SUPPLEMENTARY PARTICIPANT INFORMATION ABOUT GENERAL DATA PROTECTION REGULATION (GDPR)

SCOPE1: A randomised phase II/III multicentre clinical trial of definitive chemoradiation, with or without Cetuximab, in carcinoma of the oesophagus

Research Ethics Committee for Wales ID: 07/MRE09/16

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

Prior to your participation in the SCOPE1 study, your local hospital consultant provided you with a SCOPE1 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. The ICF was used to obtain your consent to collect and manage this 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 my information?

Velindre University NHS Trust is the Sponsor for this study based in the United Kingdom. The Sponsor has delegated some of the data management responsibilities for this study to the Cancer Group, formerly known as the Wales Cancer Trials Unit (WCTU), within the Centre for Trials Research (CTR) at Cardiff University. Cardiff University and Velindre University NHS Trust will act as joint data controllers for this study.

Both Cardiff University and Velindre University NHS Trust 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. This means both organisations are responsible for looking after your information and using it properly.

Cardiff University will also act as a data processor for this study because they will hold and process your data. Velindre University NHS Trust will not hold or process your data.

What is the legal basis for processing your personal data?

We only process your personal data with your consent, and we obtained your consent by virtue of the ICF.

What data have we collected directly and indirectly about you?

When you signed the SCOPE1 ICF you consented to the collection of one or more of the following personal data fields that could potentially be used to identify you, without any further input from you:

• Forename, surname and initials

• Date of birth (dd/mm/yyyy)

• Hospital Number (the number assigned to you by the UK hospital that entered you into the study) • NHS Number

• Post code

This data was provided **indirectly** by your hospital care staff from previously collected medical records or database(s).

You also gave permission for relevant sections of your medical notes to be looked at and the data to be collected. Under associated Data Protection legislation, health data is regarded as '**special category data'**. Some of this special category data about has been collected **indirectly** by your hospital care staff from previously collected medical records or database, e.g. historical data to determine your eligibility to enter the study. With some special category data about you being provided **directly**, e.g. documented by your hospital care staff following trial interventions, lab tests, etc.

What will happen with the personal data I provide?

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. If you withdrew from the study prior to the date of closure of the study with the Research Ethics Committee (REC) and/or Medicines and Healthcare products Regulatory Agency (MHRA) and the primary study analysis, we have kept the information about you that we had already obtained. To safeguard your rights, we have used the minimum personal data information as possible.

Your initials, date of birth, and hospital number, alongside a unique SCOPE1 Trial Number assigned by the CTR at study entry, was used by the CTR and your participating NHS Site to identify you on some of the paper forms that the hospital site uses to send study research data to the CTR, and by the CTR in the databases that the CTR uses to collate SCOPE1 research data.

If you consented to be registered with the National Health Service Information Centre (NHSIC) or equivalent (e.g. Community Health Index (CHI) number in Scotland)), your forename, surname, initials, date of birth, NHS number, and post code may have been used by your local hospital site and the CTR to register you with NHSIC or equivalent in order for us to follow up your health status (e.g. confirmation of your death if you are lost to follow up). NHSIC or equivalent in return may have sent us data about your death, including date of death and registration data, where available.

Will all my information be kept confidential?

Yes. 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.

Your participating NHS Site will have used your name, NHS number and contact details 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.

Individuals from your local hospital, the CTR and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your participating NHS Site will pass these details to the CTR along with the information collected from you and/or your medical records. Only authorised staff members at the CTR and Velindre University NHS Trust will have access to information that identifies you, and these will be staff who may need to contact you to audit the data collection process, or are directly involved in the NHSIC or equivalent registration and data collection process described above. Staff who are required to carry out an analysis of information will not be granted access to your personal data and they will not be able to find out your name, NHS number or contact details.

Your participating site and Cardiff University will keep identifiable information about you from this study for 15 years after the study has finished. The study closed with the REC on 01/05/2015. Cardiff University will continue to hold and process your data until 15 years after this date, i.e. until 01/05/2030. After this time, we will destroy all the information we have saved.

You can find out more about how we use your information at:

https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection
http://www.velindre-tr.wales.nhs.uk/privacy-policy

If you have a concern about any aspect of this study, please contact the Sponsor's Data Protection Officer at:

Email: VNHSTInformationGovernance@wales.nhs.uk

Address: Velindre University NHS Trust, Unit 2 Charnwood Court, Parc Nantgarw, Nantgarw, Cardiff, CF15 7QZ

Or Cardiff University's Data Protection Officer at:

Email: inforequest@cardiff.ac.uk Address: Data Protection Officer, Assurance Services, Cardiff University, Friary House, Greyfriars Road, Cardiff, CF10 3AE

If you remain unhappy and wish to complain formally, you can do this through the Information Commissioner's Office (ICO) telephone helpline on 0303 123 1113 or https://ico.org.uk/global/contactus/live-chat/

What information about me will be published by the Sponsor/CTR/Cardiff University?

As a university 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.

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

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. 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.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.