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

I would like to invite you to participate in this research project. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

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 or your family member 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.

We also invite healthcare professionals with experience treating patients with the after-effects of brain infections, or researchers who conduct studies in this area, to take part.

What will happen if I take part?

Before the project begins, we will contact you to explain the project's objectives and answer any questions you may have.

If you agree to take part, you will need to complete a study consent form. After that, you will take part in two rounds of voting, with several meetings in between. Here is what you can expect:

1. Workshop 1 (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.

2. 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.

3. Workshop 2 (60-90 minutes) – We will share the overall results from Survey 1 (without showing anyone's individual answers) and talk about them together.

4. 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.

5. Consensus Meeting – After second survey there might be a need for a final meeting to agree and discuss the results of survey round 2.

Throughout the process, participation takes place online. The information you provide will help ensure the outcomes we agree upon reflect what matters most to those involved in or affected by this topic. We will only record meetings (audio or video) with your permission. All data you share will be treated as confidential and used solely to prepare a summary of the study results.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you make a decision about taking part.

All questions are optional and include the option not to respond. If you do decide to take part, but later change your mind, you may withdraw at any point.

The quality of the study depends on participants completing both Survey 1 and Survey 2. Therefore, please consider if you'll be willing to do both surveys before you decide to participate. This helps us to ensure that all participants are heard and contribute to the results equally.

If you decide to take part, after reviewing the general information about the survey, you will be asked to tick a box to confirm your consent to participate in the study before proceeding to the survey questions. A separate signed consent form is not required.

What are the possible risks of taking part?

There are no anticipated risks associated with participating in this study. However, reflecting on personal experiences with meningitis, encephalitis, or meningoencephalitis may be emotionally challenging for some participants. You are free to skip any questions that make you uncomfortable.

This research will not involve any form of treatment or drug trial.

What are the possible benefits of taking part?

There will be no direct benefit to you as a result of completing this research, but your participation will be valuable and is likely to help to improve the design of future research related to brain infection. This will ultimately benefit patients by ensuring that treatment studies focus on the most important outcomes.

Data handling and confidentiality

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

Data Storage and Security

We are committed to protecting your privacy and handling your data responsibly, in accordance with UK data protection laws, including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

What personal data will we collect?

We will collect:

- Your email address, to send you information about the study and links to the online surveys.
- Basic demographic information, including your age, age at diagnosis, gender, ethnicity, country of residence, and stakeholder group (e.g. patient, clinician, researcher).

When you participate in the online meeting, we may also collect:

- Your name (if you choose to share it during the meeting introduction – you may use a pseudonym if preferred).

A video and audio recording of the meeting, to ensure accurate documentation of the discussion. This will be made only with your verbal consent at the start of the meeting. If any participant does not agree to being recorded, the session will not be recorded, and detailed notes will be taken instead.

AI-generated notes may also be used to support the transcription process.

How will your data be stored?

All data will be stored securely on encrypted servers at King's College London. Access to identifiable data (e.g. email addresses, video recordings) will be restricted to authorised members of the study team. Survey responses will be anonymised and stored in a password-protected file for up to 25 years, in line with King's College London's research data retention policy.

How will we use and share your data?

Your email address will be used only for sending you the survey and informing you about the study results. It will be stored separately from your survey responses.

No person outside the research team will have access to your identifiable information.

Once you submit the survey, your responses will be anonymised. The research team analysing the data will not be able to link your answers to you personally.

Anonymised and summarised survey results will be used in presentations, publications, and reports aimed at the academic, public health, and patient communities.

Survey results may also be shared with other Delphi participants in later rounds, but only in anonymised, aggregated form.

International data sharing

Your identifiable data will not be shared outside the UK

How long will your data be kept?

Email addresses and recordings will be deleted once the study is complete or earlier if you request withdrawal.

Anonymised survey responses and transcripts will be stored securely for 25 years.

What happens to the recordings and transcripts?

Recordings will be used to create accurate transcripts and meeting summaries.

Transcripts will be pseudonymised and reviewed for accuracy.

Once transcripts are finalised, the original recordings will be permanently deleted.

Future use of data

An anonymised version of the final dataset may be archived for ethically approved future research. If this happens, it will only include non-identifiable data.

Further information on how King's processes research data can be found at:
https://www.kcl.ac.uk/research/support/research-ethics/kings-college-london-statement-on-use-of-personal-data-in-research

Please contact the research team if you require further information on data processing or a printed version of the webpage link above.

What if I change my mind about taking part?

You are free withdraw at any point of the project, without having to give a reason. Withdrawing from the project will not affect you in any way.

You may withdraw the data you provided before the discussion meeting held between Round 1 and Round 2 of the survey. After this point, withdrawal of the data will no longer be possible, as the anonymised results will

have been presented to participants during the meeting and may have influenced their opinions and subsequent discussion.

How is the project being funded?

This project is being funded by WHO

What will happen to the results of the project?

The results of the project will be published in an open-access academic journal. We will report the overall findings of the study, including aggregated survey results and summarised demographic information of participants. Reports from the consensus meeting and related discussions will also be included in anonymised form.

You may indicate whether you would like your name to be acknowledged in the study reports. This is entirely your choice. In line with our usual practice, we aim to list all study participants as authors on the publication; however, this will not be linked to any specific responses you have provided. If you prefer not to be named, we will fully respect and support your decision.

If the anonymised dataset is made publicly available, we will include information on how to access it in the final publication. A copy of the published research will also be shared with participants who express interest.

Who should I contact for further information?

If you have any questions, you can ask them now or later. If you wish to ask questions later, or have any concerns, you may contact study team at COS@isaric.org or Dr. Daniel Munblit at daniel.munblit@kcl.ac.uk

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.