

Healthcare research on the intensive care unit (ICU)

Information for relatives,
partners and friends

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Introduction

The Royal Free London NHS Foundation Trust has an international reputation and a long history of pioneering, world-leading clinical research into disease which has had revolutionary outcomes for patients.

We are a member of UCL Partners (UCLP), one of five accredited academic health science centres (AHSC) in the UK. The purpose of UCLP is to harness world-class academic and clinical specialty expertise to accelerate the development of new treatments, diagnostics and prevention strategies to transform the health of the population. We are also part of the National Institute Health Research (NIHR) Clinical Research Network (CRN) North Thames which provides the infrastructure and support for research in our area.

Evidence suggests that patients who receive care in research-active institutions have better health outcomes than patients who are treated in a non-research environment. By joining the research community you are actively helping to drive up the standard of healthcare for yourself and others.

On the intensive care unit (ICU) at the Royal Free Hospital, our mission is to improve clinical outcomes, quality and patient experience by delivering world-class healthcare treatment, clinical research and teaching excellence.

We are a team made up of doctors, nurses and other healthcare professionals. We are committed in ensuring that patients and their relatives, partners and friends have the opportunity to be involved and/or participate in clinical research.

This booklet provides information about healthcare research on the ICU and guidance about what to expect and what to do if you are approached by a member of the research team.

The benefits of healthcare research

Healthcare research can help us to:

- Identify people at risk of getting ill and help to prevent illness.
- Improve our knowledge and understanding of different medical conditions.
- Provide the best advice and treatments and improve clinical outcomes.
- Improve health and wellbeing.
- Develop new treatments.

Why we do research on ICU

Staff in the ICU work as part of a multi-disciplinary team, looking after patients with life-threatening conditions. Patients may need specialist treatment because one or more of their body systems, such as their heart, lung or kidneys, are not working properly.

Our patients are often very sick and can rapidly deteriorate. This means they need a high level of care and very close monitoring, usually with a dedicated nurse.

We need to understand more about the underlying biology of critical illness and to develop treatments that will improve the survival rates and long-term quality of life of our patients. We can do this by carrying out clinical research in our ICU.

For example, the ‘CALORIES’ study was a large trial designed to investigate how best to provide nutrition to critically-ill adults on ICU. Two options exist for this, either providing nutrition via a tube in the stomach or through a drip into a vein. It was not known whether one route was better than the other. The trial lasted three years and involved 33 ICUs in the UK. A total of 2,400 patients were enrolled into the trial, many of them from the Royal Free Hospital.

We learnt from this study that early nutritional support through an intravenous drip is neither more harmful nor more beneficial than nutritional support delivered via the stomach. This means we can now use either route to provide nutrition to patients, in the knowledge that we will not be disadvantaging patients by selecting the route most suitable for them.

About our research

We may conduct studies comparing one treatment to another (known as clinical trials), including:

- testing new drugs, machines or investigations
- testing current treatments in a new or different way.

We may also examine other approaches to disease prevention and cure, including:

- collecting information in the form of questionnaires

- collecting clinical information from patient records and notes
- collecting blood or other specimens from patients.

These methods will be discussed by the research team, and described in detail in research study specific information sheets. The results of these studies help us understand more about critical illness and to decide which treatments are most effective.

Frequently asked questions

Why have I been approached about a study that my relative/partner/friend could be involved in while they are on intensive care?

Your relative/partner/friend may have been selected for consideration to take part in a study based on a number of specific criteria.

However, it may be that we feel they are unable to decide whether to participate in this research. This may be due to the severity of their illness or because they are receiving sedative drugs as part of their treatment.

To help decide if they should join the study, we'd like to ask your opinion whether or not they would want to take part. We will ask you to consider what you know of their wishes and feelings, and to consider their interests.

We understand that it can be an incredibly stressful time for you while your relative/partner/friend is unwell and being treated on our ICU.

What do I need to do?

We will discuss the purpose of the study with you, what it involves and why we feel your relative/partner/friend is eligible. We will give you an information sheet and the opportunity to ask any questions. Please read the information carefully and give your opinion as to whether or not you think your relative/partner/friend would be willing to participate in this research study. You may wish to discuss this with others.

Please be aware that due to the nature of our studies, we will sometimes ask for your opinion as soon as possible (sometime within 24 hours). This is to ensure we can start the treatment promptly.

When your relative/partner/friend has regained the ability to make decisions and to understand the purpose of the study, we will explain it to them and seek their permission to continue participation. Their decision to continue or withdraw from the study will override the advice you have given the research team.

What if I don't feel able to give an opinion?

It is up to you to decide whether or not you wish to provide us with advice about your relative/partner/friend. If you feel unable to do this, the research team may

approach a nominated consultee (a medical professional independent of the study). We appreciate your time and consideration of the information that has been given.

I would like my relative/partner/friend to participate in the study, what happens next?

The research team will meet with you again to answer any further questions. If you are happy to proceed you will be asked to sign a personal consultee declaration form giving approval on behalf of your relative/partner/friend for their participation in the trial.

What may happen if my relative/partner/friend does take part?

Specific information about the study will be provided on an information sheet. The research team will discuss this with the intensive care consultant and any other relevant medical and surgical teams looking after your relative/partner/friend to ensure they are all aware of the study.

The research team will visit your relative/partner/friend frequently while they are in the study, so if you have any questions or concerns, you will be able to speak to them.

You can withdraw your relative/partner/friend from the study at any time without giving a reason. Not taking

part or withdrawing from the study will not affect the care they receive.

Who approves the study?

All our research studies are carefully designed by healthcare professionals, including doctors and nurses.

They have to be reviewed and approved by an independent group called the Research Ethics Committee (REC), as well as the Health Research Authority (HRA) and the Royal Free London research and development department to protect your relative/friend/partner's safety, rights, wellbeing and dignity. They oversee the running of the study and ensure it is being performed safely and according to plan.

What are the possible benefits of taking part?

The research may not directly help your relative/partner/friend but it will provide information to help people in the future. It is important to note each study is different in its design and methods. This will be explained to you.

What are the possible risks of taking part?

When a research study is designed, every effort is made to eliminate any risk to patients. Each study is different so the risks will vary and this will be explained to you by the research team. The research team will

closely monitor your relative/partner/friend throughout the study period.

Is the information you collect from my relative/partner/friend confidential?

We often use information from medical records during research and will act as the data controllers for this study. This means that we are responsible for looking after medical information and using it properly. We will use the minimum amount of personally-identifiable information possible and it will be held securely on paper and electronically.

This information will be available to hospital staff authorised to work on the study and may also be made available to external organisations authorised by the sponsor (the organisation responsible for ensuring that the study is carried out correctly). Further details of how we collect and store data for the purpose of the study will be outlined in the study information sheet you have been given.

Will I be able to see the results?

Yes, once the research has been completed the results will be published and made available. Please contact the research team if you would like this to be sent to you.

Can I be involved in research on the ICU?

Currently we are only looking to recruit patients for research. However, if you would like to take part in research please contact the research team.

To ensure our research is relevant and meaningful you can be involved in the design of our studies. This is known as 'public and patient involvement'. The research team will record your contact details and will get in touch with you to explain how you can help us with future studies we have planned.

More information on how you can take part in research can found at the end of this booklet.

What if I have concerns?

If you have a concern about any aspect of our studies, please speak to the research team who will do their best to answer your questions. You can also speak with the consultant who is overseeing the care of your relative/partner/friend.

Confidentiality

Your relative/partner/friend's rights to access, change or move their information are limited, as we need to manage this in specific ways in order for the research to be reliable and accurate.

If your relative /partner/friend is withdrawn from the study, we will keep the information about them that we have already obtained. To safeguard their rights, we will only use the minimum amount of personally-identifiable information.

You can find out more about how we use this information at:

- **NHS Health Research Authority**
www.hra.nhs.uk/information-about-patients
- **Understanding Patient Data**
<https://understandingpatientdata.org.uk/what-you-need-know>
- **Royal Free London privacy notice**
www.royalfree.nhs.uk/patients-visitors/privacy-statement/

The hospital is registered with the Information Commissioners Office (ICO), which regulates how

information is shared (registration number: Z6460180). There is more information about the ICO below.

If you or your relative/partner/friend wishes to raise a complaint on how their personal data has been handled, you can contact our Caldicott Guardian, data protection officer or senior information risk owner (SIRO) who will investigate the matter. They all have a responsibility to ensure patient data is kept safe and only shared with those who need to see it.

Caldicott Guardian

Dr Kilian Hynes
Royal Free London NHS
Foundation Trust
Barnet Hospital
Wellhouse Lane
Barnet, EN5 3DJ
Email: kilian.hynes@nhs.net

Data protection officer

Mr Tosh (Subir) Mondal
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street
London, NW3 2QG
Email: smondal@nhs.net

Senior information risk owner

Mr Peter Ridley

Royal Free London NHS Foundation Trust

Royal Free Hospital

Pond Street

London, NW3 2QG

Email: peter.ridley@nhs.net

If you are not satisfied with our response or believe we are handling your relative /partner/friend's personal data in a way that is not lawful you can complain to the ICO.

You can also find further details of their rights set out in the General Data Protection Regulation from the ICO:

Website: <https://ico.org.uk/for-the-public/>

Helpline: 0303 123 1113

Contact us

Intensive Care Research Team

Intensive Care Research Office

4th Floor, Intensive Care Unit

Royal Free Hospital, Pond Street, London, NW3 2QG

Tel: 020 7794 0500

Internal ext: 24534, 39673

If you still have a concern, please speak to our patient advice and liaison service (PALS):

PALS team at the Royal Free Hospital

The PALS team are located in the hospital's main reception. The service is open from 10am to 4pm, Monday to Friday.

Alternatively you can:

- **Phone:** 020 7472 6446 or 020 7472 6447
- **Email:** rf.pals@nhs.net

Further information

There are other organisations who provide helpful information about ICU and research including:

ICUsteps

Intensive care patient support charity, run by former intensive care patients and relatives.

- Kemp House
152 City Road, London, EC1V 2NX
- Website: www.icusteps.org

INVOLVE

A national advisory group, part of the National Institute for Health Research (NIHR), which supports public involvement in NHS, public health and social care research.

- Alpha House
University of Southampton Science Park
Chilworth, Southampton, SO16 7NS
- Phone: 0238 059 5628
- Website: www.invo.org.uk
- Email: involve@nihr.ac.uk

National Institute for Health Research (NIHR)

The research arm of the NHS that aims to improve the health and wealth of the nation through research.

- Websites: www.nihr.ac.uk
www.iamresearch.co.uk

Royal Free Interpreting and Translation Services

We are committed to ensuring effective communication and full participation with patients, their relatives and carers. If you need further assistance:

Royal Free Hospital PALS team

Email: rf.pals@nhs.net

Head of patient experience & interpreting

Email: stephen.evans9@nhs.net

Royal Free London research and development office

- Lower Ground Floor Finance office (LG/306)
Royal Free Hospital, Pond Street, London,
NW3 2QG
- Phone: 020 7317 7558 extension 33211
- Email: rf.randd@nhs.net

More information

For more information about research at the Royal Free London, please visit our website:

www.royalfree.nhs.uk/research

Your feedback

If you have any feedback on this leaflet or for a list of references for it, please email:

rf.communications@nhs.net

Alternative formats

This leaflet is also available in large print. If you need this leaflet in another format – for example Braille, a language other than English or audio – please speak to a member of staff.

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