Participant information sheet and consent document

For **FRONT-LINE PARTICIPANTS** (who have received ibrutinib for 6 years as their first and only line of treatment in either the FLAIR or IcICLLe studies)

Delete this line, then print first page of Information Sheet and Consent Form on Trust/Hospital headed paper

STATIC
Intermittent vs. continuous treatment strategies in CLL

A Study Comparing Intermittent with Continuous Treatment with Ibrutinib in Chronic Lymphocytic Leukaemia (CLL)

A large-print version of this sheet is available on request

For patients who have received ibrutinib for 6 years as their first and only line of treatment in either the FLAIR or IcICLLe Trial

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

You are being invited to take part in a research study called STATIC

- Please take time to read this information carefully. Discuss it with your doctors, friends, and relatives if you wish. Take time to decide whether or not you want to take part.
- You are free to decide whether or not to take part in this study. If you choose not to take part, this will not affect the care you get from your hospital doctor.
- You can stop taking part in the study at any time, without giving a reason.
- Ask us if anything is not clear, or if you would like more information. Contact details are shown on page 2.
- Thank you for reading this information sheet. If you decide to take part, you will be given a copy of this sheet and asked to sign the consent form.

Why have I been invited?

- You are being invited to take part because you have already had finished, or nearly finished, 6 years of your ibrutinib treatment in the FLAIR or IcICLLe study.
- We want to find out whether patients with CLL who have had a good response to treatment with ibrutinib or acalabrutinib can take a break from their treatment and restart it only if the CLL comes back.
- To do this we are testing two different ways of taking ibrutinib/acalabrutinib *either*
    - having a break from ibrutinib/ acalabrutinib and only restarting if the CLL comes back,

    or
    - continuing to take it without a break.

  This study is being conducted to see whether these two ways of taking ibrutinib/ acalabrutinib have the same effect in controlling CLL.
- The clinic visits that will take place for STATIC fit into your usual care. However, when you are first considering whether or not to join the study, there might be 1 or 2 extra hospital visits. Once you are in the study there are no more extra hospital visits or tests, and the study blood samples will be taken at the same time as your usual blood tests. If you decide not to take part in STATIC, you will stop ibrutinib when you complete the FLAIR or IcICLLe study and your CLL care will continue as usual in the NHS.

More information about the STATIC trial can be found on the study website https://ctru.leeds.ac.uk/static/

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How to contact us

If you have any questions about this study, please talk to your hospital doctor at

<<Enter PI, nurse name >>

<< Contact details for site>>

Thank you for reading this information sheet.

1. Why are we doing this study and what will I need to do to take part?

Ibrutinib and acalabrutinib are part of a group of drugs for chronic lymphocytic leukaemia (CLL) called targeted drugs. These drugs are very effective in treating patients with CLL. Targeted drugs, including ibrutinib and acalabrutinib, have fewer side effects than traditional chemotherapy. However, as the drugs are usually taken for several years, these side effects can be a burden for patients.

There is some evidence that, if targeted drugs are taken for several years, the CLL is more likely to become resistant to this treatment. We do not know whether taking a break from targeted drugs will avoid or reduce this possibility, but if it did then the targeted drugs might continue to control the CLL for longer. The STATIC study may help to clarify this.

Currently ibrutinib and acalabrutinib are available on the NHS for patients whose CLL has either come back or has not responded to their first treatment. Ibrutinib is also available for certain other groups of patients. This includes patients taking part in the FLAIR and IcICLLe studies (as a first treatment for CLL); and for a small number of persons with CLL who have disease which is more active or who have tests which may predict a shorter duration of response to therapy and patients in Scotland who had this as their first treatment for CLL during the Covid-19 pandemic. Up until now, ibrutinib and acalabrutinib have been given continuously until either they stop working, or the side effects become a problem, or if you have been in FLAIR or IcICLLe until the end of the trial period (6 years).

What are we trying to find out?

For persons with CLL who have had a good response to ibrutinib or acalabrutinib, we are testing whether now having a break from the targeted drugs will work as well as continuing the treatment without a break.

We will also test whether taking a break from the targeted drug reduces side effects, whether it lowers the risk of CLL becoming resistant to the drug (either ibrutinib or acalabrutinib), and whether there is any difference in the overall cost of CLL treatment.

We also want to test whether having a break from the targeted drugs changes how patients are feeling emotionally, and what you like and do not like about your treatment. We will do this by asking you to complete short questionnaires every few months.

To find out which way of using the targeted drugs is best we need 800 patients to take part in the STATIC Randomised trial. These 800 patients will include:

- those who had ibrutinib or acalabrutinib when their CLL either came back or did not respond to initial treatment
- those who had ibrutinib as the only treatment for their CLL (either in the FLAIR study, IcICLLe study, or within the NHS).

As everyone on the FLAIR and IcICLLe trials has been taking ibrutinib, and it is not possible to change to acalabrutinib during the study, this document now just refers to ibrutinib.

We anticipate that a small number of patients finishing FLAIR and IcICLLe will be advised to continue ibrutinib as their CLL is not well controlled enough for them to take part in the randomised trial. They can continue ibrutinib in STATIC. This part of the study is called the 'clinical need group'. Information from this group will help us understand more about the long-term benefits and hazards of ibrutinib.

Can I definitely take part?

Not everyone will be able to take part in this study, and some tests will need to be completed first to see whether you are able to take part. These include:

- Blood tests for your CLL, kidneys and liver
- Physical examination of your lymph nodes and spleen
- Pregnancy test (only if you are female and able to have children)
- Measuring your blood pressure
- Tests to review the function of your heart

You will probably need to have one or two extra clinic visits to get these tests done and decide whether you want to take part.

What if the tests show I can take part?

If these tests show you can take part in STATIC, and you agree to join, we will ask you to sign a consent form (a copy of this is at the end of this document).

If you join STATIC you will receive the same targeted drug you have been having as part of your NHS treatment. So as you have been having treatment with ibrutinib you will continue to receive ibrutinib in STATIC. You will not be able to change targeted drugs.

There are two separate treatment schedules in the STATIC randomised trial:

Pausing treatment. Take a break from ibrutinib, and only restart if your CLL gets worse again. If restarting ibrutinib controls your CLL again, you will be able to take another break from it.

Continuous treatment. Continue to take ibrutinib every day. You will continue ibrutinib without a break as long as you are benefitting from it.

Which group will I be in?

The decision about which schedule you are given, either pausing or continuous, will be decided by chance, rather like tossing a coin. This process is called randomisation. Neither you, nor your hospital doctor or nurse, will be able to choose which group you will be in. A computer will choose which ibrutinib schedule you will get. This ensures a fair test between the two groups, as participants in the two groups are as similar as possible to start with. It also ensures that any differences between the groups at the end of the study are only due to the different treatment schedules, either pausing or continuous ibrutinib.

What will happen to me during the study?

You will have your CLL monitored every 3 months in clinic, as is usual for care in the NHS. This is the same whether you are in the randomised trial or the clinical need group. The checks and blood tests will be the same as for your usual care.

If you are in the STATIC randomised trial, we will also ask you to complete questionnaires. If you agree to complete these we will ask you to do this when you first join STATIC, after 6 weeks of being in the study and at each 3 monthly clinic visit for the first 6 months, and then at alternate visits (i.e. every 6 months) until the end of the study.

How long will I be in STATIC?

We anticipate the study will run for 9 years. You will stay in STATIC until the end of the study, which we expect to be in 2031. You would receive between 3 and 9 years of treatment as part of the STATIC study, depending on when you join the study. This is the same for the randomised trial and the clinical need cohort.

If you are allocated to join the pausing ibrutinib group, you will restart ibrutinib if your CLL comes back. If restarting ibrutinib controls your CLL again, you will be able to pause it again.

What if I am not getting any benefit from ibrutinib?

If you are no longer benefitting from ibrutinib, your hospital doctor will discuss alternative treatment options with you. Medical advice and decisions regarding treatment will be made in your best interest at all times.

We would still like to know how you are. So you would continue to have yearly follow ups for the study for 3 years, or until the end of the study. If you are in the randomisation trial and have agreed to complete questionnaires we will ask you to continue to complete these.

If you gave consent for long-term follow-up survival data to be collected, we will still collect this from your digital NHS data or other central UK NHS bodies.

Will any genetic tests be done?

Yes, we will complete some genetic tests on your blood samples. Certain genetic changes in the CLL cells are important in the development of CLL, for predicting whether individual patients responding will respond to specific treatments and in the development of resistance to targeted drugs like ibrutinib. We will test for these genetic changes at the study central laboratories. In order to understand more about CLL and improve its treatment it is, therefore, necessary to examine the CLL cells for genetic abnormalities. However, such genetic tests will not look into whether other persons in your family are susceptible to CLL, neither will they predict your risk of other health problems in the future.

In addition, if you are in the randomisation trial and you decide to take part in the additional UK CLL Biobank project then samples will be taken to be tested in the future at the central laboratories, these samples will be stored at the University of Liverpool in a facility called a biobank.

Will I be reimbursed for taking part?

You will not be reimbursed for taking part in the study. Most clinic visits required for the study will be the same as regular clinical appointments. All of the samples and blood tests will be collected as part of your routine care.

2. What are the possible benefits and disadvantages of taking part?

Possible benefits of taking part in STATIC

We hope that you will be helped by taking part in this study, but we can't guarantee this. However, the information we get from this study will help us to improve medical research and help us to improve future treatments for people like you who have ibrutinib treatment for their CLL.

As we learn more about the effects of patients taking ibrutinib for long periods of time, pausing ibrutinib for periods, and how this changes the side effects, this may lead to a possible change in your treatment and for others with CLL, with the aim of it being better for you.

Currently we do not know whether pausing ibrutinib treatment when the CLL is well controlled works as well as continuing ibrutinib without a break. The STATIC Randomised trial will help us to answer this question.

By taking part you will be helping to answer important questions about the benefits and safety of ibrutinib the overall survival of patients receiving treatment, and it is hoped that this will improve treatment for you now and for future patients.

Both the randomised trial and clinical need group will give us information about the effects of taking ibrutinib for a long time.

Possible disadvantages and risks of taking part in STATIC

As you will be aware from the FLAIR or IcICLLe study, you may have side effects during or following treatment with ibrutinib. You will be monitored regularly whilst in the study. If you notice any change in side effects, please tell your hospital doctor or study nurse as soon as possible.

If you take part in the STATIC randomised trial, we will ask you to complete questionnaires about your health and wellbeing. These are for the research study only and are not part of your usual care. If you complete these questionnaires during your clinic visit this may mean the visit takes slightly longer. If you prefer, you can take the questionnaires home to complete, rather than doing this in clinic. The questionnaires are confidential and neither your hospital doctor nor research team will see what you have written. You are however, encouraged to discuss any problems or symptoms that the questionnaires highlight, including feelings of low mood or depression, with your medical team. These questionnaires are different from the questions your hospital doctor or research nurse will ask you as part of normal care for your CLL.

What are the side effects of ibrutinib?

As you have already been taking ibrutinib for some time, you may have experienced some of the side effects of ibrutinib. If your ibrutinib dose has already been adjusted to reduce your side effects, you can continue at that adjusted dose when you take ibrutinib in STATIC.

We will ask you to tell us about any side effects you might have. If you are in the STATIC Randomised trial in the pausing ibrutinib group, we will ask you to continue to tell us about any side effects, as we want to know if these change, for example which ones reduce, stop, or start..

The side effects associated with ibrutinib are listed in Appendix 1 of this information sheet on pages 17-20. These will be similar to those you have been told about as part of your involvement in the FLAIR or IcICLLe study. Your hospital doctor and nurse team will in any event explain these to you. However, if you do have a side effect which affects your health or wellbeing during your treatment on STATIC, your hospital doctor may stop your study treatment and recommend other treatments. You may experience some or none of these side effects. It is important that you tell your medical and research teams if you suffer any side effects, whether or not in the list, so that where possible they can help to manage these and so that we can continue to collect information about the side effects experienced with ibrutinib.

What if I am pregnant, or you or your partner becomes pregnant during the study?

If you are pregnant (or breastfeeding), think you may be pregnant, or are planning to become pregnant, you will not be able to take part in this study.

If you are a woman who could become pregnant you **must** take specific precautions not to become pregnant whilst taking ibrutinib (this does not include during treatment breaks if you are randomised to the pausing ibrutinib arm) and for three months after the last dose of ibrutinib as part of the study (this includes the last dose taken when starting a treatment break in the pausing ibrutinib schedule).

You will need to have a pregnancy test and **must** use a highly effective form of contraception (this **must** include a barrier method if you are using hormonal contraceptives).

If you become pregnant while on this study, the ibrutinib will be stopped immediately, you should inform your hospital doctor immediately and the pregnancy will be monitored. The hospital doctor will advise you of any possible risks to your unborn child and will discuss options for managing the pregnancy with you.

For men, the drugs used in this study may pass into the semen. Because of this, if your partner might become pregnant, or is already pregnant, you **must** use effective barrier contraception during sexual contact throughout study treatment (this does not include during treatment breaks if you are randomised to the pausing ibrutinib arm) and for three months after the last dose of ibrutinib in the study (this includes the last dose taken when starting a treatment break in the pausing ibrutinib group). Please discuss this with your hospital doctor.

If your partner becomes pregnant, please report it immediately to your hospital doctor or research nurse. In addition to the initial details, we would also want to collect information on the outcome of the pregnancy.

3. Additional research

If you take part in the STATIC randomised trial, we will ask you to give consent for us to take extra blood samples. These samples will be taken at the same time as your usual blood tests; you will not have to make any extra clinic visits. We will also ask you for a spit sample, when the first of these additional blood samples is taken.

The extra samples will be stored at the United Kingdom CLL (UK CLL) Trials Biobank at the University of Liverpool. The samples sent to the biobank will be analysed for patients whose CLL has developed resistance to ibrutinib, to find out when the resistance started.

If you agree to give blood samples to the UK CLL Trials Biobank your hospital doctor will give you additional information and ask you to sign a separate consent form (see also the consent form at the end of this information sheet). Taking part in this biobank research is entirely voluntary, and your decision whether or not to do so, will not affect your participation in the rest of STATIC.

If you do not give consent for these extra blood samples at the start of the STATIC study, you can do so at a later date.

4. What will happen to the information and samples collected?

What will happen to any samples I give?

The samples will be sent to the laboratories by post. Samples sent to the Haematological Malignancy Diagnostic Service (HMDS) will include your name, initials, date of birth, sex, NHS (National Health Service) number/CHI (Community Health Index) number and study number, to ensure that the samples are correctly identified, processed, and linked with other samples. In the STATIC Randomised trial, if you have given consent, the additional samples sent to UK CLL Biobank will not include your name but will include your patient trial number, sex, initials, and date of birth to ensure that the sample can be correctly identified.

A unique reference number will be allocated to the samples which will allow them to be linked back to you in future for research purposes. Your details and the results from your samples will be held on a database at the laboratories, and some results will also be held on a database at the Clinical Trials Research Unit (CTRU) in Leeds.

Your samples will be stored in laboratories for up to 30 years as required by UK regulations.

Will my taking part be kept confidential?

There are a few things you should know about how your confidentiality will be affected if you agree to take part in this study.

- Your **GP, and the other doctors involved in your healthcare, will be kept informed** of your participation in this study. This is because they might need to know you took part when they treat you for anything in future.
- Your **healthcare records may be looked at by authorised individuals** from the research team, the University of Leeds (the study Sponsor), the regulatory authorities or other authorised bodies to check that the study is being carried out correctly. This will only be done in line with your hospital's policies to ensure your records are secure.
- Your study records **may be inspected by authorised individuals from Janssen** (the pharmaceutical company responsible for making ibrutinib and who are providing funding for the study) to check that the study is being carried out correctly.

- We would like to **collect a copy of your completed consent form** if you agree to take part in the study. This is so that we can check you have definitely agreed to take part. This means people in the study team who are authorised to deal with consent forms will see your name. However, these people are trained to treat your information with care, and the consent form will be stored securely at all times.
- You will be allocated a study number, which will be used along with your date of birth and initials to identify you.
- As part of this study, we will use some of your information (your name, date of birth, and NHS or CHI number) to obtain information about you in standard NHS patient registries held by NHS Digital or other central UK NHS bodies. We will do this because it is a more efficient way to collect certain data about your health. By using data collected from routine health visits, we can reduce the burden (such as the number of hospital visits) on you and your hospital. When we do this linking, we will only use the details mentioned above to identify you, and we will follow strict rules when working with other organisations to maintain confidentiality and to protect your information.

  Unless you clearly tell us you don't want us to, we will continue to obtain this information about you if you stop taking study treatment or stop attending study visits. This is to help ensure the results of the study are valid.
- Results of your laboratory tests (i.e. blood tests) may be shared with other research teams where you are taking part in another CTRU clinical study, to prevent the need for extra samples to be collected / analysed.

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

You can stop taking part in all of the STATIC study, or in any part of it, at any time and without giving a reason. However, we would like to know the reason if you are willing to say, because this can be useful when we produce the results of the study.

Before deciding to stop, you should talk to your hospital doctor or research nurse. They can advise you and may be able to deal with any concerns you may have. If you decide to stop taking part at any time it will not affect the normal standard of care you receive for your CLL from the NHS.

If you decide to stop the study treatment schedule, we will still ask you to continue with the study visits and assessments, and to continue completing the questionnaires.

If you tell us that you want to stop completing the study questionnaires, we will stop asking you to complete them. You can still remain in the STATIC study if you stop completing these, and you can change your mind later and start completing them again, if you want to.

If you decide to stop study visits or assessments, we will need to keep the information we have already collected about you and include it in the study analysis. This is to make sure the research is still reliable.

We will continue collecting information about your health from routine hospital visits, via your digital health records or through other contact between you and your hospital, unless you tell us not to. We will only do this if the information is relevant to the study. We do this to help make sure the study results are reliable. You can read more about this in part 12 of this information sheet.

Unless you tell us you don't want us to, we will keep any biological samples you have given for future research purposes.

Once samples have been processed by the laboratories the data linked to them cannot be deleted. This information will be stored in laboratories for up to 30 years as required by UK regulations. However, if at a later date you request that your samples are no longer used, any samples which remain will be destroyed and your data would not be used or further processed from that date forward. Some material from samples already processed may need to be kept by the laboratories for quality control purposes.

Finally, we may be legally required to collect information about any side-effects that you have during or following your study treatment, even if you have told us you did not want to provide further data for the study.

In line with Good Clinical Practice guidelines, at the end of the study your data will be securely archived for a minimum of 25 years. Arrangements will then be made for confidential destruction.

What will happen if I lose mental capacity?

It is expected to be very rare that you would lose mental capacity during this study. This could, however, happen to anybody whether or not they are taking part in this study (e.g. if someone had a head injury). If this did happen to you, you would continue with your study treatment if your hospital doctor and your family or carer thought it best for you to do so. We would continue to collect information about you for the study.

If there are any significant changes to the design of the study we would ask for consent from a legal representative on your behalf.

What if relevant new information becomes available?

Sometimes during the course of a study, new information becomes available. If this happens your hospital doctor or research nurse will tell you about it and discuss with you whether you want to continue in the study. If you decide not to continue, your hospital doctor will consider and discuss your care with you. If you decide to continue, you may be asked to sign an updated consent form. On receiving new information, your hospital doctor may consider it to be in your best interests that you stop taking any further study treatment.

6. What happens when the STATIC study stops?

At the end of the study, your own hospital doctor will decide any further treatment that you may need and will discuss this with you.

Results from the study will be presented at large medical meetings and published in medical journals to ensure that as many hospital doctors as possible get to know about the results. This is how studies can improve the treatment and care for patients. Individual patients will not be identified in any report or publication. If you wish to see the published results from this study, you should ask your hospital doctor. A summary of the study results, and intermittent study updates, will also be shared with your hospital and via patient forums, seminars, and digital platforms once the results have been published.

7. Who has organised, reviewed, and funded the research and who will be supervising it?

The study has been designed by a group of CLL doctors, statisticians, and clinical trial experts in the UK, and is being organised by the University of Leeds.

Patient representatives have also reviewed and contributed to the study design, protocol, and participant information sheets.

The study is included in the portfolio of studies of the UK CLL sub-group and the UK Clinical Research Network Portfolio.

Funding for the study is provided by the National Institute of Health Research (NIHR) and Janssen, the company who make one of the drugs being investigated, ibrutinib. Funding for some of the costs of the ibrutinib being used in the study is also being provided Janssen. These funders are not involved in the day-to-day running of the study, and the responsibility for making decisions about the study design and how it is run will always remain with the doctors, statisticians, and trial experts.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing, and dignity. This study has been reviewed and given a favourable opinion by a Research Ethics Committee.

8. Do I have to take part?

No, taking part in STATIC is voluntary.

If you decide to take part you will be given this information sheet to keep. You will be asked to sign a consent form. If you do give consent to participate in STATIC you may withdraw your consent to take part at any time, without giving us a reason.

If you decide not to take part, your hospital doctor will be happy to talk through alternative treatment options, but your treatment and care by the NHS will not be affected in any way.

9. What if something goes wrong during the study?

While you are part of the STATIC study, if a medical emergency related to your CLL occurs while you are at home, you should contact the hospital where you received your treatment or you should go the Accident and Emergency (A&E) department of your local hospital. You can also

dial 999 as with any medical emergency. If the problem is not an emergency and you are unable to get to the hospital you should contact your GP or call NHS Direct on 111.

Every care will be taken in the course of this clinical study. However, in the unlikely event that you are injured as a result of the managing organisation (University of Leeds), compensation may be available, although you may have to pay your related legal costs. The hospital where you receive your treatment has a duty of care to you whether or not you agree to participate in the study and the University of Leeds accepts no liability for negligence on the part of your hospital's employees. If you wish to complain about any aspect of the way you have been treated, please contact your hospital doctor in the first instance.

Any claims will be subject to UK law and must be brought in the UK.

If you have private medical insurance, you should tell your insurer that you are taking part in research. They will let you know if it affects your policy.

10. Complaints

If you have a concern about any aspect of this study, you should ask to speak to your hospital doctor or the research team at your hospital who will do their best to answer your questions. Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure. Details can be obtained from your hospital. Alternatively, you may contact your local Patient Advisory Liaison Office.

Any claims will be subject to UK law and must be brought in the UK.

11. Contact Details

If you have any further questions about your CLL or clinical studies generally, please discuss them with your hospital doctor.

The team at Leeds Clinical Trials Research Unit and the STATIC Patient Group have developed a website which provides more information about the STATIC trial (accessed at https://ctru.leeds.ac.uk/static/ or via the following QR code)

You may also find it helpful to contact CLL Support, a patient-led support charity, (telephone 0800 977 4396; website: https://www.cllsupport.org.uk), Leukaemia Care, a national blood cancer support charity (telephone: 0808 810 0444; WhatsApp: 0750 006 8065; website: https://www.leukaemiacare.org.uk), Macmillan Cancer Support, an independent cancer information charity (freephone: 0808 808 00 00; address: 89 Albert Embankment, London, SE1 7UQ; website www.macmillan.org.uk) or CancerHelp, an information service about cancer and cancer care for people with cancer and their

families by Cancer Research UK (Tel: 020 7061 8355; website www.cancerhelp.org.uk).

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) have published a booklet entitled 'Understanding Clinical Trials'. Contact UKCRC: Tel: 0207 670 5452; website www.ukcrc.org.

12. How we will use your information

If you decide to take part in this study, some information about you will need to be collected and used. This section explains what information will be collected, who it will be shared with and what it means for you.

We know that some people want to know more than others about how their information is used. You can therefore choose how much detail you'd like:

- You can look at the **quick access guide**, below. You should definitely read this, even if you do not look at the appendix and comprehensive guide mentioned below.
- If you have particular questions or concerns, you should look at the **optional appendix 4**. This is available at the end of this information sheet.
- If you would like more detailed explanations about anything, including why we need to do things in a certain way, you can find it in our **comprehensive guide**. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular concerns. This is available at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your study doctor or nurse. This can also be made available in large print or other formats, if you need them.

The text in each of these documents is laid out in the same order, so you can easily find more detail.

All of these documents have been written with the help of patients and the public to help make sure they are clear and accessible. As in the rest of this patient information sheet, whenever we say 'we' or 'us', we mean the study team at the Clinical Trials Research Unit, University of Leeds (https://ctru.leeds.ac.uk/).

You can find more general information from the NHS about how people's information is used in research at https://www.hra.nhs.uk/information-about-patients/.

A quick access guide to how we will use your information in STATIC

You can read more about each of the points below in the optional appendix. Use the reference numbers to find the relevant section in the optional appendix.

If you agree to take part in this study, we will collect information about you and your health. We will use this to run the study, produce the study results, and to help make sure you and other people taking part in the study are safe. The information we collect will include:

- Information from you and from your hospital medical notes
- Information from analysing biological samples you give (e.g. blood samples)
- Information about you held in NHS databases managed by NHS Digital
- Your contact details in the form of your email address, if you ask to complete questionnaires electronically (1)

Your information will be collected by the Clinical Trials Research Unit at University of Leeds (https://ctru.leeds.ac.uk/), who are running this study. The University of Leeds will have overall responsibility for how your information is used in this study, including making sure that all information is kept secure. (2)

We will keep all your information secure at all times. (3) The only people at the University of Leeds who will see your information are the people who need to run or analyse the study, or check how the study has been run. (4)

We may use the study information for additional research projects within the University of Leeds. We will only do this for worthwhile research projects with all appropriate ethical approvals. If people outside the original study team are involved, they will only receive the minimum information needed for the new project, and they will not receive any clearly identifiable information (such as your name). (5)

We will sometimes need to share your information with people outside the University of Leeds. This is so that we can run the study, keep you and others safe, comply with laws and other rules around research, and support further research in the public interest. We will never sell your information or pass it on to people who will sell it. Information that we share will never be used to make decisions about future services available to you, such as insurance. (5)

You can usually ask organisations to give you a copy of information they hold about you, or to correct your information. However, this does not apply when your information is used for research in the public interest like this, because allowing you to access or change the information could harm the quality of this research. Your contact details are different though - it's vital that you tell your study doctor or nurse if these change at any point. (6)

To comply with laws and other rules about research, we need to keep your identifiable information until at least 25 years after the study has finished. (7)

You can usually ask organisations to delete your information or restrict how your information is

used. However, allowing you to delete or restrict your information could harm the quality of this research, which is being done in the public interest. If you stop taking part in the study, we will therefore need to keep the information we already have about you. (8)

If you decide to stop attending your study visits for any reason, we will keep collecting information from any other hospital visits you have, if they are relevant to the study. We will also keep collecting information about you from NHS Digital or other central UK NHS bodies. This way you can keep contributing to the study without giving any more of your time, if you want to. If you are not happy with this, you can ask us to stop collecting more information about you at any time. If you tell us you want us to stop collecting your information, we will still be legally required to collect information about any serious side-effects you may experience. (8)

If you have questions or concerns about how your information is used that aren't answered by this document or by talking to your study doctor or nurse, you can contact the University of Leeds Data Protection Officer. If you are still not happy, you can contact the Information Commissioner's Office. You can find out how to contact these people in the **optional appendix 4** and the **comprehensive guide**. For any questions or concerns that are not to do with how your information is used in this study, please contact your nurse or doctor as you usually would. (9)

Appendix 1: Possible side effects caused by ibrutinib

As with any drug treatment, the ibrutinib used in the STATIC trial is associated with side effects and you may experience some of these. We do not expect you to have all of these side effects, and we cannot predict which ones you might have or how severe or serious they may be. However, it is important that you are aware of known side-effects of the medication and have the opportunity to discuss these with your hospital doctor before you decide whether or not to take part in the STATIC study.

Your hospital doctor and research team will be monitoring you regularly for side effects. It is essential that you tell a member of your trial medical team as soon as possible about any side effects you have as your medical team is experienced in managing these, and may be able to help minimise them. If you have a severe reaction, your hospital doctor may stop the study treatment and recommend alternative options.

Definitions of the medical terms mentioned below are set out in Appendix 2.

Possible adverse reactions related to ibrutinib

Frequency	Adverse reaction
Very common may affect more than 1 in 10 people	Minor bleeding and bruising (**haemorrhage**)
	Bruises (**bruising and/or contusio**n)
	Common cold (**upper respiratory infection**)
	Constipation
	Dizziness
	Fever (**pyrexia**)
	Headache
	High blood pressure (**hypertension**)
	Increase in the number of lymphocytes - a type of white blood cell (**lymphocytosis**)
	Increased levels of creatinine in the blood (a chemical found in the blood that can indicate how the kidneys are functioning)
	Indigestion (**dyspepsia**)
	Inflammation to the tissue of the lungs (**pneumonia**)

	Joint aches (**arthralgia**)
	Loose or watery stools (**diarrhoea**)
	Low platelet count, cells that help with clotting (**thrombocytopenia)**
	Low white blood cell/neutrophil count, cells that help fight infection (**neutropenia**)
	Muscle and bone pain (**musculoskeletal pain**)
	Muscle spasms
	Nausea
	Rash
	Skin infection
	Swelling to hands and/or feet (**peripheral oedema**)
	Swelling to the mouth and/or lips (**stomatitis**)
	Vomiting
Common may affect up to 1 in 10 people	Abnormal heart rhythm stemming from the upper chambers of the heart (**atrial fibrillation**)
	Blurry vision
	Breaking and/or ridging of the nails (**onychoclasis**)
	Cardiac failure
	Change in sensation in the feet or hands such as numbness, tingling, burning, stabbing, loss of balance or muscle weakness (**peripheral neuropathy**)
	Excess of uric acid in the blood (**hyperuricaemia**). Uric acid is a waste product found in the blood that is created when the body breaks down a substance called purines.

	Hives - red, raised or puffy itchy areas of skin (**urticaria**)
	Increase in white blood cell - cells that help fight infection - counts (**leukocytosis**)
	Inflammation of the sinuses (**sinusitis**)
	Sudden decline in the ability of the kidneys to work and function as they normally would (**Acute kidney injury**)
	Low white blood cell counts with fever (**febrile neutropenia**)
	Lung disorders that cause inflammation or scarring of the lungs (**Interstitial lung disease**)
	Nosebleed (**epistaxis**)
	Severe infection throughout the body (**sepsis**)
	Skin cancers including non-melanoma skin cancer, basal cell carcinoma and squamous cell carcinoma
	Skin redness (**erythema**)
	Small red or purple spots caused by bleeding under the skin (**petechiae**)
	Urinary tract infection
Uncommon may affect up to 1 in 100 people	Abnormal heart rhythm stemming from the lower chambers of the heart (**ventricular tachyarrhythmia**)
	Benign growth (tumour) of blood vessels on the skin, especially around the mouth (**pyogenic granuloma**)
	Bleed in the head (**subdural haematoma**)
	Bleeding in the eye (**eye haemorrhage**)
	Heart problem where the electrical system controlling your heart fails (**cardiac arrest**)

	Hepatitis B reactivation
	Liver failure (**hepatic failure**)
	Lung infections (such as cryptococcal, pneumocystis, aspergillus)
	Mini-stroke (**transient ischaemic attack**)
	Painful lumps or nodules that form under the skin (**panniculitis**)
	Skin condition characterised by fever, inflammation of the joints (**arthritis**), and painful skin lesions (**neutrophilic dermatosis**)
	Stroke (**cerebrovascular accident**)
	Swollen face, lip, mouth, tongue, or throat (**angioedema**)
	Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells, which may lead to changes in kidney function, abnormal heartbeat, or seizures (**tumour lysis syndrome**)
Rare may affect up to 1 in 1000 people	Increase in the number of white blood cells causing blockages in the blood vessels (**leukostasis syndrome**)
	Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes, and genitals (**Steven-Johnson syndrome**)

Most of these side effects listed above have been mild to moderate in severity, but severe side effects have occurred. Some side effects have been severe enough to lead to stopping the targeted drug treatment, or modifying or reducing the dose, hospitalisation, disability and sometimes death. This is why it is essential that you notify your medical team if you experience even limited side-effects. Delay in doing so may harm your health.

Appendix 2: Definitions and additional advice

Non melanoma skin cancer and other cancers: Non melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma of the skin) have been reported with more frequency and maybe related to the use of ibrutinib. Other cancers have been reported such as solid tumours and blood cancers, although their relationship to the use of ibrutinib is unknown. You should tell your hospital doctor if you develop a new cancer while in the study

Hypertension: Hypertension is also called high blood pressure and has been commonly reported in subjects treated with ibrutinib. Sometimes, people with high blood pressure may have headaches, dizziness, nervousness, sweating, difficulty in sleeping, facial flushing or nosebleeds, or blackout (loss of consciousness), breathlessness, difficulty breathing when lying down, swelling of the feet, ankles or legs, weakness/tiredness, fluttering heart (palpitations), but in some cases, there may be no symptoms and it may go undetected. After starting ibrutinib, your hospital doctor will measure your blood pressure regularly. You should let your hospital doctor know if you have any of the symptoms of high blood pressure which may mean that you have developed hypertension or that your hypertension is getting worse. Your hospital doctor may adjust existing anti-hypertensive medications and/or initiate anti-hypertensive treatment as appropriate.

Infection: You may experience viral, bacterial, or fungal infections. These may be obvious, such as discolouration of fingernails or toenails. Contact your hospital doctor if you have fever, chills, weakness, confusion, body aches, cold or flu symptoms, feel tired or feel short of breath - these could be signs of an infection.

Bleeding effects: You may experience bruising or bleeding during treatment with ibrutinib. Rarely, serious internal bleeding, such as bleeding in your stomach, intestine, or brain, may occur, sometimes resulting in death. If you take other medicines or supplements that increase your risk of bleeding, such as aspirin, non-steroidal anti-inflammatory drugs (NSAIDs) or medicines used to prevent or treat blood clots or stroke, ibrutinib may increase this risk. Blood thinners such as warfarin or other vitamin K antagonists should not be taken together with ibrutinib. Supplements such as fish oil and vitamin E preparations should be avoided while taking ibrutinib. Call your hospital doctor immediately if you have signs or symptoms of severe bleeding in or around the brain such as sudden severe headaches, weakness in the arms or legs, difficulty speaking or understanding speech, or loss of balance. Also, call your hospital doctor if you have signs or symptoms of serious bleeding, such as blood in your stools or urine or bleeding that lasts for a long time or that you cannot control.

Effects on the heart:

Treatment with ibrutinib may have an effect on your heart. These side effects are more likely to happen if you already have heart diseases such as rhythm problems, heart failure, high blood pressure, have diabetes or are of advanced age. The effects may be severe and could cause death, including sometimes sudden death.

Your heart function will be checked before you join STATIC and will be monitored at your regular follow up visits within the STATIC study in the form of regular blood pressure and pulse checks at each of your CLL clinic visits.

The following side effects are commonly reported (may affect up to 1 in 10 to 1 in 100 people):

- heart failure
- missed heart beats, weak or uneven pulse, light-headedness, shortness of breath, chest discomfort (symptoms of heart rhythm problems (atrial fibrillation and/or atrial flutter)).

The following side effects are uncommon (may affect up to 1 in 100 people):

- cardiac arrest (heart stops beating)
- abnormally fast heartbeat (ventricular tachyarrhythmia, which includes ventricular fibrillation).

You should tell your hospital doctor/ CLL treatment team about any side-effects you are having. Tell your hospital doctor/ CLL treatment team immediately if you experience any of the following:

- breathlessness
- difficulty breathing when lying down
- swelling of the feet, ankles or legs
- weakness/tiredness
- fluttering heart (palpitations)
- dizziness or blackout (loss of consciousness)

Please also tell them if you have visited your GP about high blood pressure.

Abnormal heartbeats (**atrial fibrillation** and/or **atrial flutter**) have also been reported in patients treated with ibrutinib.

If you experience any of these symptoms mentioned about it may suggest you are experiencing abnormal heart rhythm and you should tell your hospital doctor immediately and seek their advice.

Effects on blood pressure: Sometimes, people with high blood pressure may have headaches, dizziness nervousness, sweating, difficulty in sleeping, facial flushing or nosebleeds. If you have any of these symptoms, please tell your hospital doctor/ CLL treatment team. Please also tell them if you have visited your GP about high blood pressure.

Within the STATIC study you should have regular heart monitoring in the form of regular blood pressure checks at each of your CLL clinic visits. If your blood pressure is high, your CLL doctor should refer you to your GP to assess if you should be given a drug to lower your blood pressure, or if your existing blood pressure drug should be changed if you are already taking one.

If you check your own blood pressure and your blood pressure is regularly 140/90mmHg or higher, it is important that you tell your hospital doctor/ CLL treatment team and your GP.

Decreased blood counts: Severe decreases in white blood cells, red blood cells, and platelets (neutropenia, anaemia, and thrombocytopenia) were reported in subjects treated with ibrutinib. If you experience symptoms such as fever, weakness, or easy bruising and/or bleeding, you should tell your hospital doctor immediately.

Rash: A maculopapular rash (flat, red areas on the skin with small bumps) has been commonly reported in patients treated with ibrutinib alone or in combination with other drugs. Most rashes are mild to moderate in severity and begin 2-3 weeks or longer after starting ibrutinib. There have been rare reports of severe skin reactions (known as severe cutaneous adverse reaction or "SCAR", involving more than 50% of the body) or rash with blisters and peeling skin, which may include open ulcers or sores in the mouth and other areas (Stevens-Johnson Syndrome). This could be life-threatening. You should notify your hospital doctor immediately if you develop a rash that spreads quickly, or if you notice peeling of your skin, with or without ulcers or sores in your mouth.

Tumour Lysis Syndrome (TLS): Tumour Lysis Syndrome (TLS): Unusual levels of chemicals in the blood caused by the fast breakdown of cancer cells have happened during treatment of cancer and sometimes even without treatment. This may lead to changes in kidney function, abnormal heartbeat, or seizures. Your hospital doctor may do blood tests to check for TLS.

Liver failure: Rare cases of liver failure have been reported in patients treated with ibrutinib. Symptoms of liver failure include yellowing of the eyes and skin (Jaundice), itching of the skin, dark coloured urine, grey or clay-coloured stools, confusion, nausea, loss of appetite, fatigue or diarrhoea. You should tell your hospital doctor immediately if you have any of these symptoms which may suggest liver disease.

Interstitial lung disease: Interstitial lung disease is a group of lung disorders in which the tissues become inflamed and may become damaged. Interstitial lung disease is not associated with infections (e.g., bacteria, viruses, fungi) and has been reported in patients treated with ibrutinib. You should report to your hospital doctor if you have cough, any signs of new or worsening respiratory symptoms such as shortness of breath or difficulty breathing.

Splenic rupture: A burst spleen (**splenic rupture**) has rarely been reported in patients after they stop taking ibrutinib.

Haemophagocytic lymphohistiocytosis (HLH): HLH is a rare immune disorder where the body reacts inappropriately or overreacts to a 'trigger', such as an infection, an immune disorder or a malignancy. HLH can be life threatening. HLH is characterised by fever, enlargement of the liver and spleen and characteristic abnormalities in blood test.

Ibrutinib interruption for any surgical procedures: Ibrutinib may increase the risk of bleeding with any medical procedure where bleeding might occur. This includes major and minor surgery, including some dental surgery or procedures. Ibrutinib should normally be withheld at least 3 to 7 days before and after any medical procedure with a risk of bleeding. Please contact your hospital doctor if you have any planned procedures that carry a risk of bleeding.

For operations and procedures, ibrutinib should be stopped after the procedure until signs of healing after the operation. Please contact your hospital doctor as soon as possible and your hospital doctor will tell you when to stop ibrutinib and when to restart it following a medical procedure with a risk of bleeding.

If you do decide to take part in the study, you may have all, some, or none of the side effects listed above. Your hospital doctors and nurses will check you closely for side effects and you must report any problems you have to your hospital nurse or doctor. There is also a contact number given at the end of this information sheet for you to phone if you become worried at any time. You may receive medicines of other treatments to prevent or reduce some of the side effects. In the unlikely event of an emergency occurring during the conduct of the study, we may contact your nominated next of kin.

Appendix 3: Lifestyle guidance, Do's and Don'ts

Whilst you are still receiving ibrutinib you should discuss foreign travel with your hospital doctor beforehand.

Ibrutinib can increase the risk of bleeding if you have minor surgery or other medical procedures. You will need to make sure that you tell any doctors treating you for other conditions that you are being given ibrutinib as part of a clinical study.

When taking ibrutinib, you should avoid certain medications that thin the blood (anticoagulants). If you doctors thinks that you need to take any anticoagulants, please contact your hospital doctor first as they may need to adjust your dose of ibrutinib.

Some foods and medicines may interfere with the way your body processes ibrutinib. This interference could cause the amount of ibrutinib in your body to be higher or lower than expected. It is very important that you tell your hospital doctor about any medicines, supplements, or herbal medicines that you are taking now or during the course of the study.

Whilst you are taking ibrutinib, you should avoid the following:

Foods to avoid:

Grapefruits and grapefruit juice

Seville oranges (including marmalade)

Starfruit

Medications that should be avoided if possible:

Fish oil	Rosuvastatin
Vitamin E	Pitavastatin
Clarithromycin	Pravastatin
Carbamazepine	Simvastatin acid
Diltiazem	Ketoconazole telithromycin
Erythromycin	Itraconazole
Verapamil	Nefazodone
Amiodarone	Cobicistat,
Citalopram	Voriconazole and posaconazole
Haloperidol	Indinavir
Warfarin or other anticoagulants, including novel anticoagulants	Nelfinavir
	Ritonavir
Atorvastatin	Saquinavir

If your doctor thinks that you need to take any of the medications listed in the table above, then it is important that you or your doctor contact your hospital doctor beforehand as your hospital doctor might want to change your dose of ibrutinib and additional monitoring, such as further blood tests and observations, may be required. Be sure to tell your hospital doctor or study staff immediately about any side effects to avoid possible harm.

Optional Appendix 4: more about how your information will be used

This optional extra section of this patient information sheet is about how your information will be used if you agree to take part in this study. It gives you more detail than the quick access guide on page 15. It is in the same order as that, so that you can easily find what you need. If you have questions or concerns after reading the quick access guide, you should look at this optional appendix, or the sections of it that interest you.

If you still have questions after reading this appendix, or would like more detail about anything, you should look through our comprehensive guide to how your information is used. You do not have to read it before taking part in this study, but you might want to look at specific sections if you have particular concerns. It is available at https://ctru.leeds.ac.uk/ctru-comprehensive-privacy-guide/ or you can ask for a printed copy from your study doctor or nurse. This can also be made available in large print or other formats, if you need them.

You should read through these sections as much as you would like to. After doing that, if you are interested in participating in the study, you can find the informed consent form at the end of this document.

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

If you agree to take part in this study, we will need to collect and use some information about you and your health. We will only use what we need to run the study, to produce the results of the study and to make sure you and other people taking part in the study are safe.

This research is in the public interest, which means our results will be used to improve the healthcare of patients in the future. Because of this, if you agree to take part in the study, we will be able to use information about you, including sensitive information about your health.

Specifically, the ways we will use information about you are:

- We will use information from you and your medical notes to run the study, to produce the study results and to confirm it is safe and appropriate for you to join the study. We will also collect information about your health from your study doctor or nurse and your medical notes to help make sure you and others are safe.
- We will collect a copy of your signed consent form so that we can be sure you have agreed to take part in the study.
- We will collect information about you and your health directly from you on study questionnaires. We will use this information to produce the study results.
- We will collect information about you held in NHS databases managed by NHS Digital or other central UK NHS bodies. To do this, we will securely send date of birth and NHS

number or CHI number for Scotland to NHS Digital or other central UK NHS bodies, and they will return the information about you that we need for the study. We do this because it means we can do the study while taking up less of your time, and less of your hospital's time.

- We will collect information about biological samples (blood and, if you are in the randomisation trial and consent for additional samples to be collected for the UK CLL Biobank, saliva) you will give in the study. These samples will be sent to HMDS with name, initials, date of birth, sex, NHS (National Health Service) number/CHI (Community Health Index) number and study number. Samples sent to the UK CLL biobank, for those who have consented, will include your NHS number/ CHI number, patient trial number, NHS number, sex, initials, and date of birth
- The results of some of the sample analyses conducted by HMDS will be sent back to your hospital, so we need to be absolutely sure that the results are for you and not for someone else. For this reason, these samples sent to HMDS will be sent with your name attached.
- If you agree for surplus material to be stored for future research, these will be sent and retained in your hospital pathology lab and HMDS. If other researchers in the future want to use the samples for worthwhile research in the public interest, they will be sent the samples and your unique study identification number. The other researchers may also ask us for other information about you for their research (see section 5, below), but they would not 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.
- Sometimes we need to ask doctors who work with us to give us advice on specific medical situations. To help the doctors do this, we might need to collect copies or scans of parts of your medical notes. These will have any details that could identify you removed before they are sent to us.
- If you join this study, and agree to complete electronic questionnaires, we would like to send you study questionnaires and reminders to complete the questionnaires. To do this, we will need to collect your email address. You can choose whether you wish to complete paper or electronic questionnaires, we will not require your email address if you complete paper questionnaires, and will only use it for the purposes mentioned here.

If you want to find out more about any of these, please refer to the comprehensive guide to how your information is used.

Who is collecting my information?

Your information will be collected by 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/.

University of Leeds has overall responsibility for what information is collected, how it is collected, and making sure people's information is used securely and correctly. If you want to contact someone within the University about how your information has been or will be used, you can see section 9, below. See the **comprehensive guide** for more about what this means for you.

We will make sure we follow the principles of data protection in everything we do. This means we will keep your information secure, keep it only for as long as we need it, only use the minimum information we need for specific, necessary purposes, and we will be open, transparent, and fair with you about how we use your information. You can find out more about how we follow the principles of data protection in the **comprehensive guide**.

Will my information be kept secure?

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

Your study doctor or nurse will enter most of the information needed for the study directly into our secure study database. Your study doctor or nurse will also send us your completed consent form or questionnaires by post. This will be sent separately to any other study forms. If you choose to complete paper questionnaires at home, you will be given envelopes and postage to post them back to the CTRU.

Sometimes we will also get information about you by email. Emails will never contain your name, only your trial identifying number and sometimes your initials and date of birth.

Finally, some particularly sensitive documents, such as your consent form, will be sent to us via a 'secure file transfer'. This means information is sent by the internet in a very secure way.

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.

Who will see my information in the research team?

We will make sure that the only people at the University of Leeds who can see your information are people who need to run or analyse the study.

See section 4 (pg 8) of this information sheet for more on who may see your medical notes and other confidential information if you agree to take part in this study.

Who else will see my information?

There are some specific situations where 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 information that could identify you whenever possible. We will never sell your information or pass it on to people who will sell it. We will only share information when it is necessary for the study, necessary to protect your safety or the safety of others, or in the public interest. Information we share will not be used to make decisions about future services available to you, such as insurance.

We will share your information for the following reasons. You can find out more about these in the **comprehensive guide**.

- To run and analyse parts of the study, we need to share your information with collaborators (such as doctors, statisticians, or other experts) outside the University of Leeds.
- To obtain additional information from your medical records, we need to share your information with NHS Digital or other central UK NHS bodies. They will send us information about you that we need for the study. This is an important way we can do the study while saving time and money for you and for the NHS.
- To keep you and other people safe, we will need to share some information about health-related events you may have with authorised organisations. None of these organisations will be able to identify you from this information.
- To report to authorised people about the progress of the study, we will need to share some basic information with some authorised organisations, including the Research Ethics Committee that has approved this study. None of these organisations will be able to identify you from this information.

- To allow other researchers to carry out future research in the public interest. We will only share your information for worthwhile research with all appropriate approvals. We will only share your information in such a way that researchers outside the University of Leeds will not be able to identify you. Your information will not be shared if you have explicitly said you did not want this to happen.
- We may also use study information for additional research projects within the University of Leeds. We will only agree to do this for worthwhile projects with all appropriate approvals, and we will not share any clearly identifiable information with researchers outside the original study team.
- Due to storage space limitations, we will store information securely away from the University of Leeds for a period after the main part of the study is over. The archiving companies we use to do this for us will only store your information and will not access it or see your details.

See section 4 (pg 7) of this information sheet for more on who may see your medical notes and other confidential information if you agree to take part in this study.

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

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, this does not apply in the same way to information used for research in the public interest, because allowing people to access or change their information could harm the quality of the research. You therefore cannot ask to access or correct information we have about you. However, most of the information we will collect will also be in your medical notes, which you can get access to if you want to. You should speak to your study doctor and nurse if you would like more information about care you have received.

If you have provided us with contact details for use in the study (email address) it is important that we find out about any changes to these. Please let your study doctor or nurse know about any changes so that they can let us know. Otherwise, we might lose contact with you or send messages for you to your previous contact details.

How long will my information be stored for?

If you agree to take part in this study, we will need to keep your information for at least 25 after the end of the study. We need to do this in order to comply with laws and other rules about research, which say it must be possible to check the results of the research for a period of time after it has finished. We will keep your information secure during all this time. For practical reasons, we may ask reputable archiving companies to store information securely on our behalf, away from the University of Leeds.

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

What will happen if I stop taking part in the study?

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

Usually, when an organisation or a company has information about you, you can ask them to delete it, or not use it for a certain purpose. However, this does not apply in the same way to information used for research, because it would harm the quality of the research if people could delete or remove their information. We also need to comply with laws and other rules about research that say we need to keep all information used in research for a period of time after the research finishes. If you agree to take part in this study, it will therefore not be possible for us to remove or delete your information later on, although you can ask us to collect no further information after a given time.

Some other things you should know about what will happen to your information if you stop taking part:

- If you stop all study visits, you should discuss with your study doctor and nurse. If you still occasionally go to your hospital for routine visits, we would like to hear from your study doctor or nurse about these visits, if they are relevant to this study. This way, you can still contribute to the study and help make the study results more reliable, without giving any more of your time. However, you can tell your study doctor or nurse that you do not want any more information sent to us, and they will make sure your wishes are respected.

- In this study we will get some information from your electronic medical records held in NHS databases by NHS Digital or other central UK NHS bodies. If you ask to stop your study visits, we will continue doing this. Again, this means we can make sure the results of the study are reliable, without you having to give any more of your time. However, you can tell your study doctor or nurse at any time that you would like us to stop doing this, and they will make sure your wishes are respected.
- If 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.
- If you stop attending your study visits without telling anyone at your hospital, or you change your contact details or move house and do not tell your hospital, they will lose contact with you. If this happens, 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.

If you want to know more about what might happen to your information if you stop taking part in the study, including why we need to use your information in the ways we do, please see the **comprehensive guide**.

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

Your study doctor or nurse should be your first contact for any questions about your participation in this study. If you still have questions that they cannot answer, and which are not answered by any of these documents, you can contact the University of Leeds Data Protection Officer (the University's main contact for anything to do with how your information is used). You can do this using any of the details below. If you do contact them, please mention the name of this study STATIC and the Clinical Trials Research Unit.

- Email: DPO@leeds.ac.uk
- Telephone number: +44 (0)113 243 1751
- Postal address for data protection issues: University of Leeds, Room 11.72 EC Stoner Building, Leeds, LS2 9JT

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

- General website: ico.org.uk
- ICO contact webpage: 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

Delete this line, then print on Trust/Hospital headed paper

Participant ID:	Initials:
Date of Birth:	NHS/CHI/Hospital Number:
EudraCT Number: 2021-005854-27 ISRCTN: 51675454	Principal Investigator:

STATIC FRONT-LINE PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

FOR FRONT LINE PARTICIPANTS ENTERING THE STATIC TRIAL AFTER FLAIR OR IcICLLe:

PARTICIPANT INFORMED CONSENT FORM

	Please initial for each statement
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	_ _ _ _ Initials
2. I understand that my participation in this study is voluntary and that I am free to withdraw at any time without my medical care or legal rights being affected. I understand that even if I withdraw from the above study, the data and samples collected from me will be used in analysing the results of the study and in some cases further information about any unwanted effects of my treatment may need to be collected by the study team.	_ _ _ _ Initials
3. I understand that my healthcare records may be looked at by authorised individuals from the study team, regulatory bodies, or Sponsor in order to check that the study is being carried out correctly.	_ _ _ _ Initials

4. I agree for my details (which will include my name, date of birth, NHS number) to be submitted to NHS Digital, and Public Health Scotland so that information about my health status may be obtained by the Leeds Clinical Trials Research Unit (CTRU).	_ _ _ _ Initials
5. I understand that some of my data may be passed to other organisations, such as the pharmaceutical company Janssen, (possibly in other countries where the data protection standards and laws may be different from the UK) to monitor the safety of the treatment(s) that I am receiving. I understand that my identity will remain anonymous.	_ _ _ _ Initials
6. I understand that my data and results of my laboratory tests (from blood sample collections) may be shared with other research teams if I am taking part in another clinical study being run by the University of Leeds.	_ _ _ _ Initials
7. I agree to a copy of this Consent Form being sent to the Leeds CTRU.	_ _ _ _ Initials
8. I agree that my GP, or any other doctor treating me, will be notified of my participation in this study.	_ _ _ _ Initials
9. I agree to take part in the STATIC trial.	_ _ _ _ Initials
<u>QUESTION FOR ALL FLAIR PATIENT'S ONLY:</u>	
10. I agree for data and results collected from the FLAIR trial to be shared with the STATIC research team for the purpose of the STATIC trial.	_ _ _ _ Initials

The following points are OPTIONAL.

Even if you agree to take part in this study, you do not have to agree to this section.

Please initial in box

	Yes*	No
If I am able to take part in the randomisation trial, I give permission for additional blood samples to be collected and sent to the UKCLL Biobank and used as part of the research for the study. *If yes once eligibility is confirmed complete the CLL **Biobank PIS and Informed consent document**	☐	☐

	Yes	No
I give permission for long term follow-up survival data to be collected from NHS Digital or other central UK NHS bodies after the study is complete. I agree for my details (which will include date of birth and NHS number or CHI number for Scotland) to be submitted to NHS Digital or other central UK NHS bodies in order to obtain this information.	☐	☐

	Yes	No
I give permission for surplus material from samples collected from my cancer that have been stored in the hospital pathology laboratory to be retrieved and used in the future for CLL cancer research that receives ethical approval. I understand that my samples and data collected from them may be shared on a collaborative basis with researchers in the UK and, potentially, centres abroad.	☐	☐

	Yes	No
I give permission for surplus material from samples that I provide to be used in future research that receives ethical approval. I understand that my samples and data collected from them may be shared on a collaborative basis with researchers in the UK and, potentially, centres abroad.	☐	☐

Patient:

Signature……

Name (block capitals) ……

Date……

Investigator:

I have explained the study to the above named patient and he/she has indicated his/her willingness to participate in the randomised pathway of the STATIC trial.

Signature……

Name (block capitals)……

Date……

(If used)Translator:

Signature……

Name (block capitals)……

Date……

(1 copy for patient; 1 for the CTRU; 1 held in patient notes, original stored in Investigator Site File)