Participant Information Sheet
(Recovered Capacity_Scotland)

ANAEMIA MANAGEMENT WITH RED BLOOD CELL TRANSFUSION TO IMPROVE POST-INTENSIVE CARE DISABILITY ('ABC post-intensive care trial')

During your hospital admission you were unable to give consent for entry into the above research study. You were entered into the research study by a process approved by the research ethics committee. This is permissible under the Adults with Incapacity (Scotland) Act 2000. As part of this process we sought approval from a Legal Representative (welfare attorney, welfare guardian or nearest relative to enter you into the study. You were eligible to take part because you were being treated in an intensive care unit (ICU) and blood tests showed that you were anaemic (had a low level of haemoglobin in your red blood cells).

Before you decide whether or not to continue to take part, it is important for you to understand why the research is being done and what it has and will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to continue to take part.

Thank you for your time

What is the purpose of the study?

The purpose of this study is to find out if we can improve the health of ICU patients by treating their anaemia with blood transfusions from the time they leave ICU. We aim to recruit 305 patients to the trial from 15 Intensive Care Units (ICU) in the UK.

You have spent time in ICU and routine blood tests show that you are anaemic (a low level of haemoglobin, which attaches to and carries oxygen in the blood). Anaemia is the result of either not having enough red blood cells containing haemoglobin to take oxygen around the body, or faulty red blood cells that are unable to carry enough oxygen. Anaemia is very common in patients who have received intensive care treatment and can occur for several reasons. Bleeding can make people anaemic as can the blood sampling necessary for routine tests in the ICU. Severe illnesses also prevent new red blood cells (RBCs) being produced in the bone marrow, probably because inflammation in the body stops the bone marrow working correctly.

The main way we treat anaemia is by giving people a blood transfusion, which can increase the haemoglobin level in the RBCs. When patients are in ICU they can tolerate being anaemic quite well so we try not to give blood transfusions unless haemoglobin levels are very low. However, many patients are severely anaemic when they leave ICU and we know that it can take many months for their anaemia to recover.

After discharge from ICU it is common for patients to feel tired and fatigued. Tiredness and fatigue are typical signs of anaemia. Regaining energy and health after being in ICU can take a long time and impact on many areas of life. Currently we don't know if treating anaemia can improve energy levels and recovery after ICU. We do know treating anaemia can improve health for patients in other situations. Before recommending this for post-ICU patients, we need to be sure that giving blood transfusions really benefits these patients too because blood is in short supply and transfusions can have complications.

We want to find out if treating anaemia with blood transfusions can improve energy levels and recovery after ICU.

Do I have to take part?

No. It is up to you to decide whether or not you want to take part. If you agree you will be given this information sheet to keep and be asked to sign a consent form. If you agree you are still free to change your mind **at any time** without giving a reason.

Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive now or at any stage in the future.

What will happen if I take part?

When you were recruited to the study, we used a computer to randomly decide which of two different approaches to treating anaemia with blood transfusions to use while you remain in hospital. When patients leave ICU the current approach is not to actively treat anaemia (current standard care). After starting on the study one group continued with this standard care. The other group received a more liberal approach to blood transfusion, where anaemia was more actively treated with blood transfusion(s).

The two groups are detailed below:

Standard care group	Intervention group
Patients will receive blood transfusions as per current standard care to treat their anaemia and allow their red blood cell count to be at a lower level (Haemoglobin level 70 to 90 g/L)	Patients will receive more blood transfusions to treat their anaemia and keep their red blood cell count at a higher level (Haemoglobin level 100 to 120 g/L)

You are in one of the above two groups and will remain in that group until you are discharged from hospital.

All patients in the study have their blood tested to check the haemoglobin level at least once a week while they are in hospital and after receiving any blood transfusion. This blood test is part of routine care while patients are in hospital. In addition to these routine blood tests we may, in accordance with the consent given, have taken a 20mL blood sample (about 3 teaspoons full) at the start of the study to identify which patients could benefit most from blood transfusions. These samples will be analysed by our collaborators at the University of Oxford. The details included with the samples did not

include identifiable information. Samples were labelled with a unique study number and only the local site and the trial management team will have access to the identifiable data. The trial management group will require your identifiable data for the purposes of follow up.

All other aspects of care during the hospital stay will be decided by the doctors and nurses looking after you. Your care will not be affected by you being in the study.

We will follow you up three times after joining the study, at 1 month, 3 months and 6 months.

1 month:

If a blood sample was collected at the time of enrolment into the study, at 1 month, with your consent, we will take a further 20ml blood sample (about 3 teaspoons full) to check your haemoglobin level and identify which patients benefit most from blood transfusions. Again these samples will be analysed by our collaborators at the University of Oxford. We will also ask you to complete some questionnaires which will ask about

- your quality of life,
- symptoms of fatigue,
- your ability to carry out daily tasks,
- how you are currently feeling,
- your health service use and any expenses you have had as a result of your health.

The questionnaires will take around 30 minutes to complete. You will be invited into the hospital for this follow up visit and we will cover reasonable travel expenses, however if you are unable to manage, a member of the research team from the hospital will visit you at home.

3 and 6 months:

The follow up at 3 and 6 months will only involve completing questionnaires - the same ones used at the 1 month follow up visit. You will be offered different options for completing and returning these questionnaires, which will be organised by the research team in Edinburgh. You can decide to complete the questionnaires by post, by phone with a member of the research team or alternatively online using a link provided by the

research team. There is no requirement for you to come back to the hospital for these 2 later visits.

We may also use blood samples and data collected to answer other important questions if ethical approval is given for these additional studies.

What are the possible benefits of taking part?

Taking part in this study may help to improve outcomes for patients who are anaemic following a stay in ICU in the future. There are no direct benefits to you from taking part in the trial.

What are the possible disadvantages of taking part?

We are doing this study to find out whether it is better to receive more blood transfusions to treat anaemia after leaving intensive care than is current standard care. Although blood transfusions are safe, they do carry some risks. These can include transfusion reactions which can occur after up to one in a hundred transfusions. Transfusion reactions are usually mild (for example a fever or rash) but very rarely can be severe. Other complications include breathing problems and infections, although these are very rare. We will be closely monitoring what happens to patients in both groups to make sure that we find out about any problems quickly and treat them appropriately.

What if there are any problems?

If you have a concern about any aspect of this study please contact <enter contact name for local research team>, telephone <enter contact number>, who will do his/ her best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against NHS XXXX (site details to be added) but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you and won't be affected by agreeing to take part in the study.

What will happen if I don't want to carry on with the study

You are free to withdraw your consent to participation **at any time** without giving a reason and any study treatment would be stopped. This would not affect the standard of care you receive in any other way or your legal rights. If you choose to withdraw from the trial, we will ask you to complete a withdrawal form. On the form you will have 2 options for your withdrawal:

- You can be withdrawn from any further study activity/ data collection, in this case you are happy for us to use the information collected up to the point of withdrawal, but we cannot collect any new data.
- You can be withdrawn from any further involvement in the study. In this case we would not carry out any further interventions with you (i.e. no additional blood transfusions while you are in hospital unless prescribed as part of your routine care and we would not ask you to complete any questionnaires or take any additional blood samples for the purpose of the research), but we could review your medical notes for blood results and details of your recovery from critical illness. We can also request the long-term follow up data through routinely collected information.

What happens when the study is finished?

You will be active in the study until you have completed your 6 month follow up. Follow up over a longer period is expected to take up to 5 years and will be completed from routinely collected information, which will not require you to be contacted. We plan to publish the results shortly after all the long term follow ups have been completed, through medical publications, websites, and press releases, but individual patients will not be identifiable in any published results.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard patients' privacy at every stage.

We will write to your General Practitioner to let them know that you have agreed to take part in the study.

All information and samples will be stored by the University of Edinburgh and Edinburgh Clinical Trials Unit. They would only be transferred to other researchers after all necessary approvals were in place.

In order to monitor and audit the study we will ask your consent for responsible representatives from the study sponsors to access your medical records and data collected during the study, where it is relevant to taking part in this research.

We may link records about you with nationally held databases to find out about your health status over a longer period without having to contact you directly, but this would only be done after all necessary approvals were in place. In order to identify you on these databases we will collect your Community Health Index (CHI) number. The Community Health Index (CHI) is a population register, which is used in Scotland for health care purposes. The CHI number uniquely identifies a person on the index.

For additional details on what data will be held about you and who will hold and store this information please refer to the Data Protection Information Sheet.

Who is organising and funding the research?

This study has been sponsored by the University of Edinburgh and NHS Lothian. It is funded by the JP Moulton Foundation.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from Scotland A Research Ethics Committee. NHS Management Approval has also been given. Previous ICU patients and relatives also helped us design this trial.

Researcher Contact Details

If you have any further questions about the study please contact <insert name> on <insert phone number> or email on: <insert email address>.

Independent Contact Details

If you would like to discuss this study with someone independent of the study please contact:

Dr Elizabeth Wilson

Consultant in Anaesthesia and Intensive Care Medicine

The Royal Infirmary of Edinburgh

0131 242 1186.

Complaints

If you wish to make a complaint about the study please contact:

<insert contact details> to be adapted depending on research site.

Participant ID:		Centre ID (if applicable)	

CONSENT FORM
Participant (Recovered Capacity_Scotland)

ANAEMIA MANAGEMENT WITH RED BLOOD CELL TRANSFUSION TO IMPROVE POST-INTENSIVE CARE DISABILITY ('ABC post-intensive care trial')

Please Initial Boxes

1.	I confirm that I have read and understand the information sheet (14Jan2020_Ver2) and the Data Protection Information Sheet (DD MMM YYYY and Version Number) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my medical care and/or legal rights being affected.	☐
3.	I give permission for the research team to access my medical records for the purposes of this research study.	☐
4.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and/or NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records.	☐
5.	I give permission for my personal information (including name, address, date of birth, telephone number and consent form) to be passed to the University of Edinburgh and Edinburgh Clinical Trials Unit for administration of the study.	☐
6.	I give permission for my Community Health Index (CHI) number/hospital number to be collected and passed to the University of Edinburgh and the Edinburgh Clinical Trials Unit.	☐
7.	I agree that the information held and maintained by NHS Digital, NHS National Services Scotland, ISD (Information Services Division, Scotland) and other central UK NHS Bodies may be used to provide information about my health status.	☐
8.	I agree to my General Practitioner being informed of my participation in this study.	☐

Participant ID:		Centre ID (if applicable)	

9.	I understand that data collected about me during the study may be converted to anonymised data.			☐
10.	I understand that a blood sample was obtained at the start of the study. (*Select **NA** if no sample collected at enrolment)*	Yes ☐		NA ☐
11.	I agree to provide a blood sample at 30 days (after enrolment) as part of the research study. (*Select **NA** if no sample collected at enrolment)*	Yes ☐	No ☐	NA ☐
12.	I agree to my identifiable data and/ or blood samples being used for future ethically approved studies.	Yes ☐		No ☐
13.	I agree to my anonymised data and/ or blood samples being used in future studies.	Yes ☐		No ☐
14.	I agree to take part in the above study			☐

Name of Person Giving Consent	Date	Signature
Name of person receiving consent	Date	Signature

1x original – into Site File; 1x copy – to Participant; 1x copy – into medical record