(To be printed on local headed paper)

Stereotactic Body Radiotherapy for the Treatment of Oligo-Progressive Disease

PATIENT INFORMATION SHEET

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ICR The Institute of Cancer Research

CANCER RESEARCH UK

INVITATION TO TAKE PART IN A RESEARCH STUDY

We would like to invite you to take part in a research study called HALT.

Before you decide if you would like to take part it is important that you understand why the research is being done and what it will involve for you if you take part. One of your doctors or nurses will go through this information leaflet with you and answer any questions you may have or explain anything you don't understand.

Please take the time to read the information carefully and discuss it with your family, friends and your GP if you wish.

It is entirely up to you whether you want to take part or not. If you decide not to take part this will not affect the care you get from your own doctors in any way.

HALT is a clinical trial that is being run to see whether a certain type of radiotherapy, called **stereotactic body radiotherapy (SBRT)**, which targets radiotherapy very precisely at cancer cells, may help increase the length of time patients with some forms of advanced lung cancer benefit from their current treatment with drugs called **tyrosine kinase inhibitors (TKIs)**.

This information sheet contains information about the trial, why we are running it and what we hope to find out as well as information about what it will involve for you if you decide to take part.

Please read Part 1 of this leaflet fully. If you are interested in the study and wish to find out more then please continue to read Part 2 before making your decision to take part in this trial. A glossary can be found at the end of this leaflet, which may help you when reading the information.

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HOW TO CONTACT US

If you have any questions about this trial please talk to your doctor or nurse:

<local name and contact number>

PART 1- About the HALT trial

1. What is the purpose of the study?

Some patients with lung cancer can develop changes in the structure of some of their genes. These changes are called **mutations** and can be the driver of their disease. We know that mutations can occur, for example, in the **EGFR** (epidermal growth factor receptor) or **ALK** (anaplastic lymphoma kinase) genes and patients who have mutations in these genes respond better (compared to people without the mutation) to drugs called **Tyrosine Kinase Inhibitors** (TKIs) rather than to standard chemotherapy.

TKIs are used to control or stop the spreading of cancer however, they eventually stop working and the existing sites of cancer either get bigger and/or spread to other places in the body. When this happens, the cancer is said to be 'progressing'.

HALT is looking at a treatment called **stereotactic body radiotherapy (SBRT)**. We want to see whether the use of this treatment can help increase the amount of time a patient benefits from TKI therapy.

2. What is Stereotactic Body Radiotherapy (SBRT)?

Radiotherapy involves the use of targeted beams of high energy X-rays to kill cancer cells. Radiotherapy cannot tell the difference between cancer cells and normal cells and your medical team carefully plans the treatment so that only the cancer and as few normal cells as possible receive the highest dose of radiotherapy.

SBRT is a way of targeting radiotherapy very precisely to the cancer using lots of beams at different angles to ensure that a very high radiation dose is given to the cancer and as low a dose as possible is given to surrounding healthy tissues.

3. Why am I being invited to take part?

You are being asked to take part today because:

- Some of your cancer cells have a mutation that can be targeted with TKI therapy.
- Your cancer has initially responded well to TKI therapy but now some of the cancer cells have stopped responding to the TKI therapy and your cancer has progressed.
- Your cancer has only progressed at a small number of sites (5 or less at any one time). This is called **oligo-progression** or **oligo-progressive disease (OPD)**

HALT will look to see if, by targeting the small number of OPD sites with SBRT, the length of time patients' benefit from TKI therapy will be longer.

4. Do I have to take part?

No, you do not have to take part; it is up to you to decide. If you do want to take part you will be asked to sign a consent form and you will be free to withdraw at any time, without giving a reason if you don't want to. This will not affect the standard of care you receive.

5. What will happen if I decide to take part?

If you decide you would like to take part in the HALT study we will give you this information leaflet to keep and you will need to sign a consent form to record your agreement to participate. Before you are able to take part, you will need to undergo some tests. Most of these are routine but others are needed to check that it is safe for you to take part and that the study is right for you.

These assessments will only be carried out after you have agreed to take part. They may all be performed in one visit or over a number of visits, and your doctor/nurse will discuss this with you in more detail.

These assessments and tests will include:

- Medical history and any current medications you are taking
- Physical examination including blood pressure, height and weight
- Blood tests to confirm you are able to undergo SBRT safely
- A pregnancy test (where appropriate)

Brain CT with contrast or brain MRI

Everyone will need to have a scan of their brain to see if there are any cancer lesions there before they can continue in the trial. This will be either a **CT or MRI of the brain** and will often involve an injection of a small amount of contrast dye into a vein, which allows the brain to be visualised more easily. In some cases you may have had cancer in the brain previously that had been treated and remains stable. If this is the case you may still be eligible to enter the study, you will be able to discuss this with your doctor. If any new cancer lesions are found in the brain, and your doctor thinks these are treatable with either surgery or stereotactic radiotherapy then you would have treatment to the brain first (arranged by your own hospital not within the trial), before entering into HALT. If the cancer lesions are not treatable with surgery or stereotactic radiotherapy your doctor will discuss further treatment options for you as this trial will not be suitable for you.

DMSA scan

Depending on where your cancer has progressed, it may mean your kidneys will receive a high dose of radiation during the SBRT treatment. It is important to find out if your kidneys are functioning properly before delivery of any SBRT. To do this a scan called a **DMSA scan**, which stands for dimercaptosuccinic acid (DMSA), may be performed depending on your hospital's standard practice. Not everyone will receive this type of scan and your doctor/nurse will discuss this in more detail with you.

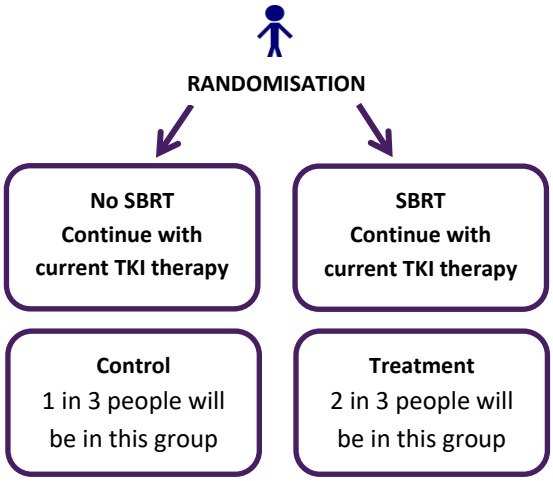
Further details about the types of scans you may receive in this study can be found in the Imaging section on page 10.

The following tests may also be needed depending on where in your body your lung cancer has progressed:

- If your cancer has progressed in the liver – blood tests will be carried out to find out how your liver is functioning and whether there is any existing liver damage. Your kidney function will also be looked at to make sure this is working well before any SBRT treatment is given.
- If your cancer has progressed in other areas of the **lung** – lung function tests will be carried out.
- If your cancer has progressed in a **spinal bone** - an MRI of the whole spine will be carried out. More information about what is involved in an MRI scan is provided below.
- If your cancer has progressed in an **adrenal gland** – blood tests will be carried out to check the adrenal gland is functioning and your kidneys are working well.

Trial Treatment

Once all the tests are complete and you are able to take part in the trial, the treatment you will receive will be decided. This will not be decided by you or your doctor or any other person. The choice is made at the time you enter the study and is made at random (by a computer). This process is called **randomisation** and it is the best way to make sure that the patients in each treatment group are as similar as possible. If one group does better than another group it is more likely to be because of the treatment and not because patients in one group are somehow different from those in the other group.



In HALT, for every **ONE** patient in the control group **TWO** patients will be randomised to the SBRT group. This is so that as many people as possible can have SBRT treatment. But to be able to say if one treatment is better it has to be compared with patients who don't receive the SBRT, so patients in the control group will not receive any SBRT. All patients, whatever group they are in, will continue the TKI therapy they receive as part of their standard care.

Whichever group you are randomised to, everybody who takes part in the trial will receive the best possible care and regular monitoring by his or her clinical care team.

Control Group

If you are randomised into the control group you will continue with your standard treatment, TKI therapy, as previously.

SBRT Group

If you are in the SBRT group, you will have some additional procedures and visit the hospital more frequently at first. More information about this is given below in the Section 'What do I have to do before my SBRT treatment' on page 7.

Follow-up visits

Patients in both the control and SBRT groups will need to come back for a clinic visit 8 weeks after they start the trial so that the research team can find out how you are. After this you will need to return to clinic every 3 months for further follow up as per usual care.

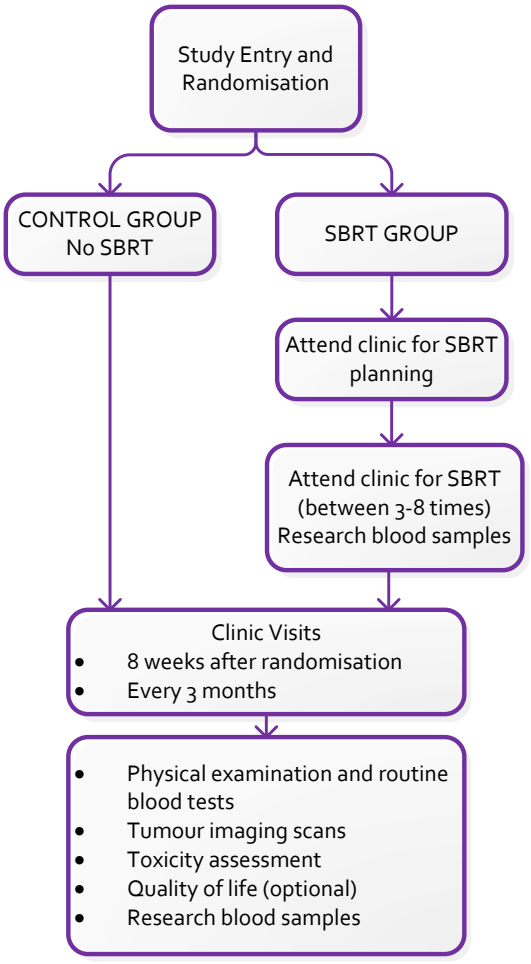
At these visits the following assessments will be performed:

- Physical examination and routine blood tests
- Toxicity assessment to find out if you are having any adverse reactions to the treatment you are receiving.
- Tumour imaging assessment to check the status of your disease. The types of scans you have at your follow up visits will depend on your hospital's standard practice. In most cases this will be either a CT scan or a PET/CT scan. But depending on where your cancer has progressed this could also involve further brain scans or scans of your spine.
- Blood samples for research

If you have agreed to participate in the Quality of Life study, questionnaires will also need to be completed at your 8 week visit and your first 3 month follow-up visit.

More information about the Quality of Life and Research Sample sub-studies can be found in Section 7 'Will I be asked to do anything else?' on page 8.

This flow chart shows the visit time points and assessments to be conducted as part of the HALT study:



You will continue to attend regular clinic visits every three months until your doctor thinks you should stop your TKI therapy and change to a different treatment.

After this the research team will collect information on how you are doing and what treatments you are receiving but you will not undergo any further HALT assessments.

6. What will happen if I receive SBRT treatment?

What do I have to do before my SBRT treatment?

Your SBRT treatment is designed specifically for you and has to be carefully planned by your cancer specialist and other specialised staff at the hospital (radiographers, physicists). For some patients 'markers' will need to be placed within or around the tumour. The markers, called fiducial markers, show up clearly on X-rays and CT scans and help us to see exactly where the cancer is located. Inserting the markers is very similar to having a biopsy and it will allow us to give treatment very accurately. Your doctor will tell you if you need this procedure before your SBRT. More information about these markers is provided in Section 8 'Fiducial marker side-effects' on page 11.

Before you receive SBRT you will need to have a radiotherapy planning scan. This will take place at the radiotherapy department and will take about 30 minutes. It will involve a CT scan being taken of the sites to be treated and you may in some instances also have an MRI scan depending on where your cancer has progressed. These procedures will allow measurements to be taken that are needed for planning the treatment, including the location of the tumour and the normal organs and tissue surrounding it. It is important that the position you lie in during your planning scan is the same position you are in when having your SBRT as this will help to make sure that we are treating the cancer cells very accurately at each treatment. In some circumstances you may be given an immobilisation device to use and your doctor will provide information on this.

To ensure that the SBRT treatment delivered in the trial is safe and the same for all patients taking part in the trial the National Radiotherapy Trials Quality Assurance (RTTQA) team will look at the planning scans for all patients randomised to receive SBRT. This will involve the research team at your hospital uploading the scans to a central, digital 'platform' which has been developed by Quality Assurance experts at the European Organisation for Research and Treatment of Cancer (EORTC). All data that is uploaded to the EORTC QA platform will have all patient identifiable information removed before it leaves your hospital and will be labelled with your unique trial ID.

Access to the EORTC QA platform is restricted so only people working on the HALT trial and the administration team working on the EORTC platform will have access to your information. We ask that

you initial the consent form to show that we have your permission to do this.

The QA team that will review your scans will be made up of members of the HALT trial team and members of the RTTQA team. To ensure that the treatment being planned is safe, the team will need to know if you have received any prior radiotherapy treatment as this will affect whether the trial SBRT can be delivered safely or not.

So along with your scans, information about any previous radiotherapy treatment you have received will also be uploaded to the QA platform. This information will be anonymised so no one will be able to identify you from this. We would ask that you initial the consent form to say that we have your permission to do this.

What do I have to do during my SBRT treatment?

The number of treatments or fractions you will need will depend on where the lesion being treated is located. You can expect to receive treatment every other day or every day. The minimum length of treatment will be 3 treatments given over 5 days. However, you could receive up to 8 treatments given over 19 days per lesion. Your doctor will discuss your treatment programme with you.

Your radiotherapy treatment will be similar to having an X-ray and you will not feel anything. The length of time each treatment will take will depend on the type of machine used at your hospital.

- A **Linac** (Linear Accelerator) machine will deliver the treatment over a few minutes but you will need to lie still for about 20 – 30 minutes whilst the machine moves around the body to deliver the radiotherapy
- A **Cyberknife®** (robotic radiosurgery system) machine will take longer, usually 45-60 minutes but in some cases may take up to an hour and a half.

Once you have completed your treatment you will see your hospital doctor and/or nurse who will assess how you are feeling and if you are experiencing any side effects from the treatment. After this visit you will be seen regularly at 3 monthly intervals as per your usual standard care.

What are the possible side effects of SBRT treatment?

Patients who have SBRT treatment can experience some side effects. No one can predict whether you will experience any side effects and how minor or severe they may be. They are usually mild but can sometimes be more serious. The possible side effects will depend on which part of your body is being treated. You are unlikely to experience side-effects outside the site that was treated with SBRT.

Acute side effects (first few weeks):

- Tiredness
- Shortness of breath and dry cough
- Nausea and / or vomiting
- Temporary worsening of original symptoms
- Skin changes at treated sites

- Hair loss (temporary/permanent)
- Diarrhoea
- Swallowing problems / pain on swallowing

Late side effects (months to years):

- Skin changes at treated sites
- Bone fracture
- Chest wall pain / rib fracture
- Reduction in breathing capacity
- Liver impairment
- Kidney impairment
- Small risk of serious bleeding
- Small risk of late swallowing problems
- Small risk of damage to the gut
- Small risk of damage to heart function
- Small risk of nerve damage
- Small risk of spinal cord injury

If you experience any side effects or feel unwell then you should contact your study doctor as soon as possible to let them know.

7. Will I be asked to do anything else?

Quality of Life Study

One of the reasons we are carrying out the HALT study is to see if patients have any side effects from SBRT. If you decide to take part in the study we would also like you to take part in the Quality of Life Study. We would like patients in both the control or SBRT groups to take part and this will involve you completing questionnaires to describe any side effects that you may experience.

If you agree, we will ask you to complete a total of three questionnaires: one before you are randomised, one at 8 weeks and one 3 months later. Each questionnaire should take no longer than 20 minutes to complete. The Quality of Life study is optional so you don't have to take part if you don't want to and you can still take part in the HALT trial.

Tissue Collection Study

If you agree to take part in HALT, we will ask you to donate blood and tumour tissue samples which we will use as part of the trial to find out more about the effects of SBRT.

Blood Samples - We ask that all patients who take part in the trial consent to the collection of blood samples. Samples will be taken at the start of the trial and then again 8 weeks later. For patients receiving SBRT treatment we would also like to take blood samples after your first fraction of SBRT. After this, we will need to take blood from all patients at your first and second 3 monthly clinic visits. If your cancer progresses again we would take another blood sample at that point as well.

Optional tumour samples - We would also like to ask you to donate samples of your tumour tissue. This is optional and will involve the use of **archival tissue** taken from the tumour sample which was used to confirm your cancer diagnosis or at another time point prior to starting the study. This will already

be stored in the pathology department of your hospital and will not require any additional tissue to be taken from you. We would also like to ask for **fresh biopsies** from sites of further disease progression although we understand this is not always possible. This will be entirely optional and you will only be asked if your clinician thinks it is appropriate and your tumour was in a suitable location to biopsy. If you didn't want to donate fresh tumour tissue you can still take part in the HALT study.

8. How to decide whether to take part in the study?

What are the possible benefits and disadvantages to taking part?

There is no guarantee that you as an individual will benefit directly from taking part in this study. The aim of HALT is to find out whether there is any benefit to patients with OPD from receiving SBRT in addition to TKI therapy as this is not currently known. The information gained from this study may help in the treatment of future patients with cancer similar to yours.

By taking part in this research study you may need to visit the hospital more often than normal, especially if you are in the SBRT group. During this study blood samples will be taken to perform a variety of tests, some for safety purposes and some specifically for research purposes. The number of blood tests required in this study will be more than if you were not taking part in a research study. Risks linked with blood sampling include pain from the needle being inserted, light headedness, possible fainting and (rarely) infection.

Where it is possible and you have agreed to the procedure, a biopsy may be taken from a new site of disease progression. Possible risks, discomforts or inconvenience associated with the collection of biopsies will depend on the location and type of biopsy to be performed. The local anaesthetic you receive before the biopsy procedures will be injected using a syringe and a small needle and may cause a brief stinging sensation. If you have any known allergies relating to anaesthetics these should be discussed with your study doctor. The taking of biopsies may cause some pain, redness, swelling and slight bruising at the biopsy site. There is also a small risk of bleeding, infection and wound healing problems following your biopsy. For lesions within the lung, there is a small risk of lung puncture (pneumothorax) that may require a short hospital stay to treat. You will have the opportunity to discuss all the possible side effects and the type of biopsy your tumour will require with your study doctor.

Imaging

More information about the types of scan you may receive as part of taking part in the HALT study is provided below. Not everyone will have all of these scans and this will depend on where your cancer has progressed in and your hospital's usual practice. This can be discussed in more detail with your doctor/nurse.

CT Scan: CT stands for **computerised tomography** and this type of scan uses X-rays and a computer to create a detailed image of the inside of your body. You may have an injection of a contrast medium dye before the scan. This is a dye that shows up some body tissues more clearly and you have the injection through a small thin tube (cannula) in your arm. Before having the contrast dye your radiographer will ask you about any medical conditions or allergies as some people can be allergic.

MRI Scan: You may receive this type of scan to see if you have any cancer lesions in your brain or if your cancer has progressed in your spinal bones. MRI stands for **magnetic resonance imaging** and this type of scan uses magnetism and radio waves to build a picture of the inside of your body. When having an MRI scan you will be made as comfortable as possible before you start. You will be asked to remain still during the entire procedure. People who are afraid of enclosed spaces may feel anxious or nervous while in the scanner. Some people may also find it hard or painful to hold one position for more than a few minutes. If you have any concerns about having this type of scan you should discuss these with your doctor/nurse.

PET Scan: PET stands for **positron emission tomography** and this type of scan produces a detailed 3 dimensional (3D) image of the inside of your body. PET scans are often combined with CT scans (PET/CT) to produce even more detailed images. A PET scan involves you having a very small amount of radioactive drug injected first. The amount of radiation is very small and does not make you feel unwell; it goes out of your body very quickly. Not everyone will need to have a PET/CT scan and this will depend on your hospital and whether they normally use these types of scans.

DMSA scans: DMSA stands for dimercaptosuccinic acid and a DMSA scan may be performed to find out if your kidneys are working properly before you receive any SBRT. This will involve a small amount of radioactive material being injected into a vein which allows the activity of the kidneys to be calculated. Not everyone who takes part in HALT will need a DMSA scan and this will also depend on your hospital and they type of scans they normally use.

The number and type of scans you receive by taking part in the HALT study may be different to what you would receive if you were not taking part in the study. If you are in the SBRT group you will receive an additional CT scan which is the radiotherapy planning CT scan. You would not receive this scan as part of your normal care if you were not taking part in this study.

Risks associated with CT scans, X-rays or radioactive tracers

As a patient in this study you may be randomised to receive SBRT – a significant ionising radiation dose which wouldn't normally be considered part of the routine care for your cancer. Such ionising radiation can cause cell damage that may,

after many years or decades, turn cancerous leading to another primary tumour. However this radiotherapy is considered standard care for some other patients with similar cancers, and therefore the risks from the radiation dose associated with it may be considered to be similar as that for those other patients.

The radiation dose from the non-therapeutic radiation – the planning CT scans, the verification scans done during the treatment sessions, and other follow-up CT or PET scans (for patients randomised to receive SBRT) will be very small compared to the dose from any SBRT, but will nevertheless also add to the overall risk of participation. For patients randomised to receive standard care TKI therapy (no SBRT), the dose received from the follow up CT or PET scans will be no higher than that received as part of your normal care outside of the trial.

Overall the fatal cancer risk to a healthy 40 year old from the total non-therapy radiation dose involved in this study (for those patients randomised to receive SBRT) could be up to 1 in 40 (or 2.5%), a small increase on the overall lifetime risk of about 1 in 4 (25%). However, due to your pre-existing clinical condition, taking part in this study will not significantly alter the chances of this happening to you.

Fiducial marker side-effects

You may need the use of fiducial markers to help direct the SBRT and this will be discussed with you before your planning visit. The fiducial markers will need to be inserted before your radiotherapy planning scan. The insertion of fiducial markers is similar to having a biopsy and lasts approximately 10-15 minutes. If you experienced a lot of discomfort with previous biopsies your doctors may offer you sedation (or if necessary, general anaesthetic). Markers are inserted with a needle into or near the location of disease with local anaesthetic. This is usually through the skin. You can go home after your procedure. The markers do not interfere with your treatment. Your doctor may give you antibiotics to prevent infection.

For a few days afterwards you may also notice a small amount of discomfort. Please let your doctor or nurse know about any side effects that you are concerned about so they can advise you what to do. Their telephone numbers are at the end of this information leaflet. There is also 24 hour support available from your hospital to provide access to immediate medical care in the event of any serious problems.

Potency and fertility side effects

Men and women may be infertile after radiotherapy, depending on the site treated. If you are still intending to have children please discuss this with your doctor before you receive any treatment. It is important to ensure that contraception is used at all time as radiation may cause abnormalities in sperm and eggs.

Pregnancy

Radiotherapy can be harmful to a developing baby. We would therefore strongly advise against the possibility of pregnancy during SBRT treatment. Appropriate contraception should be used by female patients receiving SBRT during the treatment period. Your clinical team can advise you on appropriate methods of contraception. If you think you may be pregnant please discuss with your doctor before you receive any treatment.

What are the alternatives for treatment?

You and your hospital doctor should have discussed the treatment options available to you. Make sure that you have discussed these with your doctor before deciding whether to take part in this study or not.

This completes Part 1 of the Patient Information Sheet. If you are still interested in participating in this trial please read the additional information in Part 2 before making your decision.

Part 2 – General Information about the HALT trial

The Institute of Cancer Research, sponsor of the HALT trial, will be using information from you and your medical records in order to undertake the study and will act as the data controller for the study. This means ICR are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for 20 years after the study has finished.

1. Confidentiality

Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least 5 years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the General Data Protection Regulation (GDPR).

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency .

[Insert appropriate name for NHS site] will collect information from you and your medical records for this research study in accordance with our instructions.

[Insert appropriate name for NHS site] will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly

confidential. When you join the trial, your full name, hospital number, date of birth, postcode and NHS/CHI number will be passed to The Institute of Cancer Research Clinical Trials and Statistics Unit (ICRCTSU) where the study is being coordinated. You will be given a unique trial ID number, which will be used together with your initials and date of birth on forms that the research staff at your hospital will send to ICR-CTSU. All information about you will be stored securely. It will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this trial ID number to be linked to you.

From time to time we would like to know how you are getting on. Ideally we would like to do this for life, and we would like to use national records, which are kept on everyone's health status to find this out. One of these is held at the General Register Office (GRO). We will need to give them enough information to identify you. This is usually your name, date of birth postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland). Any details we receive from any source are confidential and will only be used for the purposes of the trial. Please initial the consent form to show that we have your permission to do this.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research, the Medicines and Healthcare products Regulatory Agency (MHRA) and ethics committee approving the trial and third parties approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

[Insert appropriate name for NHS site] will keep identifiable information about you from this study for at least 5 years after the study has finished.

Will information about me be shared with other researchers?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only

be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee

Our main privacy policy can be found at https://www.icr.ac.uk/legal/privacy. If you have any questions about your rights under the GDPR or how we use your information please contact our Data Protection Officer at dataprotectionofficer@icr.ac.uk.

2. Blood and tissue sample information

What will happen to any samples I donate?

In the HALT study we ask that all patients consent to provide blood samples for research and to allow the use of some of their initial tumour tissue, taken either at the time of diagnosis or at another time point prior to starting the study, where this is available. We would also like to ask patients to consent to a fresh tumour biopsy if your cancer further progresses whilst in the study. This is optional and will depend on whether it is possible to safely biopsy your progressing lesion. Details of the samples requested are described in Part 1 of this information leaflet. We would ask that you sign the appropriate part of the HALT consent form if you agree to the collection of all or some of these samples.

The samples you donate will be used to help us better understand the effect of SBRT treatment, identify better ways to monitor response to treatment and find out more about your cancer.

The group of medical professionals overseeing the HALT trial will also oversee the sample collection. Your tumour tissue or blood samples may be labelled with your initials and hospital pathology number when they are sent to the research lab. When they arrive at the laboratory they will be coded meaning that your personal details will be removed and replaced with a unique number. By doing this your confidentiality will be maintained whilst still allowing biological information to be compared to treatment findings.

The blood and tumour samples will be stored securely at The University College London Hospital (UCLH) biobank facilities and it is intended that much of the analysis of these samples will happen here. But some of the samples may also be sent to other research institutes (which may be outside the UK) or companies approved by The Institute of Cancer Research for analysis. In all cases your confidentiality will be maintained.

Any tumour and/or biopsy material will be stored at the UCLH laboratories indefinitely and in some cases returned to the local pathology laboratories once the study is complete depending on local

practice. We ask for your permission for possible future research using these samples. Where information from the samples and/or associated data could identify you, the information will be held securely with strict arrangements about who can access and use the information. Any other research using your tissue will first be reviewed and approved by an ethics committee.

3. General information about HALT

What happens if I don't want to carry on with the trial?

Your participation is entirely voluntary. If you agree to take part and then change your mind later on you can withdraw from the study at any time without giving a reason. If you withdraw from the trial it will not affect the standard of care you receive. Your doctor will discuss alternative treatment with you and offer you the most suitable treatment available.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information as possible.

What if there is a problem?

If you have any concerns about any aspects of the study you should ask to speak with your study doctor / nurse who will do their best to answer your questions. Their contact details can be found in Part 1. If you remain unhappy and wish to complain about any aspect of the way you have been approached or treated during the course of this trial the normal NHS complaints mechanisms are available to you. Concerns should be raised by speaking to a member of staff at your hospital or by talking to the local Patient Advice and Liaison Service (PALS), which has been established in every NHS Trust and Primary Care Trust (PCT).

Your progress will be watched closely and you will be offered whatever help is available to cope with any side effects observed. Occasionally some patients need a short stay in hospital for side effects to be treated, and on rare occasions these can be serious. If this were to happen, full details of what has happened will be reviewed carefully by the consultant oncologist who has overall responsibility for the HALT trial. We may also need to send this information to the ethics committee who approved the trial, and all the doctors who are responsible for patients in this study. We are required to provide this information to these parties by law, but you will not be identifiable in any of the information that is sent, and all information will be kept confidential.

Healthcare professionals working on clinical trials are covered by NHS Indemnity and if you are harmed by taking part in this trial you may have grounds for a legal action, but you may have to pay for it.

What if I have private medical insurance?

If you have private medical insurance, please check with the company that your medical insurance policy will not be affected before agreeing to take part in this trial.

What will happen to the results of the clinical trial?

Independent experts will review the progress of the research, and the results will be published in a scientific journal as soon as there is enough information to be sure the results are reliable. The results will help to decide how to treat lung cancer in the future. The results from this trial may also contribute to reviews of worldwide evidence about this type of cancer and its treatment. You will not be identified in any report or publication relating to this research.

What if relevant information becomes available?

Sometimes we get new information about the treatment being studied, which may affect your willingness to continue in the study. If this happens, your study doctor will tell you in a timely manner and discuss whether you should continue in the study. If you decide to continue in the study, you may be asked to sign an updated informed consent form. If you decide to discontinue, your study doctor will make arrangements for your future care.

If the study is stopped for any other reason, we will tell you and arrange your continuing care.

Who is organising and funding the research?

The research trial is being carried out by a network of doctors across the UK. The trial is coordinated by The Institute of Cancer Research and the research is approved and funded by Cancer Research UK (CRUK). Your doctor will not receive any payments for including you in this research trial.

Who has reviewed the trial?

The trial has been approved by Cancer Research UK's Clinical Research Committee and the Committee for Clinical Research on behalf of the Sponsor, The Institute of Cancer Research (ICR). The study has also been approved by London Fulham NHS Research Ethics Committee.

What do I have to do now?

You will have some time to think about the trial and make your decision. You may wish to discuss it with your GP, family or friends. Please keep this information sheet and a copy of the signed consent form. If, at any time, you have any questions about the trial you should contact your consultant.

4. Further information

Who else can I contact for further information?

You have the right to ask questions about this study at any time and are encouraged to do so. You can call the study doctor / nurse if you feel that you are developing any unwanted side effects or if you believe you have been injured as a result of your receiving study treatment or if you have any questions about this study or your participation in this study.

Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer patients and their families. You can contact one of their Cancer Information Nurse Specialists on the **Macmillan Support Line**: Freephone 0808 808 00 00 Monday to Friday 9:00am to 8:00pm. In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

You can learn more about clinical trials on the Cancer Research UK patient website (www.cancerhelp.org).

Contact details for PALS – Please contact the Patient Advice and Liaison Services (PALS) team at your hospital on

<site to insert telephone number>

Thank you for your interest in our research

Glossary

Lesion – An area of abnormal tissue. A lesion may be benign (not cancer) or malignant (cancer)

Metastases – Cancer which has spread from the part of the body where it started to a different place in the body.

Mutation – A change to the DNA sequence that makes up a gene.

Progression – Cancer which has either got bigger and/or spread to another place in the body.

Oligo-progression – Cancer which has either got bigger and/or spread to a small (1-5) number of places in the body.

Randomisation – A method used to randomly select a treatment group.

Tyrosine Kinase Inhibitors – A class of anti-cancer drugs used to block chemical messengers (enzymes) called tyrosine kinases.

Tyrosine Kinase Inhibitor therapy – Targeted anti-cancer drugs e.g. Erlotinib, Gefitinib, Afatinib, Osimertinib, Crizotinib, Ceritinib, Brigatinib, Alectinib.