK	Prof. Kathryn Maitland.

Introduction:

Your child has been examined by the doctor and found to have severe malnutrition plus signs of severe fluid loss (called dehydration) as a result of an illness which causes diarrhoea and vomiting called gastroenteritis. We need to admit your child to a hospital, take some blood tests and treat them to replace these losses. Currently, the country is following the World Health Organization (WHO) recommendation of giving Oral rehydration solution (ORS) and ONLY giving fluids through the veins for those with danger signs. WHO also recommends fluids through the veins if the patient cannot take oral fluids.

Who is carrying out this study?

This research is being carried out by insert institution/hospital which is a governmental or non-governmental organization that carries out medical research to find better ways of preventing and treating illness in the future for everybody's benefit.

What is this study about?

In this research, we aim to find out what is the best way to replace the fluid losses, whether we need to replace the fluid losses orally or through the veins either rapidly or more slowly. We also intend to find out for those with moderate dehydration (following resolution of severe dehydration), whether the currently recommended solution ReSoMal is better than standard ORS which is the solution used in those without severe malnutrition.

We aim to enroll 336 participants in 7 sites in 4 countries in Africa, 2 in Uganda, 2 in in Kenya and Medicine Sans Frontières centres in Nigeria and Niger.

What will it involve for me/my child?

Participants will be selected depending on how they present (Group A with severe dehydration, Group B for those with moderate dehydration to one of three options below:

Group A

i) Rapid fluids by a drip using 100mls/kg of a fluid called Ringers Lactate over 3-6 hours
ii) A slower rehydration by drip (100 mls/kg Ringers Lactate) given over 8 hours
iii) WHO rehydration regime: ORS and with the drip (Fluids through the vein) being used for those with danger signs. (current Standard of care)

Group B

Following resolution of severe dehydration and for those with moderate dehydration, the participants will receive one of the two options below oral fluids

i) Standard WHO ORS given for non-malnourished (experimental) versus
ii) WHO low-sodium rehydration solution called RESOMAL for children with severe acute malnutrition.

Each of the types of treatment a child is given will be decided by chance.

- All children will be closely watched to decide whether to make any changes to treatment. This monitoring will be through regular checks by the nurses. In this study, we will take a blood sample on admission and at 24 hour (one day) after admission. The sample when your child is admitted we will take 2 teaspoons? to help understand how sick your child is and how to treat them. The second sample after one day be 1/2 teaspoon will help check on whether your child is recovering
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- We will take daily measurements of weight and MUAC to check on the child's progress from enrollment until discharge with more focus on 3 days measurements.
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- Where children are unable to take fluids by mouth we will insert a tube through the nose into the stomach. This procedures will be done by well trained staff using clean equipment to minimize risk of infection.

- Where possible we will also ask you to come back to the hospital/clinic for follow up to check on your child's progress on day 7 and day 28. This will include measuring your child's weight and record other observations. If you are unable to attend these visits we will call you by phone to check on how your child is .

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Are there any risks or disadvantages to me/my child of taking part?

- Our priority for every participant is his or her well-being.

- Giving fluids by drips is extensively used in children in insert country and other parts of the world. We will be monitoring your child very closely. If for any reason the doctor thinks that it is not in your child's best interest to be in the trial, then s/he will not be enrolled in the trial but will be given normal standard of care. There are no costs for being included in the trial.

- Taking blood from the arm causes a small amount of pain, swelling, discomfort and minimal chance of infection. If this happens, we will provide treatment. The amount taken is too small to affect your child's health.

- For children who will come back to the clinic for routine health examination so we can find out how your child is doing. We will pay for your transport to hospital and back so you can attend these visits (depending on where you come from and the amount you spend on public transport). We will also compensate you for study related out of pocket expenses while attending this clinic visit at the rate of insert amount for each follow-up visit. During the follow up visits, we will treat any illnesses we find your child has or arrange a referral to appropriate clinic or hospital if need be. These referrals will be done through the usual insert country government procedures using insert specific levels/ e.g district, county, or regional government resources e.g., ambulance and nurses. We expect the follow up visits will take approximately an hour excluding travel time.
- An independent committee will monitor this research continuously to ensure participants safety and rights are respected at all times.

Are there any advantages to me/my child for taking part?

Your child will get close observation and our usual standard treatments during the trial, and by taking part your child may help us improve the care of children who have severe dehydration and Severe Acute Malnutrition in the future.

If for any reason the doctors looking after your child think they would benefit from leaving this trial, they

will recommend this and ensure that your child receives the normal treatment given to children who are not in the trial.

What happens if I refuse to participate?

All participation in research is voluntary. You are free to decide if you want your child to take part. Your child will still receive the recommended standard of care if they do not take part. If you do agree you can change your mind at any time and withdraw your child from the research. This will not affect your child's care now or in the future.

What happens to the samples?

Individual names will be removed from all samples and replaced by codes, to ensure that samples can only be linked to the participants by people closely concerned with the research. All the research tests that will be done on the sample will be done here in insert institution/hospital.

After the research, a small portion of the blood sample will be stored in our laboratories in insert institution/hospital.
In future, new research may be done on these samples. Future research must first be approved by the national independent ethics committee to ensure participants' rights and safety are respected

Who will have access to information about my child in this research?

All our research records are stored securely in locked cabinets and password protected computers. Only a few people who are closely concerned with the research will be able to view information from participants.

In future, information collected or generated during this study may be used to support new research by other researchers. In all cases, we will only share information with other researchers in ways that do not reveal individual participants' identities. For example, we will remove information that could identify people, such as their names and where they live, and replace this information with number codes. Any future research using information from this study must first be approved by a local or national expert committee to make sure that the interests of participants and their communities are protected.

In order to do this study, we will share anonymized individual and summary information we collect or generate with other collaborators involved in the study in ways that do not reveal individual participants' identities.

Who has approved this research?

All research at insert institution/hospital must be approved before it begins by several national, local, and international committees who look carefully at planned work. They must agree that the research is important, relevant to insert country and follows nationally and internationally agreed research guidelines. This includes ensuring that all participants' safety and rights are respected.

What if I have any questions?

You are free to ask me or any of our staff any questions about this research. If you have any further questions about the study, you are free to contact the research team using the contacts below:

Insert contact details

If you want to ask someone independent anything about this research, please contact:

Insert contact details

And

Insert contact details

Insert Institution/hospital consent form for:

Giving fluids to children admitted with Malnutrition and diarrhoea

I, [being a parent/guardian of_____(name of child),] have had the research explained to me. I have understood all that has been read/explained and had my questions answered satisfactorily. And I agree to allow my child to take part in the research.

Please initial the sentences that reflect your choices, and then sign below:

_____I do wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. **Yes** □ **No** □

_____I agree that the study team use the identifier that I have provided (telephone number, country ID number, etc.) to locate me in the future if need be. **Yes** □ **No** □

I agree to my child's samples being stored and used for future research **Yes** □ **No** □

understand that I can change my mind at any stage, and it will not affect my child in any way.

Parent/guardian's signature:_____**Date** _____

Parent/guardian's name:_____**Time** _____

(Please print name)

Where parent/guardian cannot read, ensure a witness* observes consent process and signs below:

I attest that the information concerning this research was accurately explained to and apparently understood by the parent/guardian and that informed consent was freely given by the parent/guardian.

Witness' signature:_____**Date** _____

Witness' name: _____**Time** _____

(Please print name)

Thumbprint of the parent/guideline as named above if they cannot write:

_____

I have followed the ethical procedure to obtain consent from the parent/guardian. S/he apparently understood the nature and the purpose of the study and consents to the participation of the child in the study. S/he has been given opportunity to ask questions which have been answered satisfactorily.

Designee/investigator's signature:_____Date _____

Designee/investigator's name:_____Time _____

(Please print name)

THE PARENT/GUARDIAN SHOULD NOW BE GIVEN A SIGNED COPY TO KEEP