



LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE



Insert hospital letterhead and local team contact details

CONSENT FORM

British Heart Foundation Randomised Trial of Routine Cerebral Embolic Protection in Transcatheter Aortic Valve Implantation (BHF PROTECT-TAVI)

| | |
|--|---|
| Patient name: | Site name and ID |
| <input type="text"/> | <input type="text" value="[PREFILL SITE NAME and ID]"/> <input type="text" value="I"/> <input type="text" value="D"/> |
| PROTECT-TAVI ID: | Investigator name: |
| <input type="text" value="P"/> <input type="text" value="R"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | <input type="text"/> |

If you agree, please initial

| | |
|---|--|
| I confirm that I have read and understand the BHF PROTECT-TAVI Patient Information Sheet, Version 4, 17 October 2022. I have had the opportunity to consider the information and ask questions which have been answered satisfactorily. | |
| I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. | |
| I understand that relevant sections of my medical notes including images, databases of cardiovascular outcomes and data collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities, from the London School of Hygiene and Tropical Medicine and from, INSERT LOCAL NHS TRUST where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. | |
| I understand that you wish to access my health records held with NHS Digital, the Office for National Statistics (ONS) and other central UK government bodies that collects outcomes data for linkage, and to do this you will send my NHS number/CHI number/H&C number and date of birth to these organisations to link to Hospital Episode Statistics (HES), mortality data and cardiovascular and neurological procedure and outcome data. | |
| I agree to be contacted by research staff for follow-up between 6-8 weeks after my TAVI procedure and 12 months after my TAVI procedure. | |
| I understand that information collected about me from this research study may be used to support other research in the future and may be shared with other researchers in the UK and abroad in a form that does not identify me. | |
| I agree to take part in the BHF PROTECT-TAVI study. | |

Please sign and date below. Your consent will be witnessed by a member of the local research team.

| | |
|---|--|
| <input type="text" value="Patient signature"/> | <input type="text" value="Print name"/> |
| | <input type="text" value="Date and Time"/> |
| <input type="text" value="Signature of person taking consent"/> | <input type="text" value="Print name"/> |
| | <input type="text" value="Date and Time"/> |

One copy for patient, one for research site, one to be kept with hospital notes