Barrett's oESophagus Trial 4 (BEST4)

PLEASE INITIAL EACH BOX

Consent form

By agreeing to take part in BEST4, I understand that:

1. I confirm that I have read the information sheet dated [Version X.X DD Month YYYY]. I have been able to ask questions and have had these answered to my satisfaction. ☐

2. Taking part in this trial is voluntary and I can stop at any time. I do not need to give a reason to stop. My medical care and legal rights will not be affected. If I choose to stop taking part, samples and data collected before I withdraw will continue to be used as part of the trial. ☐

3. I agree to have the capsule sponge test and repeated procedures (if required). ☐

4. My results, if abnormal may be shared with my GP and hospital care team. Negative results will be communicated directly via text message. My GP and hospital care team will also share information with the research team where needed. ☐

5. I understand Queen Mary University of London and the University of Cambridge, Cambridge University Hospitals will store and use my personal details to carry out this research. This may include my name, date of birth, NHS number, telephone number and email address. ☐

6. I understand that my capsule sponge samples will be sent to commercial laboratories, run by Cyted UK Ltd, for testing needed to carry out this research. These samples will be sent with my NHS number, initials, DOB, and sex to ensure the sample can be tracked and reported appropriately. Once the sample has been processed, it will be pseudonymised (coded). ☐

7. I understand that employees of third-party providers may require access to my personal details to fulfil their role. Some of these organisations may be based outside the UK. All third parties must keep my records and information strictly confidential under appropriate contracts and in accordance with UK GDPR standards. ☐

8. I understand that my samples and information collected about me can be used to support other research in future, including by approved researchers from other organisations. My personal details, ☐

such as my name or address, will not be shared without my permission.

9. The study team may collect further information from my hospital record relevant to my health. This may include endoscopy results and images. ☐

10. Coded research data collected about me in this trial will be added to my Heartburn Health record. This may include my capsule sponge test results and endoscopy results. I understand this means approved researchers will be able to use this information in studies running as part of Heartburn Health. ☐

11. I understand that my data, collected by Heartburn Health from NHS England and other central UK health service bodies, will be used in this trial. ☐

12. Relevant sections of my medical notes and data collected during the study, may be looked at by people from the organisations running this research and regulatory authorities where it is relevant to my taking part in this research. I give permission for these people to access my record. ☐

13. If I have an endoscopy based on my capsule sponge results, I will be invited to give a blood sample to support future research. These samples may undergo whole genome sequencing. ☐

14. The samples I give in this trial will also be added to my Heartburn Health record. The samples will be coded and will not include any personal information. I understand this means approved researchers will be able to use this information in studies running as part of Heartburn Health. No one will be able to work out who I am from the information shared. ☐

15. I agree to take part in the above trial. ☐

Participant's signature: _____ Date:_____

Full name: _____

Research nurse / healthcare professional's signature:_____

Date:_____

Time:_____

Full name: _____

I confirm that I was present as a witness for the consent process for this trial. I confirm that the participant named ..... was read the information in the consent document and the participant has agreed to take part in the trial.

……	……..	…….
Witness Full Name	Witness Signature	Date

1 copy for the participant, 1 copy for the researcher, 1 copy added to the medical record.