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**SCOPE2** - A randomised Phase II/III trial to study radiotherapy dose escalation in patients with oesophageal cancer treated with definitive chemo-radiation with an embedded Phase II trial for patients with a poor early response using positron emission tomography (PET)

## **SUPPLEMENTARY PARTICIPANT INFORMATION ABOUT THE GENERAL DATA PROTECTION REGULATION (GDPR)**

**You do not need to do anything – this notice is only to provide you with information.**

### **What documentation has the Sponsor previously provided to you about GDPR?**

Prior to your participation in the SCOPE2 study, your local hospital consultant provided you with a SCOPE2 Participant Information Sheet (PIS) and Informed Consent Form (ICF). The PIS provided information about what personal and medical data we will collect and how we will manage it.

### **What is the legal basis for processing your personal data?**

The ICF was used to obtain your consent to collect and manage your data.

### **What additional information do we now need to provide?**

We have developed this document to provide additional transparency information to you about what information we hold about you and what we will do with it.

### **Who is responsible for looking after your information?**

Velindre University NHS Trust is the Sponsor of this study based in the United Kingdom. Both Cardiff University and Velindre University NHS Trust will act as Data Controllers and Data Processors for this study. This means that we are responsible for looking after your information and using it properly. We recognise that your personal data is very valuable, and so we take its security very seriously. The personal data we collect from you and/or your medical records will be used solely for the purpose of your participation within this study. You can contact the Cardiff University Data Controller and Protection Officer through the details found here:

<https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>

You can contact the Velindre University NHS Trust Data Controller and Protection officer through details found here: <https://velindre.nhs.wales/use-of-site/privacy-policy/>

### **What is the purpose of the processing of your personal data?**

We will be collecting your health data in order to answer the research questions being investigated by the study. We are trying to find out whether a higher dose of radiotherapy results in better patient outcomes. We collect some data directly from the hospitals at which you have your treatment. However we also need to collect some personally identifiable information so that we can accurately track what happens to you using data collected by public health registries (e.g. NHS Digital). We will pass your name, date of birth, postcode and NHS number (or equivalent) to the registries and they will pass data about the outcomes back to the research team at Cardiff University.

### **What rights do you have under GDPR?**

#### *Right of access*

Under Data Protection legislation, you have the right to know if we hold personal data relating to you, and if so, what personal data we hold and why. You also have the right (with certain exceptions) to a copy of

any personal data that we hold in order that you can be sure that it is accurate and up to date. Not all rights under Data Protection legislation are absolute, and your rights to change or move your information may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate.

#### *Right to restriction*

To safeguard your rights, we have used the minimum amount of personal data as possible. You may withdraw your consent at any time but we will keep the information about you that we have already obtained in order to preserve the scientific integrity of the whole study.

#### *Right to object*

You may exercise your rights, or raise an objection or concern about any aspect of the processing of your data with the Cardiff University Data Protection Officer through the details found here:

<https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection>  
<https://velindre.nhs.wales/use-of-site/privacy-policy/>

You also have the right to lodge a complaint with the Information Commissioner's Office:

<https://ico.org.uk/make-a-complaint/>

### **What information about you will be published by the Data Controllers?**

As universities we use personal data information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personal data information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research. You will not be identifiable in any reports or publications.

### **What data is intended to or likely to be used for future research?**

When you agree to take part in a research study, anonymised information about your health and care may be provided to researchers in this organisation and in other organisations in order to answer questions related to this study.

### **Will all your information be kept confidential?**

Yes. This study and the data processing methods have been approved by a UK research ethics committee. We follow ethical and legal procedures. All information you give us about yourself will be managed in strict confidence. All members of the study team and regulatory authorities are trained in data protection issues. They are also bound by the terms of the General Data Protection Regulation (GDPR) (EU) 2016/679.

Although we collect some personally identifiable information about you (name, date of birth, postcode, NHS number or equivalent), this will only be used for the purposes of the Data Controllers obtaining routinely collected data about you from public health registries for the purposes of answering the research questions in this study. The personally identifiable information will be kept separately to the health data we have about you and will never be passed to any other organisations. Only the authorised members of the research team who will be managing, auditing, or analysing the data will have access to it.

### **How long will your data be kept for?**

Your participating site and the Data Controllers will keep identifiable information about you from this study for 15 years after the study has finished (we expect the study will finish in January 2026). After this 15 year timepoint, we will destroy all the information we have saved.