A comprehensive guide to how we will use your information.

This information is for people taking part, or thinking of taking part, in a study run by the Clinical Trials Research Unit (CTRU) at University of Leeds.

If you agree to take part in a research study run by the CTRU, we will need to collect and use some information about you. Before you join one of our studies, you will be given a 'patient information sheet', explaining what the research is about, and also what information about you will need to be collected and used, if you agree to take part.

We hope that the patient information sheet answered most of your questions, but if it didn't, this leaflet goes into detail about why and how we use people's information in our

studies. This content has been written with the help of patients and the public to help make sure it is clear and accessible. You do not have to read it before joining one of our studies, but you might want to look at specific sections if you have particular concerns.

You can look through all the detail if you like, or go to areas you are particularly interested in. Some parts may not apply to a specific study you are participating in, so you should look back at your patient information sheet to see exactly what applies. Your study doctor or nurse can provide another copy of that if you no longer have it.

If you still have queries that cannot be answered by this leaflet or talking to your study doctor or nurse, go to section 9 below to see who you can contact. You can see more general information from the NHS about how people's information is used in research at: **https://www.hra.nhs.uk/information-about-patients/.**

Whenever this leaflet says 'we' or 'us', it means the study team based at the Clinical Trials Research Unit in the Leeds Institute of Clinical Trials Research, University of Leeds.

This same content is available online at **ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide.**

The document you have open is the accessible version, designed to be as easy as possible to read. If you would like this information in another format, please speak to your main contact for relevant study (for example, your study doctor or nurse).

This leaflet was last updated on 04/08/2020. This describes how we use your information in our studies in general. If any details are different to what is in a patient information sheet you have received for a study, it is the patient information sheet which is correct.

Contents.

1. What information will be collected, and what will it be used for?

Key message:

If you agree to take part in one of our studies, we will need to collect and use some information about you and your health. This is needed to produce the results of the study, to run the study, and to help make sure you and other people taking part in the study are safe.

If you agree to take part in this study, we will need to collect and use some information about you and your health. Some of this information will be used in the study analysis to help find out the results of the study. Other information is needed in order to run the study, make sure you and other people taking part stay safe, and make sure the study results will be

reliable. The sections below explain the sorts of information we collect and why we need to do this.

We are able to use your information because we are conducting research in the public interest – this means the research results will be used to improve healthcare for patients in future. This also means we are allowed to use some types of information that have special protection in the law because they are particularly sensitive or private. In our studies, these special types of information can include information about your health, your ethnicity or race, your sex life or sexuality, or genetic information (for example, information about your DNA from biological samples you have given). We will never collect more information than we need for the research, and it will never be possible to identify you in any published research results.

1.1. Information we need to collect to confirm it is safe and appropriate for you to join a study.

If you agree to take part in a study, your study doctor or nurse will send us some information about you through our secure website or an automated phone system. This will contain your date of birth, your initials and some information about your health that will confirm that it is safe and appropriate for you

to take part in the study, and that you have given your consent to take part. This information may also contain your NHS or CHI number, usually so that we can check you have not already joined the study. We will keep this information secure, use it to enrol you in the study and give you a unique study identification number that will go with all of your study information. We will then send an automated message by email back to your study doctor or nurse to confirm that you have been enrolled in the study. This message will contain a copy of the information they provided to us, for their records.

Your study doctor or nurse will then post us a copy of your completed consent form, so that we can be sure you have agreed to take part in the study. They will send this separately to other information about you, so that in the unlikely event that it does not reach us, it is not with the other information about you and your health. When the consent form gets to us, we will store it securely, again separately from any other information about you.

1.2. Information from your medical notes for running and analysing the study.

Most of the information we collect about you will be from your medical notes, which contain details of all hospital visits and

tests you have had. If you agree to take part in one of our studies, your study doctor or nurse will take information from your medical notes about you, about the health condition relevant to the study, and about other aspects of your health, and put it onto our study forms. The information will include results of tests and assessments done for the trial, and also information that was already in your medical notes, such as aspects of your past medical history.

These study forms collect only the information that we need to run and analyse each study, to help make sure that you are safe and to make sure that the study is being run correctly. The forms do not show your name, but only your initials, date of birth and the unique study identification number that we give to each study participant when they join a study. We need all three of these identifying pieces of information to make sure we know the information is about you, and not someone else.

In some studies, your study doctor or nurse will post the completed forms to us at the University of Leeds. When the forms arrive at the University, only specific members of the study team see them. The information on the forms is added to our secure study database, which only the study team can

access. The paper forms are securely filed in locked cabinets within the CTRU office.

In other studies, your study doctor or nurse will add the information directly into our secure database. The only people who can access your information are your study doctor or nurse, and people at the CTRU who need access in order to run or analyse the study.

We then do some work to make sure the information is correct. This sometimes means we might need to contact your study doctor or nurse to ask them questions about the information they have given us. Whenever we contact your study doctor or nurse about any aspect of your trial participation, we usually only use your unique study identification number to refer to you. If we ever need to make sure there is no doubt that we are asking about your information (and not someone else's), we will also use your date of birth and initials.

1.3. Questionnaires we will ask you to complete.

Some other information we collect will be on questionnaires that we will ask you to complete. These will ask you about

topics relevant to the research. They will only show your unique study identification number, date of birth and initials.

In some studies, we will ask you to complete questionnaires on paper. You may be asked to complete these at your study visits, but your study doctor and nurse will not see your answers when they do not need to. These will be dealt with just like the paper study forms mentioned above. Your study doctor or nurse will post them to us, then we will enter them into our database and securely file them.

In some other studies, we may send you copies of these paper questionnaires in the post so that you can complete them at a time to suit you. We will need to collect your home address in order to do this. When you have completed them, you should post them back to us, taking care to follow the instructions and use the correct address. When we have received them, we will enter your responses into our database and then securely file them.

In other studies, we may ask you to complete questionnaires in a secure online system. We will send you a message by email or text (depending on your preference) when your next questionnaire is ready to complete. We will need to collect your email address or phone number in order to do this. The

answers you provide will be saved securely in our database, and only members of the study team who need to run or analyse the study will have access to them.

1.4. Information from your electronic health records for study analyses.

As well as the information that your hospital will send to us on the paper study forms or enter into our database, we may also obtain information about you held in NHS databases managed by NHS Digital (**https://digital.nhs.uk/**) or other providers. To do this, we will securely send some of your information (such as your name, your date of birth or your NHS or CHI number) to the information provider, and they will send back the information about you that we need for the study. The patient information sheet you get when you are considering taking part in a trial will make clear how this works, if this sort of thing is happening in your study.

We do this because it is a more efficient way to collect certain information about your health. By using information collected from routine health visits, we can reduce the amount of time you and your hospital need to give to a study. When we do this, we will only use the information mentioned above to identify you. We will follow strict rules when working with

other organisations to maintain confidentiality and protect your information.

NHS Digital and other providers will only provide information to us when they are satisfied that you have agreed to us doing this and that we need your information for research in the public interest. They also need to be satisfied that we will handle all your information securely. When they share your information with us, they can visit us to carry out an audit at any time to check that we are using your information correctly.

You can find out more about the work of NHS Digital at their website: **https://digital.nhs.uk/.**

1.5. Information relating to your biological samples (for example your blood or urine).

The patient information sheet you get before you agree to join one of our studies will explain which samples you might need to give if you agree to take part.

When studies involve collection of biological samples, the samples will be collected by your hospital team. They will then be sent to study labs, usually just with your unique study

identification number, and sometimes also with your initials and date of birth. The labs will analyse the samples, and send the results securely to us so that we can use them in the study analyses. In these studies, the staff at the labs will not be able to identify you from the information they have.

In some studies, the samples may also show your name and NHS or CHI number when they are sent to the labs. These details are needed because the results of the tests will be sent back to your hospital and used in your care, and we need to be absolutely sure that your test results get to you and not to someone else. The labs will also send the test results securely to us so that we can use them in the study analyses.

If you agree to provide samples for future research, these will be sent to a study lab (sometimes called a ‘biobank’) and securely stored with your unique study identification number. In some cases, there may also be other information that may identify you, but you will have been told about this if so. In any case, the staff at the lab will not be able to identify you from the information they have. If other researchers in future request to use the samples for worthwhile research in the public interest, they will be sent the samples but usually

without your unique study identification number (a different unique number, created specifically for this purpose, may be used instead). They are likely to need a bit more information about you for their research, to link their analysis of the samples to other information about your health. If they do need this information, they will contact us to request it. See section 5, below, to find out more about how we share information for future research. These researchers will never be able to see who you are from the information they have, even when they combine the results of analysing your samples with the other information we share with them.

1.6. Information we need to collect to make sure you and others are safe.

During and after your time on a study, your hospital will need to inform us urgently if you experience certain serious types of event, such as if you unexpectedly have to go to hospital overnight for any reason. This sort of reporting is required by laws and other rules about research. Your hospital reports this to us on a study form (usually a paper form that is faxed to us) that will show your unique study identification number, initials and date of birth, but nothing else that could identify you.

We will then need to share this information with other organisations. In studies involving medicinal products (for example drugs or chemotherapy), we will need to share the information with regulatory authorities who oversee drug safety (such as the UK regulator, the Medicines and Healthcare products Regulatory Agency, or MHRA (**https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency**)) and with the company that makes the medicine, so that they have up-to-date information about how safe the medicine is. In all studies, we have to share this information with the Research Ethics Committee that has approved the research. We sometimes also need to share the information with the other healthcare centres taking part in a study. No one in these organisations will be able to identify you from the information we share with them. See section 5, below, for more about how we share this information.

In some of our studies, your study doctor and nurse will not know what treatment you are receiving. This is so that their decisions and behaviour are not influenced by their knowledge of your treatment. This sort of study is called a ‘blinded’ study, and can have more reliable results than studies that are not blinded. The patient information sheet about a study will make clear if your study is a blinded study.

In the unlikely event of a medical emergency happening while you are on a blinded study, your study doctor and nurse might need to urgently find out what treatment you have had. They can do this by providing your unique study identification number either to a specific team at the University of Leeds, or through a service provided by another organisation. Your study doctor or nurse will then instantly receive the details of your treatment. No other information about you will be used in this process.

1.7. Other types of information.

Various other kinds of information may be needed for our studies. The patient information sheet about a study will make clear if these apply, or you can ask your study doctor or nurse if you are not sure.

- In some studies, we might need to ask doctors who work with us to give advice on specific situations, or check the information that your study doctor or nurse have provided to us on the study forms. To do this, we might need to collect **copies or scans of parts of your medical notes**. If this is needed, we will ask your study doctor or nurse to remove all information that could identify you, and just add your unique study identification number before sending it to us (or sometimes also your initials and date

of birth if we need to be absolutely certain that the information is your information).

- In some studies, it is particularly important that we check the study processes are being followed, or check that study measurements are being taken correctly. To do this, we will need to collect **videos, sound recordings or photographs** of parts of your body, or of surgery or other medical procedures you have done. Your study doctor or nurse or someone working with them will usually be the person to make the recording or take the photograph. They will then remove any identifiable details and just add your unique study identification number (or sometimes also your initials and date of birth if we need to be absolutely certain that the information is your information). They will then send them securely to us, usually by a very secure internet transfer system. We will make sure they are securely stored, separately from any information that could directly identify you. We will then share the recordings with authorised doctors who are reviewing them on our behalf (see section 5, below, for more information on this). If this applies to a study you are taking part in, or considering taking part in, the details will be in the study patient information sheet.

- In some studies involving radiotherapy, we need to check that the radiotherapy is given in the same way to different people at different hospitals. To help us check this, some **information about your radiotherapy** and other medical information may be sent to a specialised team at a hospital in the UK. Any information that can identify you (such as your name) will be removed before it is sent to them. The team at the hospital will carry out a review of the radiotherapy information, and send the results of this review securely back to your study doctor. In some cases, we may also receive a copy of the results, but without any information that could identify you. This network of specialists around the UK is called Radiotherapy Trials Quality Assurance (RTTQA) and you can find out more about them on their website: **http://rttrialsqa.org.uk/rttqa/.**

- In some studies, we need to check that study measurements have been done correctly. To do this, we will need to collect images from **medical imaging such as X-rays, MRI scans or CT scans**. We will make sure that any information that could identify you is removed from the scans before they are sent to us. Instead, they will just show your unique study identification number (or sometimes also your initials and date of birth if we need

to be absolutely certain that the information is your information). The scans will be sent to us securely, and we will store them securely, separately from any information that could directly identify you and accessible only by people who need to run and analyse the study. We will then share the recordings with authorised doctors who review them on our behalf (see section 5, below, for more information on this).

- In some studies, we will collect your **postal address, email address, phone number or other contact details** so that we can send you things such as study questionnaires, reminders to complete study questionnaires, thank you cards when you have completed the study, or the results of the study when they are available. We may also need to collect your address in studies where we deliver study treatment (bottles of pills, for example) directly to your home. You can usually choose which details to provide. We will ask you to add them to a contact details form, which your study doctor or nurse will then post to us, separately from other information about you. Once we receive this form, we will store it securely and separate from other information about you. We will enter your details into a secure database separate from any of your medical information.

We will only use your contact details for the purposes specified in the study patient information sheet.

- In some studies, we will be able to reimburse you for extra travel you might need to do, or for any other costs. If this is relevant to you, it will be made clear to you in the study patient information sheet. In order to reimburse you for the costs, we need to collect your **bank details**. We will ask you to provide these on a specific form, and post the form back to us, taking care to use the right address. We will pass the bank details and some identifiable information (including your name) to the University of Leeds Finance department, who will use them to process the payments you are owed. We will store your details securely, separately from any other information about you. The Finance department will keep your details as long as needed, in line with University of Leeds policies on data retention (find at more at this website: **https://dataprotection.leeds.ac.uk/**).

- There may be other types of information about you needed for a certain study. If this is the case, it will be made clear to you in the patient information sheet before you agree to take part.

2. Who is collecting my information?

Key message:

Most study information is collected at the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds.

Each study has one or more organisations that have overall responsibility for how your information is used. You can see which organisation(s) have this role for a study by looking in the patient information sheet you received before you joined.

Information will be collected at the Clinical Trials Research Unit within the Leeds Institute of Clinical Trials Research, University of Leeds. You can find out more about our work at

https://ctru.leeds.ac.uk/. We have over 20 years' experience of running studies, and tightly-controlled processes in place to make sure we use people's information carefully and correctly when they take part in our studies.

In each study, there will be one or two organisations that have overall responsibility for what information is collected, how it is collected, and making sure all information is used securely and correctly. In legal terms, these organisations are known as the 'data controller' for each study. In the unlikely event that something went wrong with the study information, the data controller(s) would be responsible.

Each study patient information sheet will make clear to you who has overall responsibility for how your information is used, and who you should contact if you have any queries. In many of our studies, University of Leeds has overall responsibility. In some studies, University of Leeds will have joint responsibility with another organisation. In a few studies, another organisation has overall responsibility, and University of Leeds follows their instructions. In these cases, University of Leeds is acting as a 'data processor', in legal terms.

If you want to find out more about the University of Leeds, or contact someone within the University about how your information has been used, you can see section 9, below.

Data protection laws (including the Data Protection Act 2018) say that people's information must only be used according to a set of principles. Whether or not we are the 'data controller' for a study, we will always work hard to make sure all information used in our studies is used according to these principles:

- Information will be used **lawfully**: we will follow all aspects of data protection law, and only use information that we need for our research, which is in the public interest.
- Information will be used **fairly** and **transparently**: before we use your information, we will make clear to you what the information will be used for, how it will be handled, what your rights are and how you can act on those rights. During and after the study, we will use your information in the way we said we would, and not do anything else.
- We only collect and use your information for clear and **specific purposes** (which means for our research), and we will **only use as much information as we need** for these purposes, and no more than that.

- We will spend a lot of time and effort making sure the information remains **accurate**, as this is vital to the reliability of our research.
- We only keep information that could identify you for **as long as we have a legitimate reason to keep it.**
- We ensure your information is stored and used in ways that keep it **secure and confidential**, and only accessible to people who need to access it for specific, valid reasons.

3. Will my information be kept secure?

Key message:

We will take all necessary measures to ensure that information about you is sent and stored securely by us or by anyone else acting on our behalf.

We will take all necessary measures to ensure that information about you is stored securely by us or by anyone acting on our behalf. We will also make sure that when information is sent to us, or by us to someone else working on the study, it is done securely, in a way that means your information will get to the correct person.

In some of our studies, we collect information about you on paper forms. Your hospital will send most information about you to us by post. This will include a copy of your completed consent form, so that we can be sure you have agreed to take part in the study. For some studies, we will also collect

your contact details on a paper form. We will ask your study doctor or nurse to send the consent form and contact details form (if applicable) separately from other information about you. This means that, in the very unlikely event that these forms did not reach the right person, the person receiving them would only have limited information about you. The study forms only show your initials, date of birth and a unique study identification number, so in the unlikely event that they do not reach the right person, no one will be able to know that the information is about you.

In some other studies, we ask your study doctor or nurse to enter information directly into our secure study database. This information is stored securely within the database from the moment it is added. Each member of staff working on the study at your hospital has their own login details to access the database, and they can only see information about you and other patients at your hospital. This means staff at other hospitals cannot see any information about you.

Sometimes we will also receive information about you by email or fax. Emails we get from your study doctor or nurse will never contain your name, only your unique study identification number and sometimes your initials and date of

birth. Fax is used to securely send us documents such as your completed consent form, or information that we need to receive urgently (for example, to find out about issues affecting your safety – see section 1.6, above). Fax machines are located in secure areas, meaning only authorised people can access any faxes received.

Some particularly sensitive documents (for example, medical images or photographs, if these are needed for a study) will be sent to us via a ‘secure file transfer’. This means information is sent by the internet in a very secure way.

All information will be sent to the Clinical Trials Research Unit (CTRU) at the University of Leeds. All information on paper documents is stored securely in locked cabinets, accessible only to people who need access to help run the study. Everyone who works at the CTRU signs a confidentiality agreement when they begin their employment. This agreement says that they have to treat all study information correctly and confidentially.

Information stored in our databases or other electronic storage locations is held very securely, in a way that would make it very difficult for any unauthorised people to access it.

When we need to share information with other organisations or individuals (see section 5, below), we will send it to them securely, and we will not send any information to them until we are sure that they will store all information securely.

4. Who will see my information in the research team?

Key message:

We will make sure that the only people at the University of Leeds who have access to information about you are people who need to, in order to run or analyse each study.

Please see your information sheet for more on who may see your medical notes and other confidential information if you take part in one of our studies.

We will make sure that the only people who have access to information about you within the University of Leeds are people who need to have access, in order to run or analyse each study. Only specific members of each study team will see any information sent to us by post. When information is stored electronically, for example in study databases, each

member of staff has their own login details and can only see information they need to see for studies they work on.

The CTRU office at University of Leeds is access-restricted, meaning that only CTRU staff can access it.

5. Who else will see my information?

Key message:

There are some specific situations when we need to share information with other people or other organisations. We will always do this carefully and only when it's really necessary. We will avoid sharing identifiable information about you whenever possible.

The patient information sheet you will get before you take part in any of our studies will go into detail about who will be able to see any confidential information about you for a specific study, including who might have access to your medical notes if you agree to take part.

Please see your information sheet for more on who may see your medical notes and other confidential information, if you take part in one of our studies.

There are some specific reasons why we sometimes need to share information with other people or other organisations. When we do, we will always share only the minimum information required for a specific, valid purpose. Whenever possible, we will share information in a way that means people who get it cannot see who you are. When we can't do this, it's because we need to share your details for a valid reason (see details in the sections below).

We will also make sure there is always an agreement or contract in place before we share any information. This will make clear that people who get the information can only use it for a specific purpose, must keep it secure, and cannot share it with anyone else.

We will never sell your information, or pass it on to people who will sell it. We will never share information for a reason that is not in the public interest, necessary for the study, or necessary to protect your safety or the safety of others.

Information we share will not be used to make decisions about future services available to you, such as insurance.

In general, we do not share your information with anyone outside the United Kingdom in such a way that they could identify you. It is important you know this, because data protection laws may not be as strong in other areas of the world. If it might be necessary to do this for a particular study, this will be made clear to you in the patient information sheet before you agree to take part.

We will share your information for the following reasons, which you can find out more about below:

- To run and analyse the study;
- To get additional information from your medical records,
- To keep you and other people safe;
- To report to authorised people about the progress of the study;
- To allow other researchers to carry out future research in the public interest;
- Due to storage space limitations, we will store information securely away from the University of Leeds after the end of the study.

5.1. Running and analysing the study.

On some studies, we work with collaborators outside the University of Leeds who can help us because of specific expertise they have. The following is a list of examples of this, but other situations may apply – see your study patient information sheet for more information.

- In some studies, a group of medical experts (for example, clinicians or radiologists) will review audio recordings, videos, photographs or medical images (for example, CT scans, MRI scans or X-rays) to check that your study treatment has been given correctly or that study measurements have been done correctly. These people will usually be based in the UK and will have agreed to keep all study information secure. We will send the information to them securely. When we share your information with them, it will only have your unique study identification number on, so they will not be able to see who you are. We will require them to destroy their copies of your information when the study is finished.
- We may sometimes need to share information about you with doctors who work on a study, for further medical advice. This might include copies of medical reports and test results that your hospital has sent us, but they will

always remove all information that could identify you before sending these to us (leaving only your unique study identification number). The doctors are usually based at NHS organisations in the UK. They are bound by their professional roles to treat your information securely at all times.

- It is important for the reliability of some studies involving radiotherapy that we make sure people at different hospitals get the same sort of radiotherapy treatment. We use a team of radiotherapy experts at hospitals in the UK to help us check this. Your study doctor or nurse may securely send some details of your radiotherapy to the team at one of the hospitals involved. They will carry out their quality assurance checks, then send a summary report back to your study doctor. Sometimes a copy of the results will also be sent to us at the University of Leeds. The specialist team will only receive information with your unique study identification number on it, so they will not be able to see who you are. This network of specialists around the UK is called Radiotherapy Trials Quality Assurance (RTTQA) and you can find out more about them on their website: **http://rttrialsqa.org.uk/rttqa/**.
- In some studies, researchers away from the University of Leeds will carry out study data analysis because they

have particular expertise. We will only share the minimum information with them for them to do this, and this may include your unique study identification number but nothing else that could identify you. They will therefore not be able to see who you are from the information we share with them. We will send the information to them securely, and put in place a contract with them to make sure they use and store your information correctly. They will be required to securely destroy your information when the research is finished**.**

5.2. Accessing health information from your electronic health records.

As well as the information that your hospital will send to us on the paper or electronic study forms, we will also obtain information about you held in NHS databases managed by NHS Digital (**https://digital.nhs.uk/**) or other providers. To do this, we will securely send some of your information (such as your name, your date of birth or your NHS or CHI number) to the information provider, and they will return the information about you that we need for the study. The patient information sheet you get when you are considering taking part in a trial will make clear how this works, if it's happening in your study.

We do this because it is a more efficient way to collect certain information about your health. By using information collected from routine health visits, we can reduce the amount of time you and your hospital need to give to a study. When we do this, we will only use the information mentioned above to identify you. We will follow strict rules when working with other organisations to maintain confidentiality and protect your information.

NHS Digital and other providers will only provide information to us when they are satisfied that you have agreed to us doing this and that we need your information for research in the public interest. They also need to be satisfied that we will handle all your information securely. When they share your information with us, they can visit us to carry out an audit at any time to check that we are using your information correctly.

You can find out more about the work of NHS Digital on their website: **https://digital.nhs.uk/.**

5.3. Keeping you and other people safe.

It is very important to us that you remain safe when participating in our studies. If we learn anything new about the safety of treatments involved in our studies, we must share it quickly with relevant organisations so that people outside the study taking the same treatments are also kept safe.

When we run our studies, we have to follow laws and other rules that help protect your safety and the safety of others receiving the same treatments. These laws and rules require us to urgently collect details of certain types of serious health event from your hospital (for example, if you have a problem that means you have to stay in hospital overnight). We share these reports with doctors working on our behalf, usually in the UK. They can advise us on whether any urgent action needs to be taken to protect you or other people taking part in the research. The reports we share will contain only your unique study identification number, initials and date of birth, so there isn't any way that these doctors could identify you from the limited information we share with them about this.

If an event seems like a new type of side effect that no one else has had before, we must report this urgently to the

Research Ethics Committee that has approved the study. For studies involving medicines, we must also report urgently to the regulatory authority (the Medicines and Healthcare products Regulatory Agency, or MHRA). We also sometimes need to share the information with doctors at other healthcare centres taking part in a study.

This information sharing is very important because if we find a previously unknown type of side effect of the treatment, we need to tell doctors and patients about it quickly (but without identifying you). We will also report to the pharmaceutical companies that make the treatments involved, so that they have a complete record of any problems occurring. The information we share with these organisations has only your unique study identification number on (not any other identifier), so there isn't any way they could identify you.

Collection of this type of information is required by law in studies that involve medicines, so we will need to continue doing it even if you decide to stop taking part in the study. See section 8, below, for more about this.

To help us with protecting patient safety, you should always tell your doctor about any health events you have experienced during or after you take part in the study.

Other ways we may use information about you to keep you safe:

- In some of our studies, your study doctor and nurse will not know what treatment you are receiving. This is so that their decisions and behaviour are not influenced by their knowledge of your treatment. This sort of study is called a ‘blinded’ study, and can have more reliable results than non-blinded studies. The patient information sheet about a study will make clear if your study is a blinded study. In the unlikely event of a medical emergency happening while you are on a blinded study, your study doctor and nurse might need to urgently find out what treatment you have had. They can do this by providing your unique study identification number either to a specific team at the University of Leeds, or through a service provided by another organisation. They will then instantly receive the details of your treatment. No other information about you will be used in this process.

5.4. Reporting on the progress of the study.

We are required to provide updates on our studies to various organisations and groups. Each study cannot start until it is reviewed and approved by a Research Ethics Committee and, for studies involving medicines, the regulatory authority (the Medicines and Healthcare products Regulatory Agency, or MHRA). After they have approved each study, we need to send these groups regular updates so that they can check how the study is being run. We also need to provide updates to the funder of each study so that they can check we are using their funding as we said we would. We also provide some information to independent groups of experts who regularly check that the study is safe to continue. These groups can include 'Trial Steering Committees' [https://www.invo.org.uk/posttypejargon/trial-steering-committee-tsc/] and 'Data Monitoring Committees' [https://www.invo.org.uk/posttypejargon/data-monitoring-committee-dmc-also-known-as-dmec-idmc-dsmb-and-ismc/].

All these individuals and organisations are usually based in the UK. We only ever share very limited information with them. There is no way you could be identified from any reports. The reports will either just show groups of people (such as a total number of people who have joined the study), or information that does not allow individuals to be identified

(for example showing just your unique study identification number).

5.5. Making information available for other research.

Information we collect for each study is made available to other researchers in other organisations at the end of the study for additional research, including information you have already provided if you stop taking part in the study. This will not include any information that could identify you. Your information will not be shared if you have explicitly said you did not want this to happen.

Collecting information for research studies takes a lot of time and effort. Sharing the study information for future research projects is an important way we can make the most of this time and effort, including the time the research participants themselves have given.

These other organisations may be in other countries, including outside the United Kingdom where data protection laws may be different. However, information will only be shared in such a way that no individual people can be

identified from the information (either on its own or in combination with other information).

We will also only share this information for worthwhile research projects with appropriate approvals (including approval from a research ethics committee), and only when we are sure the other researchers will manage your information correctly and securely, wherever they are based. Before we share information with anyone, we will put in place contracts to make sure the other researchers store the information securely, that only authorised people will access the information and that the researchers will destroy their copy of the information when their research is over.

We may also use study information for additional research projects within the University of Leeds. We will only agree to do these projects if they are worthwhile research projects that have all the appropriate ethical approvals. If people outside the original study team are involved, we will only share the minimum information with them that they need for the new project, and we will remove any clearly identifiable information (such as your name) before sharing.

We will never sell your information, and there is no way that it could be used to make decisions about insurance or anything else that might affect you in future.

5.6. Long-term storage.

To comply with laws and policies around research, we need to keep your information for a time after each study has finished. The amount of time applying to a specific study will be made clear in the patient information sheet before you agree to take part.

Due to storage space limitations, it may be difficult for us to keep all the paper documents within the University of Leeds for the required length of time. We may therefore ask a reputable archiving company to securely store the paper documents away from the University (but still within the UK) after the end of the study. We will only do this when we are sure the company will hold your information securely, and we will always have a contract in place with the company to make sure they are accountable for how they store your information.

6. Can I see my information, or ask you to correct it?

Key message:

Usually, when an organisation or a company has information about you, you can ask to have access to that information at any time, or ask them to correct it if it needs correcting.

This does not apply in the same way to information used for research in the public interest. However, you should let your study doctor or nurse know if your contact details change, if you have given them to us for the study.

Usually, when an organisation or a company has information about you, you can ask to have access to that information at

any time, or ask them to correct it if it needs correcting. However, data protection laws (including the UK Data Protection Act 2018) give special protection to information used for research. Giving people access to research information could harm studies like ours. This is because it is important to the reliability of the study results that we do not release information before the planned analyses are complete. You therefore cannot ask to access or correct information we have about you. Most of the information we will collect will also be in your medical notes though, and you can access your medical notes whenever you like. You should talk to your study doctor and nurse if you would like more information about the care that you have received.

The same data protection laws mean you cannot ask us to correct or amend the information we have about you, in most cases. However, it is obviously crucial to the quality of our studies that the information we have is right, so we will spend a lot of time and effort on making sure the information is correct.

You cannot ask us to change most of your information. However, if you have provided us with contact details for use in a study, it is important that we find out about any changes

to these. Please let your study doctor or nurse know about a change in these details so that they can let us know. Otherwise, we might end up sending things meant for you to your previous contact details.

7. How long will my information be stored for?

Key message:

To comply with laws and other rules about research, we need to keep your identifiable information for a period of time after each study is over. The exact period of time for a study will be made clear in each study's patient information sheet.

If you agree to take part in one of our studies, we will need to keep your information for a few years after the end of the study. The exact amount of time will depend on the study, but it will be made clear to you in the patient information sheet before you agree to take part.

Laws and other rules about research state that we have to keep the study information for a long time after the study has ended. The results of research can change how patients are

treated in future. It is therefore very important that studies like ours are done correctly and produce reliable results. It is possible that, a few years after a study, the regulatory authorities or other authorised organisations will need to go back and check the results, so we need to keep the information to allow this to happen.

We will keep all information secure for all of the time we keep it. For practical reasons, it may be difficult to keep all the paper documents within the University of Leeds for that length of time, so we may ask a reputable archiving company to securely store paper documents for us away from the University.

At the end of this period of time, we will securely destroy your information.

8. What will happen if I stop taking part in the trial?

Key message:

If you decide you would like to stop all your visits in a study for any reason, we will need to keep the information we have about you to make sure the results of the study are reliable.

You can ask us to stop collecting more information about you, but if you don't say this, we will keep collecting information from any other hospital visits you have, if they are relevant to the study, and we will keep collecting information about you from information providers such as NHS Digital.

This way you can keep contributing to the study without giving any more of your time.

8.1. Can I stop taking part in a study at any time?

You can stop taking part in any part of a study at any time. You do not have to give a reason why you want to stop, although it is very helpful to the study results for us to know the reason, if you are willing to say. If you decide you would like to stop all study visits, we will need to keep the information we already have about you.

8.2. Can I ask you to delete my information or remove it from the study analysis?

Usually, when an organisation or a company has information about you, you can ask them to delete it, or stop using it for a particular purpose, at any time. However, data protection laws (including the Data Protection Act 2018) give special protection to information used for research. The results of research can change how patients are treated in future, so it

is very important that the results of studies like ours are reliable.

We also need to follow laws and policies that say we need to keep a clear record of our research. This is so that regulatory authorities (such as the Medicines and Healthcare products Regulatory Agency, MHRA) and other authorised organisations can check that we have carried out the research correctly and lawfully.

For these reasons, we can't remove or delete the information we have already collected about you because it would make the results of the study less reliable, and this might harm future patients. We will nonetheless treat your information securely and with care, and use your information only in the ways we've told you about.

8.3. Will more of my information be collected if I stop my study visits?

If you have decided you would like to stop all parts of a study, including the study visits, it is important that you discuss this with your study doctor and nurse and let them know if you are not happy for us to collect any further information. If you still

occasionally go to your hospital for routine visits, we would like to hear about these from your study doctor or nurse, if the visits are relevant to the study. This way, we can still include you in the study without you having to do any extra hospital visits. This means you can still contribute to the study and help make the results more reliable, without giving any extra time.

You can tell your study doctor or nurse at any time that you do not want any more information to be sent to us. They will inform us, and we will make sure your wishes are respected. However, if you do **not** say that you do not want any more information to be sent, we will still ask your study doctor or nurse for updates about your health from time to time.

In some of our studies, we get some information about you from your electronic medical records held in NHS databases by NHS Digital or other organisations. This is so that we can do some parts of the study while taking up less of your and your hospital's time. You can tell your study doctor or nurse at any time that you would like us to stop doing this. They will let us know, and we will make sure your wishes are respected. However, if you ask to stop your study visits but do **not** tell your study doctor or nurse that you want us to stop collecting

information from your electronic medical records, we will continue doing it.

If you are taking part in a study that involves medicines and you tell us you do not want us to collect any more information about you, we will still be legally required to collect information about any serious side-effects you experience, or health events that might be related to the treatment you have received. This is so that doctors using the same treatment have all the information they need about possible side-effects, so this is important in protecting other patients' safety. Your study doctor will report any relevant information to us if we need to have it, so you won't need to do anything else. We will make sure that any information that could identify you is kept to a minimum and only collected if needed.

8.4. What will happen if I lose contact with the study doctor or nurse?

If, for any reason, you stop attending your study visits without telling anyone at your hospital or clinic, or you change your contact details and do not tell your hospital so that they lose contact with you, we may ask your study doctor or nurse to contact your GP to check if you are OK and still happy to take part in the study.

9. What if I have concerns about how my information is being used?

Key message:

If at any time you have questions or concerns about how your information is used that aren't answered by this information or by talking to your study doctor or nurse, you can contact the relevant Data Protection Officer (see your study patient information sheet for details).

If you are still not satisfied, you can contact the Information Commissioner's Office.

If you have a question or concern about how your information is used in one of our studies, you should first check the information in the patient information sheet you were given

before you agreed to take part in the study. Your study doctor or nurse may also be able to help advise you.

If you would still like more information, you should contact the relevant Data Protection Officer for the study. Every organisation has a Data Protection Officer, who is their main contact for anything to do with how your information is used. The person to contact will be listed in your study patient information sheet. If you need another copy of that document, talk to your study doctor or nurse.

The details of the Data Protection Officer at University of Leeds can be found on this webpage: **https://ctru.leeds.ac.uk/privacy/**, though you should know that this might not be the best person to contact about a particular study. The University of Leeds data controller registration number provided by the Information Commissioner's Office is Z553814X (**https://ico.org.uk/ESDWebPages/Entry/Z553814X**). The general postal address for the University is University of Leeds, Leeds LS2 9JT, UK.

If you are not happy with the Data Protection Officer's response to any queries or complaints, or believe your information is being used incorrectly or unlawfully, you should contact the Information Commissioner's Office if you are based in the UK:

- General website: **https://ico.org.uk/;**
- ICO contact webpage: **https://ico.org.uk/global/contact-us**;
- Telephone number: 0303 123 1113;
- Postal address: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF.

If you are not in the UK, you should contact the relevant supervisory authority for data protection in the country where you live.