# LEGAL REPRESENTATIVE INFORMATION SHEET

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**Title of Study: The Metoclopramide for Avoiding Pneumonia after Stroke (MAPS-2) study**

**IRAS Project ID**: 290474 **ISRCTN:**40512746 **CTA ref : *03057/0075/001-0001***

**Name of Chief Investigator**: Prof Christine Roffe

**Local Researcher(s):**

**Introduction**

As part of routine clinical care, research staff check if patients are eligible for research studies. Your relative, friend, or the patient you have been asked to provide independent physician consent for (referred to as ‘relative’ in the text below) is eligible to take part in the MAPS-2 study. If you are an independent physician acting on behalf of the patient, then you are being approached as a close friend or relative of the patient is not available to provide consent on their behalf. If you are the patient’s professional carer, then you will not be able to provide consent on the patient’s behalf for this study. This study aims to assess whether metoclopramide can prevent pneumonia and death in patients who have had a stroke.

**Invitation**

Your relative is being invited to take part in a research study. They are unable to understand the information given about the study and to make a fully informed decision whether to participate or not. We therefore ask you act on their behalf. Before you decide whether you agree to their participation it is important for you to understand why the research is being done and what it will involve. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

**What is the role of the legal representative?**

The legal representative advises the researcher on what the participant’s wishes and feelings would be if they were able to consent for themselves, and on whether they should take part. This should be a relative, or person close to the participant, who would know what their feelings would be in this situation. Only if such a person was not available, after making every attempt to contact them, would an independent doctor be asked to make this decision on the participant’s behalf. legal representatives will be provided with information about the research project and will be given the opportunity to discuss it and their role as the participant’s legal representative. All legal representatives must be able to understand their role and be willing to undertake it. Once read and understand the information provided, and agreed that this would fulfil the patient’s wishes, legal representatives will be asked to provide consent on behalf the patient.

**What is the purpose of the study?**

Pneumonia is a major cause of death after stroke and delays recovery in survivors. It is likely to occur in stroke patients who have lost the ability to swallow safely and need a feeding tube to maintain nutrition. The most important causes of pneumonia in stroke patients are inhalation, regurgitated or vomited stomach content.

A small study has shown that prophylactic treatment with metoclopramide, a drug which prevents vomiting and regurgitation could reduce pneumonia after stroke. While these results are promising, the study was too small to be certain that the treatment was effective.

The purpose of this study larger study is to test whether metoclopramide can prevent death and pneumonia in patients who have has a stroke.

## Why has my relative been chosen?

Your relative has been invited because they have had a stroke, which has affected their ability to swallow safely and we feel that your relative fits the requirement for this research study. Your relative will be one of over 2,000 patients throughout the UK who are asked to take part in this study.

## Does my relative have to take part?

No, it is up to you. If you decide that you would like your relative to take part, you will be given this information sheet to keep, we will answer any questions you have and then you will be asked to sign a consent form. You are free to withdraw your relative at any time without giving a reason. If you decide later that they no longer wish to take part in the study, please inform us and they will be withdrawn from the study. You do not have to give a reason and it will not affect the standard of care your relative will receive.

Your relative cannot take part in the study if any of the following apply to them:

* They already have pneumonia.
* They are allergic to metoclopramide.
* They already take anti-sickness for another medical condition on a regular basis.
* They have Parkinson’s Disease.
* They have problems with their liver.
* They have problems with their kidneys.
* Your relative is pregnant or breast-feeding.

**What will happen to my relative if they take part?**

The researcher will ask your relative a few questions and examine their swallow, speech, eyesight, head, arms and legs to determine how the stroke has affected them. If your relative is a woman of childbearing age and there may be a possibility that she is pregnant we would do a pregnancy test, but only with your permission.

Your relative will then be assigned at random to the trial treatment (metoclopramide) or control (dummy treatment).

The trial treatment will be given three times a day via a feeding tube or through a vein for 2 weeks, or until discharge from hospital, if this is earlier.

**What are the drugs being tested?**

Metoclopramide is a drug which has been used for many years to prevent sickness and vomiting. It reduces the sensation of sickness in the brain and allows the stomach to empty faster. It is usually prescribed for a few days only, but can be given up to 3 months, if needed.

**Expenses and payments**

Participants will not be paid to participate in the study. There will be no additional travel as result of taking part in this study.

Will there be any additional assessments or clinic visits?

* For the first 2 weeks of the trial research staff will record details of your relative’s condition, their test results and their medication on a clinical log.
* After 6 months a member of the MAPS-2 trial team will contact your relative’s GP to check on their condition and to confirm their contact details.
* A member of the MAPS-2 team will then contact you/your relative to find out how well your relative is recovering from their stroke, and whether they have had any medical problems or hospital admissions. This will take about 15-30 minutes. If we cannot contact your relative, we will approach the person(s) you nominated to find out whether they have changed address and how they are doing.
* We also ask your permission to check missing information about your relative’s health and recovery with the NHS Health and Social Care Information Centre and the Sentinel Stroke National Audit Database or similar.
* We will also contact the Office of National Statistics to find out whether your relative is alive 6 months after the stroke.
* Your relative will not have any additional blood tests, X-rays or scans for this study however imaging data from the standard care will be shared with the study team. Typically this may involve up to two CT scans of the head, as well as 2-3 chest x-rays but they would receive this imaging as part of routine care even if they did not participate in the research, so there is no additional radiation risk as a result of taking part.

## What are the possible benefits of taking part?

The treatment in this study may lower the risk of pneumonia, and potentially reduce the risk of death. However, your relative may get control (dummy) treatment rather than the active drugs. We cannot promise that the study will help your relative. The information we get from your relative’s participation may help improve the treatment of people with stroke.

## What are the possible risks or disadvantages of being in the trial?

Treatment with any drug can be associated with side effects. The side effects associated with metoclopramide are generally mild. We expect no side effects from the placebo (normal saline).

**Metoclopramide side effects:**

Very common: Drowsiness

Common: Depression, uncontrollable movements such as tics, twisting movements, muscle rigidity, (symptoms similar to Parkinson’s disease) a feeling of restlessness, diarrhoea, low blood pressure, and a feeling of weakness.

Uncommon: allergies, slow heart beats, hallucinations, irregular periods, breast milk production and depressed level of consciousness.

Rare: Confusion and seizures.

Not known: These include involuntary muscle spasms after prolonged use (months), high fevers with muscle rigidity and seizures (neuroleptic malignant syndrome), changes to blood pressure and heart rate which can lead to cardiac arrest, allergic reactions and the development of breasts.

We expect the potential benefit (prevention of pneumonia) to outweigh the very low risk of serious side effects.

# What happens when the research study stops?

We would like to follow your relative’s progress over six months (180 days). When all participants have been followed up, the trial results will be analysed and published in a medical journal.

## What will happen if I don’t want my relative to carry on with the study?

Your relative’s participation is voluntary and you are free to withdraw them at any time, without giving any reason, and without their legal rights being affected. If you withdraw them we will no longer collect any information about your relative or from your relative but we will keep the information about your relative that we have already obtained as we are not allowed to tamper with study records and this information may have already been used in some analyses and may still be used in the final study analyses. To safeguard your relative’s rights, we will use the minimum personally-identifiable information possible.

## What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers’ contact details are given at the end of this information sheet. If you remain unhappy and wish to complain formally, you can do this by contacting [please provide the contact details of PALS for the hospital]

In the event that something does go wrong and your relative is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Nottingham but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

## Will my relatives’ clinical details be kept confidential?

We will follow ethical and legal practice and all information about your relative will be handled in confidence.

If your relative joins the study, we will use information collected from your relative and their medical records during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your relative’s information and using it properly. Your relative’s rights to access, change or move their information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your relative’s rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your relative’s information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to your relative as a research participant and we will do our best to meet this duty.

Where possible information about your relative which leaves the site will have their name and address removed and a unique code will be used so that they cannot be recognised from it, however sometimes we need to ensure that we can recognise your relative to link the research data with their medical records so in these instances we will need to know your relative’s name and date of birth. We will also need this information as we will need to follow up their medical records as part of the research, where we will need to ask the Government services that hold medical information about your relative (such as NHS Digital, the Office for National Statistics, among others) to provide this information to us. By signing the consent form you agree to the above.

Your relative’s personal data (address, telephone number) will be kept for 12 months after the end of the study. All research data will be kept securely for 7 years. After this time your relative’s data will be disposed of securely, unless we have permission to use it for future research projects. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your relative’s personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that your relative could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure.

## What if new information becomes available?

If new information becomes available which might influence whether your relative continues to take part in the study, we will contact you.

# Involvement of the General Practitioner/Family doctor (GP)

If you agree, we will send a letter to your relative’s GP informing them of their participation in the trial. We also ask your permission to contact your relative’s GP or check with the NHS Information Centre to check on your relative’s condition six months after the stroke and to confirm their contact details.

# What will happen to any samples I give?

We will not be collecting samples as part of this trial.

# Will any genetic tests be done?

No.

## What will happen to the results of the research study?

The results of the study will be presented at scientific meetings and published in medical and scientific journals. Results will be made accessible on the MAPS-2 website at the address https://stroke.nottingham.ac.uk/maps-2/#. The final report will also be made available to you via the local research team if requested.

## Who is organising and funding the research?

This study is being conducted by Professor Christine Roffe and the MAPS-2 collaborators. The University of Nottingham is sponsoring the study. It is funded by a grant from the National Institute for Health Research, the research body for the NHS.

## Who has reviewed the study?

All research in healthcare is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. The study has been reviewed and given favourable opinion by the Research Ethics Committee Nottingham2 REC. The Health Research Authority and the Medicines and Healthcare Products Regulatory Authority have also reviewed the study and given favourable opinion.

## Who can I contact if I need further information?

We are happy to answer any questions you may have relating to this study. Please ask the doctors or nurses on the ward, or the local principal investigator for further information.

Thank you very much for taking the time to read this leaflet.

**The member of the research team who gave you this information:**

Name:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_

**Local principal Investigator:**

Name:

Address:

Tel: (\_\_\_\_\_) \_\_\_\_\_\_ [insert detail]

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