

ELEVA TE

INFORMED CONSENT FORM – TUMOUR SAMPLE SCREENING

Study Title: An open label phase II trial of temozolomide prior to nivolumab in MGMT deficient, advanced oesophagogastric cancer Researcher: Dr Elizabeth Smyth ERGO Ref: 61191 **REC: 21/EE/0017** IRAS: 282284 Please initial each box 1. I confirm that I have read and understand the Tumour Sample Screening patient information sheet dated [Insert here] for the transfer of my tumour sample to the Laboratories of Cambridge University. I have had the opportunity to ask questions and these have been answered satisfactorily. 2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason and without my medical care or legal rights being affected. 3. I understand that relevant sections of my medical records may be looked at by the individuals from the Southampton Clinical Trials Unit (SCTU), the Sponsor or their delegates, from Regulatory Authorities, or from the NHS Trust where it is relevant to the transfer and storage of my tumour block. I give permission for these individuals to have access to my records. 4. I give my permission for a sample of my tumour, previously obtained for diagnostic purposes, to be sent to the laboratories of Cambridge University in order to determine where a MGMT deficiency is present.











<TO BE PRINTED ON LOCAL HOSPITAL HEADED PAPER>

Name of Person taking consent Signature		Date	
	Name of Patient	Signature	Date
9.	I give permission for a copy of this consent form to be sent to the Southampton Clinical Trials Unit (where it will be kept securely), to allow confirmation of my consent.		
8.	I agree that the tumour sample and consent form will be stored on behalf of the ELEVATE Trial Management Group. If I choose to participate in the ELEVATE study, my tumour sample may be used in future ethically approved projects. I understand that some of these projects may be carried out by researchers other than the ELEVATE Trial Management Group. If I choose not to participate in the ELEVATE study, my tumour sample will be returned to my treating hospital and no further analysis conducted.		
7.	I consent to the Southampton Clinical Trials Unit being informed of the result of my tumour sample analysis.		
6.	I understand that all information about me and the results will be held in stric confidence.		
5.	I understand that agreeing to does not commit me to taking	the transfer and storage of my tumour block part in the ELEVATE trial.	

REMINDER FOR RESEARCH TEAM:

- <u>Original</u> signed consent form in <u>Investigator Site File</u>
- One copy given to the patient
- One copy filed in the patient's medical records
- One <u>copy</u> to be <u>emailed</u> to SCTU via secure <u>nhs.net email</u> account, safesend or encrypted mail to allow for central monitoring







