INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: ***LRS/RGO-24/25-47491***

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

"COSMEMS. Core Outcome Set for Research in Brain Infection Sequelae: A Delphi Consensus Project"

Invitation Paragraph

My name is Daniel, and my job is to improve research by finding out which long-term effects ('outcomes') of different diseases are the most important and how the scientists can measure them. In this study we want to find the most important long-term effects of acute brain infection (meningitis, encephalitis, meningoencephalitis) in children and adults and how to measure them.

I would like to invite you to be part of our research study. You should know that your participation is completely voluntary. You do not have to decide immediately, take your time to think it through and, if needed, to discuss anything in this form with your parents or friends or anyone else you feel comfortable talking to. We have discussed this research with your parent(s)/guardian, and they know that we are also asking you for your agreement. If you are going to participate in the research, your parent(s)/guardian also have to agree. But if you do not wish to take part in the research, you do not have to, even if your parents have agreed.

If there is anything you don't understand, feel free to ask us and we will be happy to explain.

What is the purpose of the project?

The purpose of the project is to identify the most important long-term effects ('outcomes') that should be included in all future research of these conditions. The project has been initiated by the World Health Organization in collaboration with The International Severe Acute Respiratory and emerging Infection Consortium (ISARIC).

The aim of this research is to decide what long-term effects (sequelae) of acute brain infection called 'outcomes', are the most important to include in research of meningitis, encephalitis, and meningoencephalitis and how to measure them. An 'outcome' is a term we use to talk about the effects of a disease that really matters to someone's life. These could be measurements of how an individual feels, of biological markers of illness like blood tests, of an individual's ability to go about their lives, or other aspects relevant to health. The list of these important outcomes is called a 'Core Outcome Set'.

The final Core Outcome Set should represent outcomes selected as ‘critical’ by everyone involved in our research. We plan to involve health professionals, researchers, children with lived experience of these infections and their carers. When the final Core Outcome Set has been agreed on by these individuals, it will help shape research relating to sequelae of with these conditions around the world.

Why have I been invited to take part?

We are asking you to take part in our study because you have had an acute brain infection earlier in your life. It is very important for us to know your own opinion about how the disease affected your life and well-being.

What will happen if I take part?

We are inviting you to help decide which long-term effects of meningitis, encephalitis, and meningoencephalitis are the most important to study in research.

If you say yes, you will take part in two rounds of voting, with some meetings in between. Here’s what to expect:

1. **Introduction Meeting (15 minutes)** – We will introduce you to the project, explain the list of effects (called "outcomes") we want to study, and answer any questions you have. If you agree to participate, you and your parents will have to fill in the consent form for the project.
2. **Discussion Meeting (60-90 minutes)** – The whole group will be invited to discuss the results of the adult part of the project and identify any additional outcomes that should be studied in children. You will be given at least three weeks notice to confirm the date for this meeting.
3. **Survey 1 (15 minutes)** – Following the discussion meeting, you will be presented with a list of the outcomes discussed and asked to rate how important each one is. There are no right or wrong answers.
4. **Consensus Meeting (60-90 minutes)** – We will share the overall results from Survey 1 (without showing anyone’s individual answers) and talk about them together.
5. **Survey 2 (5-10 minutes)** – After the consensus meeting, you will receive a summary of the discussion and be asked to rate the same outcomes again. This time, you will also be able to see how the group voted in Survey 1. You may keep your original answers or change them based on what you have learned. There are no right or wrong answers. The results of this round will be final.

Do I have to take part?

You don't have to be in this research if you don't want to be. Its up to you. If you decide not to be in the research, its okay and nothing changes. This is still your clinic, everything stays

the same as before. Even if you say "yes" now, you can change your mind later and its still okay.

If you decide to take part, after reading the general information about the survey, you will be asked to tick a box to confirm your confirm your consent to participate in the study before proceeding to the survey questions.

What are the possible risks of taking part?

It won't hurt as you will just be participating in discussions.This research will not involve any form of treatment or drug trial.

What are the possible benefits of taking part?

You won't get any direct benefits from taking part in this study. However, your input is very important and will help improve future research on acute brain infections like meningitis and encephalitis. By sharing your opinions, you will help make sure that future studies focus on the most important outcomes, which could lead to better treatments for patients in the future.

Data handling and confidentiality

Kings College London is the Sponsor of this research and is responsible for looking after your information.

Confidentiality: Is everybody going to know about this?

No, your answers will stay private.

Confidentiality means that your personal information, like your name and email, will be kept secure and won't be shared with anyone outside the research team. Here's how we protect your privacy:

- We will collect your name and email, but your email will only be used to contact you about the study (like sending survey links and sharing results).
- Your email will be stored separately from your survey answers, so the research team analysing the results won't know which answers belong to you.
- Your IP address (the digital address of your device) will not be stored.
- Only the research team will have access to your data, and we will take all reasonable steps to keep it confidential.

Consensus Meeting Participation

- During the consensus meeting, you may be asked to introduce yourself. If you prefer not to use your real name, that's completely fine—you can use a pseudonym instead.
- With your permission, we may video record the meeting to ensure we accurately capture what was discussed. The recording will be deleted once the meeting documentation is finalised.

How long will we keep your answers?

Your survey answers will be anonymised (this means no one can link them back to you) and stored securely at King's College London for 25 years. The results will be shared in reports, presentations, and academic papers, but they will only show overall trends, not individual answers.

Will my parents know what I say?
No, we will not share your individual answers with your parents or anyone else. However, if you feel uncomfortable about anything during study, you are welcome to talk to them or someone you trust.

What if I change my mind about taking part?

You don't have to take part if you don't want to—it's completely your choice.

If you decide to join but later change your mind, you can stop at any time. If you choose to withdraw before the discussion meeting that takes place between Round 1 and Round 2 of the survey, your answers will not be included in the study analysis (if you request this).

However, if you withdraw after the meeting has taken place, it might not be possible to remove your individual answers, as they may already have been anonymised and combined with those from other participants.

Either way, there will be no consequences, and no one will be upset with you.

How is the project being funded?

This project is being funded by WHO

What will happen to the results of the project?

Once the research is finished, we will send you a summary of what we found. The results will also be published in academic journals, public health reports, and presented at

conferences. This means that doctors, researchers, and other people interested in improving care for brain infections will learn from what we discover.

Your personal answers will always stay private. If we include a list of participants in the final report, you can choose whether you want your name to be acknowledged. This is completely up to you—if you'd rather not be named, that's totally fine, and we will respect your choice.

Who should I contact for further information?

If you have any questions, you can ask us anytime—before, during, or after the study.
You can contact the study team by email at COS@isaric.org or me at daniel.munblit@kcl.ac.uk if you have any questions or concerns.
You can also talk to anyone you trust, like your parents, a teacher, your doctor, or a family friend, if you want to discuss the study with them.

What if I have further questions, or if something goes wrong?

If this project has harmed you in any way, or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

The Chair, BDM REP, rec@kcl.ac.uk

Thank you for reading this information sheet and for considering taking part in this research.