(To be printed on local headed paper)

A study to find out if a new blood test (microRNA) can be used to monitor people after surgery for seminoma or dysgerminoma cancer

PARTICIPANT INFORMATION SHEET

PART A – Older Children and Younger teenagers

Version 1.2 Date 06/01/2026

We invite you to take part in a research study called OTIS-S

- Research helps us to find out answers to questions.
- After your operation to remove your cancer, the doctors need to see you in hospital to check it is not coming back. The researchers want to find out the best ways to check this.
- Here is some information about the research study. When you have read it, you can ask us as many questions as you like.
- You and your parent(s) or guardian(s) can then decide if you should take part.

Part 1

Why is the research study being done?

We want to find out if looking at a part of your blood can help doctors to catch the cancer early if it tries to come back.

Why have I been asked to take part?

You are being invited because you had an operation to remove a seminoma or dysgerminoma cancer.

You would be one of at least 260 people, a mixture of children, young people and adults, helping us with this research.

Do I have to take part?

No. You do not have to take part. It is up to you and your parent(s) or guardian(s) to decide if you want to take part. You can change your mind at any time. Your doctor will not mind if you don't want to take part.

What will happen if I take part?

You will come into hospital to see your doctor, just like you normally would, for up to 5 years. For the first 2 years you will visit the hospital every 3 months, then you will visit the hospital every 6 months for the next 3 years.

During these visits you will have a blood test. At some visits, you will also have pictures taken of the inside of your body with a special machine (a scan). This will help the doctors see how you are doing. Everyone has these tests whether they are in the study or not. If you choose to be in the study, we'll take a little bit extra of your blood (5ml, a teaspoon) and send it to the research team to help them learn more.

Depending on what the team see when they look at your blood, you might need to come back to see your doctor.

Your hospital team will send information from your check-ups to the researchers who are running the OTIS-S study. The researchers will combine data from

everyone taking part to find out if the blood tests help to check whether a cancer is coming back.

If you move away, let your hospital team know. It will often be possible to make arrangements for you to continue in the study if you would like to.

What happens if my cancer comes back?

If your cancer starts to come back, your doctors will talk to you and your parent(s) or guardian(s) about any further treatment you might need. We would still like to collect information on how you are doing and your treatment, if you agree for us to do so.

Will joining in help me?

We can't say if the research will help you, but it might help other children and young people with the same illness in the future.

Is there anything to be worried about if I take part?

The blood tests and pictures of the inside of your body would be done whether you are in the study or not, we will simply take a little extra blood at the same time. Blood tests involve a needle which might hurt slightly when it goes in and may give you a slight bruise. Depending on the machine used to take the pictures of the inside of your body it could be noisy, but you will be given headphones to protect your ears.

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

If you don't want to be part of the study anymore, that's ok. Just tell your parent(s) or guardian(s), doctor or nurse at any time. No one will be cross with you.

What do I have to do now?

Talk to your parent(s) or guardian(s) about what we have asked you. Together you will decide whether you want to join the study. You can also talk to the doctors and nurses who are looking after you.

If you would like more written detail on the information given above, please ask to see the patient information sheet given to your parent/carer or ask your hospital team for a copy of the patient information sheet designed for older teenagers and adults.

If you decide to participate in the study, your parent/carer will be asked to sign a consent form. If you turn 16 years old whilst you are taking part, you will be asked to read the patient information sheet designed for those who are 16 and over and you will be asked to sign a consent form, if you are still happy to continue in the study.

Thank you for reading so far – if you are still interested, please read Part 2 for some extra information

Part 2 – Further information

Extra sample collection

We would also like to request a small piece of the cancer, that was removed during your operation. This is called a tissue sample and is already stored by the hospital so you will not need to do anything else. If you don't want us to collect this, you can still take part in the study.

What will happen to my blood samples and tissue sample?

The routine blood test taken at a visit will be looked at by your hospital and the results given to your doctor and the researchers who are running the study.

The extra blood that is taken at the same time will be sent to a different laboratory that is working with the study researchers. When they receive the blood, they will give it a number so that you cannot be identified from the sample. They will look at this blood to see if they can see any sign that your cancer is coming back. Any blood that has not been used will be stored at the laboratory.

If you decide to let us collect your tissue sample, these will be sent to a laboratory of the study researchers. These tissue samples will also be given a number so that you cannot be identified from the sample. These samples may be sent back to the hospital at the end of the study if they are requested, otherwise they will continue to be stored at the laboratory.

Sometimes, other researchers ask if they can use data or blood and tissue samples that have been collected. We only allow this if the research they are doing has been approved and your data is kept safe. Any samples sent to these other researchers will not have your personal details, such as name or date of birth, on them so no one would know they were yours. You and your parent or carer will need to decide if you are happy for other researchers to be able to use your data and samples in the future. If you and your parent or carer are happy for your samples to be used for future research, at the end of the study they will be held in a licensed laboratory and kept indefinitely. If you do not agree, at the

end of the study, the blood samples will be destroyed and the tissue samples sent back to your hospital.

How will we use information about you?

We will need to use information from you, from your hospital records and your GP for this research project.

This information will include your:

- Full name
- Initials
- Date of birth
- Hospital number
- NHS number or Community Health Index
- GP details
- Home address and postcode
- Email address (if available)

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

The Institute of Cancer Research (ICR) is the sponsor of this research.

The ICR is responsible for looking after your information. Our legal reason for using your information is to carry out scientific research which is in the public's interest. We will share your information related to this research project with the following types of organisations:

- research institutions including universities, hospitals and commercial laboratories involved in research into cancer and its treatment, where this sharing has been approved by the sponsor

We will keep all information about you safe and secure by:

- Using a unique study identifier number allocated to you to link all the samples and data that you provide.
- Storing all your information and samples securely.
- Treating your information and samples as strictly confidential and nothing that might identify you will be revealed to any third party.
- Using the minimum personally identifiable information possible.
- Limiting access to your information to only those who need to use it for research or regulatory reasons and regularly reviewing who has access to your information.
- Using strong encryption whenever we need to share your information.
- Ensuring everyone who has access to your information has been trained on how to use it in a safe way.
- Keeping our Data Protection Officer informed on how we use personal data so they can advise us on how to keep your information safe.

International transfer

- We may share or provide access to data about you outside the UK for research related purposes to: research institutions including universities, hospitals and commercial laboratories involved in research into cancer and its treatment, where this sharing has been approved by the sponsor

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK

- We use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details visit the Information Commissioner's Office (ICO) website.
- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.
- We need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing.
- We have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules visit the Information Commissioner's Office (ICO) website.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

We will keep your study data for a maximum of 20 years from the end of study. The study data will then be fully anonymised and securely archived or destroyed.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records / your hospital / your GP. If you do not want this to happen, tell us and we will stop.

- You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option for your data saved from this study to be used in future research.

Where can you find out more about how your information is used?

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK:

- Our leaflet: www.hra.nhs.uk/patientdataandresearch
- Our privacy notice on our website: https://www.icr.ac.uk/legal/privacy/research-privacy-notice
- By sending an email to our Data Protection Officer: dataprotectionofficer@icr.ac.uk,
- By asking our team, or
- By ringing our Data Protection Officer on 020 3437 7327.

For more information, you can watch this short video: https://www.youtube.com/watch?v=VlI6V1MgZgY

What happens if new information comes along?

Sometimes during research, new information comes along about what is being studied. If this happens, your hospital team will discuss this with you and your parent(s) or guardian(s) and check whether you want to continue with the study.

What happens when the research study stops?

When the research study has finished, we will put the results in medical magazines that doctors will read. People who read the reports will not know that you were in the study. We will also write a summary of the results which will be available for you and your parent/carer to read.

What if something goes wrong?

We don't expect anything to go wrong, but if there is a problem, you should speak to your parent(s) or guardian(s) or any of your hospital care team.

Will anyone else know I am taking part?

All your information will be kept private. We will only inform those who have a need or right to know like your GP, and those who work on the research study.

Who is organising and funding the research?

The study is being organised by The Institute of Cancer Research. The study is being paid for by Cancer Research UK.

The study is being carried out by teams at many UK NHS hospitals within the UK.

Who has checked the study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. This is a group of people who make sure that the research is OK to do. This study has been looked at by The London - South East Research Ethics Committee.