The Randomised Evaluation of early topical Lidocaine patches In Elderly patients admitted to hospital with rib Fractures (RELIEF): feasibility trial.

NOMINATED CONSULTEE INFORMATION PACK

1. Summary about the "RELIEF" trial

- We are inviting older people (aged 65 years or older) who are found to have broken ribs, and who need admission to a hospital ward to take part in a research study, known as RELIEF.
- **We want to find out if we can conduct a study exploring the use of lidocaine patches (numbing patches placed on the skin) as a means of pain control for broken ribs.** We also want to monitor the health and wellbeing of these patients for 30 days after injury.
- By taking part in this study, patients will be helping to inform whether a larger study to explore whether patients may have improved pain if they have patches put over the broken ribs. This may influence the treatment of patients in the future.

Please note: *for the purpose of this information sheet, any reference to 'we' means the study Sponsor (North Bristol NHS Trust).*

2. Invitation to become a Nominated Consultee

We feel that one of your patients is unable to decide for himself/herself whether they would like to take part in this research project, at a time that this decision needs to be made. An adult who is either temporarily or permanently unable to make this kind of decision for themselves, is described as 'lacking capacity' under the Mental Capacity Act 2005. This law protects the interests of adults (in England and Wales) who are unable to make their own decisions, including whether to take part in research. This law also allows a Consultee to be appointed to give researchers advice as to the likely feelings and wishes of an adult who lacks capacity about taking part in a research project.

Reasonable steps to obtain a Personal Consultee have failed, therefore **we would like to invite you to become a Nominated Consultee regarding your patient who lacks capacity.** You must decide for yourself whether you want to take on the role, or not. You may wish to seek independent advice before deciding.

We will understand if you do not want to take on this responsibility. Your patient's standard of care will not be affected if you tell us you do not want to take on the role of Nominated Consultee. We will approach someone else to be a Consultee.

If there are any parts of this information sheet that you do not understand, you have any questions, or you would like further information, please contact us using the details on the final page.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION. PLEASE KEEP A COPY FOR YOUR RECORDS.

3. What is a Consultee?

A Consultee can either be personal or nominated. **You are being invited to take on the Nominated Consultee role**. A person who lacks capacity can only have one Consultee at a time.

We will always take reasonable steps to identify a **Personal Consultee** regarding the person who lacks capacity, in the first instance.

A PERSONAL CONSULTEE is someone who is unconnected to the research project. They personally know the person who lacks capacity and they are able to advise on the person's wishes or feelings. This could be the person's relative, friend or a court appointee. They must not be someone who is paid to look after the person who lacks capacity.

A NOMINATED CONSULTEE is also someone who is unconnected to the research project. However, this Consultee does not personally know the person who lacks capacity. They can ask other people close to the person who lacks capacity about the person's wishes or feelings. A Nominated Consultee may have a professional knowledge of the person who lacks capacity, such as their doctor or lawyer. They can be someone who is paid to look after the person who lacks capacity.

4. What do I need to do as a Consultee?

- A Consultee needs to consider the broad aims of the proposed research, and what the practicalities, risks and benefits of taking part will be for the person who lacks capacity, at the time the person is invited to join, or afterwards.
- If you decide to take on the role of Consultee, we will ask you to advise us whether you believe your patient would want to take part in the RELIEF trial, if they had capacity to make that decision. **You are not being asked to give consent, only advice.**
- You are not being asked to give your own personal views on your patient's participation in the RELIEF trial, or about their participation in research in general. You should consider only your patient's past and present views and their interests, if you know about these.
- Please let us know of any advance decisions your patient may have made about participating in research. These should take precedence.
- The advice given by you, based on your opinion of the wishes and feelings of your patient, will help their clinical team decide whether your patient should join this project. The final decision about your patient taking part in this research will be made by the team.
- **If your advice as a Consultee is that you believe that your patient would *not* wish to take part in the RELIEF trial, he/she will *not* be included in the trial.**
- If you take on the role of Consultee, and your patient joins the trial as a participant, you could be asked to give your advice on other project-related issues for as long as the person remains a participant in the project.
- If, as a Consultee, you come to believe that your patient would want to stop being a participant in this trial, you should advise the clinical team that your patient should be withdrawn. Your advice will always be carried out and your patient will be withdrawn without delay.
- If you wish to stop being a Consultee, you can do this at any time by informing the clinical team of the person who lacks capacity. Your patient cannot remain in the trial without a Consultee, so they will be removed from the trial once you stop being a Consultee. We will approach someone else to be a Consultee and seek their advice as to whether they believe your patient would want to be involved in the trial, or not.
- If you unsure about taking on the role of Consultee you may seek independent advice.

5. What happens next?

Please read the information below about the RELIEF trial (pages 5-11); this is the **"Summary Participant Information Sheet, and more detailed Information Pack"** that your patient would have been offered if they had capacity.

Once you have considered taking on the role of Consultee and read the information about the study, please tell us (a clinical/member of the research team) that you either:

(A) Do *not* want to be a Consultee. You will not be asked to sign anything if this is your decision. The clinical (research) team will keep a record that you were asked and said no (so that you are not asked again about this role in the future);

OR

(B) Agree to take on the role of Consultee and **give your opinion as to either (i) or (ii)** as follows. You will need to complete a Consultee Declaration Form (this may be over the telephone or face-to-face where feasible). We will give you a completed copy to keep.

As Consultee:

(i) Your advice is that your patient would **want** to take part in this trial.

OR

(ii) Your advice is that your patient would **not** want to take part in this trial. In this instance, your advice as a Consultee will be recorded in your friend's/relative's notes so we will not re-approach you or anyone else about this advice in the future. For us to understand why you have come to this decision, and to help in future

research, you *may* be asked to answer a few questions, if you are willing.

If you have already read the Summary Information Sheet and provided informed advice, but on reading this more detailed information pack you would like to amend (or withdraw) your advice, please speak with a member of the study team.

6. What happens if my patient regains capacity during the study?

If your patient regains capacity during the study, a member of the research team will ask them to give their own retrospective consent when and if they are able. They will be provided with a 'Recovered Capacity Participant Information Sheet' that explains what has happened so far and what we are seeking their consent for. If your patient advises that they no longer want to take part in the study, then they will be withdrawn.

7. Will my involvement and data be kept confidential?

Yes. All personal information which is collected during the course of this research will be kept strictly confidential. Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR).

The information that will be collected about you , as a Consultee, includes personal information such as your name, address and additional contact information, to allow us to keep in touch with you during your patient's participation in the research.

Relevant information collected during the study may be looked at by authorised individuals from the Sponsor organisation or its representatives, University of Bristol, the local NHS Trust of your patient and the regulatory authorities, where it is relevant to your patient taking part in this research. North Bristol NHS Trust and the University of Bristol will act as joint data controllers for this study. This means that we are both responsible for looking after your information and using it properly. Personal information such as your name and contact details will be stored on a secure database with the central research team (University of Bristol). The University of Bristol, on behalf of North Bristol NHS Trust (Sponsor) will keep identifiable information about you for at least 5 years after the study has finished.

8. How will we use information about you?

We will need to use information from you for this research project. This information will include your:

- Initials
- Name
- Gender
- Ethnicity
- Date of birth
- Contact details (for example: postcode, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

9. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

10. Where can you find out more about how your information is used?

- You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients/
- our leaflet "How we use information from patients" available from: relief.blogs.bristol.ac.uk
- at the University of Bristol website: www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- at North Bristol NHS Trust website: www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research

- by contacting North Bristol NHS Trust's Head of Information Governance: helen.williamson@nbt.nhs.uk
- by asking one of the research team: see contact details on the final page
- by sending an email to: relief-trial@bristol.ac.uk, or
- by ringing us on 0117 331 3907.

The information below is the information sheets that your patient would have been offered if they had capacity.

The Randomised Evaluation of early topical Lidocaine patches In Elderly patients admitted to hospital with rib Fractures (RELIEF): feasibility trial.

PARTICIPANT INFORMATION SHEET - SUMMARY

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. You are welcome to ask us any questions you may have. Thank you for taking the time to read this information.

We are inviting older people (aged 65 years or older) who are found to have broken ribs, and who need admission to a hospital ward, to take part in a research study known as "RELIEF".

- We know that pain from broken ribs can be severe. Currently, to control the pain, strong pain killers (like morphine) are often used. These can cause side-effects like constipation and confusion in older people. **A patch containing a numbing medication (anaesthetic) called lidocaine, put on the skin over the broken ribs very soon after injury, may help to control pain and improve breathing with fewer side effects.** However, there is currently no research to support this.
- **We want to find out if it is feasible to conduct a study exploring the use of lidocaine patches as a means of pain control for rib fractures.** We also want to monitor the health and wellbeing of these patients 30 days after injury.
- **If you join the study**, you will be asked to complete a consent form confirming your agreement to take part, and a questionnaire which will ask about your general health, pain severity, and have your mobility assessed.
- You will be allocated to receive either **"USUAL PAIN RELIEF"** (like paracetamol and/or morphine), or **"USUAL PAIN RELIEF PLUS A LIDOCAINE PATCH"**, through a process called randomisation (i.e. you will have an equal chance of receiving either treatment)**.** The patch will be placed over your broken ribs for up to 3 days or until the time of discharge, whichever is sooner. The patches are very safe and some pain doctors already use them. Very rarely, the patch can irritate the skin. You **can still ask for stronger pain killers if the patch does not help,** and you may be seen by a pain specialist who will discuss available pain relief options with you.
- **You will be monitored closely for the next 3 days (or until time of discharge if sooner)**, including measuring pain severity every 4 hours (not if you are asleep), levels of confusion, mobility, and overall health.
- **At 30 days**, you will be asked to complete a final questionnaire about your health and wellbeing. You may also be asked if you would be happy to talk to a researcher by telephone about your experiences of taking part in the study; this is optional. Researchers will also look at your medical records to monitor your health over the 30 days. This will be the end of the study.
- By taking part in this study, **you will help to demonstrate whether a larger study is feasible to explore whether patients who have patches put over their broken ribs may have improved pain.** This may influence the treatment of patients in the future.
- The **diagram over the next page summarises what is involved if you take part**. The doctor or nurse will be happy to answer any questions you may have about the study and can provide an additional information pack for you to read now or later.
- **Taking part is entirely voluntary.** If you take part, you can leave the study at any time without giving a reason. Your treatment will continue as normal.

Use of personal data

In this research study we will use information from you, your medical records, and/or your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.

At the end of the study we will save some of the data in case we need to check it and/or use it for future research.

We will make sure no-one can work out who you are from the reports we write. The additional information pack tells you more about this.

Flow diagram for the RELIEF study

Invitation to Take Part

Read this Participant Information Sheet. Ask any questions. Read the additional Information Pack (now or later).

Eligibility Screening

The doctor or nurse looking after you will check to see if it is suitable for you to take part in the study, or not. **If it is suitable for you to take part and you want to, you will be:**

- asked to complete an informed consent form
- asked to complete study questionnaires and other study data collection
- allocated to one of two study treatment groups by a process called randomisation.

Randomisation

USUAL CARE **OR** **USUAL CARE + LIDOCAINE PATCH**

Treatment

For those in the "Usual Care" group: you will have pain killers (like paracetamol and/or morphine) prescribed in the usual way and your usual treatment will not change.

For those in the "Usual Care + Lidocaine Patch" group: you will have pain killers (like paracetamol and/or morphine) prescribed in the usual way. **In addition**, you will have a patch containing numbing medication called lidocaine placed over your broken ribs. This treatment will be started in the Emergency Department and will last for 3 days, or until the time of discharge if sooner.

Follow Up – First 3 Days (or until discharged if sooner)

A member of the research team will:

- ask you to record how severe your pain is every four hours (not if you are asleep)
- monitor you to see if you become confused
- have your mobility assessed.

Follow Up – 30 Days After Injury

A member of the research team will:

- contact you to complete a questionnaire about your health and wellbeing. ***For most people, their direct involvement in the study ends at this point.***
- look at your medical records to monitor your health and see if you develop a chest infection or side-effects from medications over the 30 days.

We may ask if you would be happy to talk to a researcher by telephone about your experiences of taking part in the study. ***Only a few people are needed for these interviews and they are completely optional.***

PARTICIPANT INFORMATION PACK - DETAILED

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. You are welcome to ask us any questions you may have. Thank you for taking the time to read this information.

Please note: *for the purpose of this information sheet, any reference to 'we' means the study Sponsor (North Bristol NHS Trust).*

Important things that you need to know

- **It is important that you understand** what the study is about, why it is being done, and what will be involved.
- **Within this information sheet:**
  - **PART A:** explains why this study is being done;
  - **PART B:** describes what taking part involves; and
  - **PART C:** provides further general information about the study, including what will happen to your data if you take part.
- **If you have already read the Summary Participant Information Sheet and provided written informed consent, but on reading this more detailed information pack (now that you are more comfortable) you would like to amend (or withdraw) your consent, please speak with a member of the study team.** More information about changing your mind is available in section 9.

PART A: Why is the study being done?

1. What is the purpose of the RELIEF study?

We know that pain from broken ribs can be severe. Currently, to control the pain, strong pain killers (like morphine) are often used. These can cause side-effects like constipation and confusion in older people. A patch containing a numbing medication (anaesthetic) called lidocaine, put on the skin over the broken ribs very soon after injury, may help to control pain and improve breathing with fewer side effects. **We think older people are likely to benefit most from these lidocaine patches but there is currently no research to support this.**

In this small study we hope to find out whether a larger study in the future could work, by seeing how many patients are willing to take part and whether the information we collect is complete. To see whether the patches could help, we will record whether patients get chest infections or any medication side-effects in the 30 days after injury.

2. Is it suitable for me to take part? Do I have to take part?

We are looking for about 100 older people (aged 65 years or older) in the Emergency Department, who are found to have broken ribs, and who need admission to a hospital ward.

You have attended the Emergency Department today because of an injury to your chest. If you are found to have broken ribs and the doctors looking after you feel it would be best for you to stay in hospital, it *may* be suitable for you to take part in the study. It is up to you to decide whether to take part. If you decide not to take part, your usual care will not be affected in any way.

PART B: What does taking part in the study involve?

3. What will happen to me if I agree to take part?

- A doctor or nurse will ask you to complete a consent form confirming your understanding of the study and agreement to take part. You will be given this information pack, and the summary information sheet to keep, as well as a copy of your completed consent form.

- You will be allocated to one of two treatment groups (either "**Usual Pain Relief"** or '**Usual Pain Relief + Lidocaine Patch"**) through a process called randomisation.* Half of the participants in this study will be in one group and half in the other.

USUAL CARE: you will have pain killers (like paracetamol and/or morphine) prescribed in the usual way and your usual treatment will not change.

USUAL CARE + LIDOCAINE PATCH: you will have pain killers (like paracetamol and/or morphine) prescribed in the usual way. In addition, you will have a patch containing numbing medication called lidocaine placed over your broken ribs. This treatment will be started in the Emergency Department and will last for 3 days, or until the time of discharge if sooner.

- After you have been allocated to a treatment group, you are enrolled in the study. One of the research team will collect some information from you about your general health and, if you feel able, assess your mobility.
- A study-specific prescription will then be authorised, and the medication will be administered in the hospital.

***Randomisation** means you will have an equal chance of receiving either treatment. Randomisation is used as it creates groups of participants that are similar except for the medication they are allocated. This will enable a fair comparison of the two groups so that at the end of the study we can reliably assess any differences. If you or someone in the study were allowed to choose the medication, the groups of people being compared may not be sufficiently similar.*

4. What else is involved in the study?

This depends on how long you stay in hospital.

- **For the first 3 days** a member of the research team will ask you to record how severe your pain is every four hours; if you are asleep, we will not wake you up to do this. You will also be monitored to see if you become confused and to have your mobility assessed.
- **Around 30 days after your injury**, a researcher will contact you and ask you to complete a final questionnaire about your health and wellbeing. A researcher(s) will also look at relevant parts of your medical records to see if you develop a chest infection or side-effects from any medications over the 30 days. For most people, involvement in the study ends at this point.
- You may also be asked if you would be happy to talk to a researcher by telephone within the next few weeks, about your experiences of taking part in the study. *Only a few people are needed for these interviews and they are completely optional.*

5. What happens if I have the patch put on my broken ribs?

It is really important to know that you can still ask for stronger pain killers if the patch does not help your pain or if the patch treatment has finished. In some cases, you may be seen by a pain specialist who will discuss your pain relief options with you.

6. What happens if I do not have the patch put on my broken ribs?

Your usual care will not change. You can discuss your pain relief options with your clinical team. In some cases, you may also be seen by a pain specialist (who may still prescribe a patch).

7. What are the possible benefits and disadvantages or risks of taking part in this study?

Benefits. Some patients may have improved pain if they have the patches put over the broken ribs. If this is the case, it may help more patients in future. We are unable to offer any payment or expenses for taking part in the main study.

Disadvantages or risks. Lidocaine patches have been shown to be very safe and some specialist pain doctors already use them. Very rarely, the

patch can irritate the skin. If this happens, please let the doctors looking after you know and the patch will be removed.

8. Will my GP be informed?

Your GP (GP Practice) will be informed by letter that you are taking part in the study. This is done so they know your treatment may have been altered and that we may access your medical records where it is relevant to this study.

9. If I take part, can I change my mind and leave the study?

Yes. You can withdraw from the study at any time without giving a reason, and your medical care and legal rights will not be affected.

If you just want to stop having the lidocaine patch applied, it will still be very valuable if you complete future questionnaires/assessments, or at least allow us to continue to access relevant sections of your medical notes. It is very important that we try and get results from everyone who took part in the study, whether they continued with the medication or not.

If you wish to completely withdraw, we will confidentially keep any information (data) collected about you up until the point of withdrawal, to use in our analysis of the study results.

10. What happens if I lose capacity during the study?

In some cases, it is possible that due to an acute medical condition, such as delirium, you may experience (temporary) mild to moderate cognitive impairment (i.e. you may lose capacity) during the study. If this happens:

- **For patients in England and Wales:** we will seek advice from a Consultee about whether you should remain in the study. A Consultee is either a Personal Consultee (i.e. your partner, or a particular friend or carer who is not seeking renumeration for doing so or acting in a professional capacity), or if not available, a Nominated Consultee (i.e. a doctor unrelated to the study).
- **For patients in Scotland:** we will seek consent from a legal representative (i.e. a Welfare Guardian or Welfare Attorney, or if not in place then your nearest relative) about whether you should remain in the study.

If your Consultee / Legal Representative and/or doctor do not think it is suitable for you to remain in the study, then you will be withdrawn. In this case, we will confidentially keep any information (data) collected about you up until the point of withdrawal, to use in our analysis of the study results.

11. What if something goes wrong?

If you are unhappy about any aspect of this study, the doctor or nurse attending you on the ward will do their best to address your concerns and/or answer your questions.

In the unlikely event that something does go wrong, and you are harmed during the study, there are no special compensation arrangements. If you are harmed and this is due to someone's negligence, then you may have grounds for a legal action for compensation against North Bristol NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

12. Will my taking part in this study be kept confidential?

Yes, all information collected about you during the study will be kept strictly confidential. Your data will be stored and used in compliance with the relevant, current data protection laws; Data Protection Act 2018 and General Data Protection Regulation 2018 (GDPR).

Relevant sections of your medical notes and information collected during the study may be looked at by authorised individuals from the Sponsor organisation or its representatives, University of Bristol, your local NHS Trust and the regulatory authorities, where it is relevant to you

taking part in this research. North Bristol NHS Trust and the University of Bristol will act as joint data controllers for this study. This means that we are both responsible for looking after your information and using it properly. Personal information such as your name, email address and phone number will be stored on a secure database with the central research team (University of Bristol). The University of Bristol, on behalf of North Bristol NHS Trust (Sponsor), will keep identifiable information about you for at least 5 years after the study has finished.

PART C: Further information about the study and what will happen to your data if you take part

13. How will we use information about you?

We will need to use information from you and/or from your medical records for this research project. This information will include your:

- Initials
- NHS number
- Name
- Gender
- Ethnicity
- Date of birth
- Contact details (for example: postcode, telephone number, email address)

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure.

Some of your information will be sent to "Sealed Envelope™". This is the company that provide the randomisation software which helps to enable the process of treatment allocation. Your local researcher will provide "Sealed Envelope™" with relevant information about you to enable the randomisation process. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

14. What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and/or your hospital. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

15. Where can you find out more about how your information is used?

- You can find out more about how we use your information at: www.hra.nhs.uk/information-about-patients/
- our leaflet "How we use information from patients" available from: relief.blogs.bristol.ac.uk
- at the University of Bristol website: www.bristol.ac.uk/secretary/data-protection/policy/research-participant-fair-processing-notice/
- at North Bristol NHS Trust website: www.nbt.nhs.uk/research-innovation/our-research/patient-information-health-care-research
- by contacting North Bristol NHS Trust's Head of Information Governance: helen.williamson@nbt.nhs.uk
- by asking one of the research team: see last page

- by sending an email to: relief-trial@bristol.ac.uk, or by ringing us on 0117 331 3907.

16. What will happen to the results of the research study?

We aim to complete this research in 2023 and once available, results will be published in a medical journal(s) and presented at conferences attended by healthcare professionals and specialists. Results will also be made accessible to participants and the wider public via a newsletter and/or our website. If this small study is successful, we will use the information we collect, to carry out a larger study. **You will not be personally identified in any report/publication.**

17. Can the study information be used to help with other research?

It is important that good quality research data can be shared with others to advance clinical research and benefit patients in the future. After the end of the study, **anonymised** information collected during the study *may* be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

18. Have patients and the public been involved in the study?

Yes. Patient volunteers have helped us design this research and continue to be involved in all aspects.

19. Who is organising the research? Who has reviewed the study?

Doctors and researchers from North Bristol NHS Trust and the University of Bristol are leading this research. The study is funded by a grant awarded by the National Institute for Health Research. Your doctors will not be paid for including you in this study. All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by 'South Central – Oxford C REC' (reference 21/SC/0019), 'Scotland A REC (reference 21/SS/0043)' and the Health Research Authority. An independent Trial Steering Committee will monitor the study to ensure it is conducted according to good research practice.

THANK YOU FOR READING THIS INFORMATION SHEET. PLEASE KEEP A COPY FOR YOUR RECORDS.

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RELIEF STUDY TEAM CONTACT DETAILS

LOCAL (HOSPITAL) RESEARCH TEAM

Local Principal Investigator(s): [insert name]
Local Research Nurse(s): [insert name]
Local Contact Details: [insert as appropriate, e.g. telephone number, address]
Local PALS Contact Details: [insert details]

STUDY OFFICE (University of Bristol)

Trial Manager: Dr Amanda Lewis
Chief Investigator: Dr Edward Carlton
Email: relief-trial@bristol.ac.uk
Telephone: 0117 331 3970
Study website: relief.blogs.bristol.ac.uk

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