Supplementary file 1_Patient consent form

Consent to Take Part in the EMBARK Study

This is an abbreviated version of the full patient consent form provided to the trial participants.

Agreement to Participate and to Process Data	Participant Initials
1. I confirm I have read (or, if I cannot read, a study team member has read to me) and understand this consent document for the study described above and have had the opportunity to ask questions. I have had enough time to review this consent document. I also have had an opportunity to ask about the details of the study and to decide whether or not to participate.	
2. I have read and understand the Privacy Supplement. I understand that taking part in the study will require the processing (including collection, use, transfer, storage, analysis and reporting) of my personal information, as explained in the Privacy Supplement. I understand and agree to the processing of my personal information within and outside my country of residence for health care, medical research and/or regulatory purposes.	
3. I understand that taking part is voluntary and that I am free to stop taking part in this study or to withdraw my consent to the processing of my personal information at any time. I do not need to give any reason and my regular medical care and legal rights will not be affected. However, even if I withdraw my consent to processing, my personal information held at that time may be kept to comply with laws and regulations and to maintain the integrity of the study. I also understand that my biological samples may not be able to be destroyed because they may no longer be traceable to me, may have already been used, or may have been given to a third party.	
4. I agree to the study team accessing my medical history, including information from medical records and test results and any medical treatment I receive during the course of the study, and if necessary, contacting my doctor or any other health care providers treating me for access to such information.	
5. I understand that the Sponsor and/or others working with or on behalf of the Sponsor, institutional review boards (IRBs) or independent ethics committees (IECs), and regulatory agencies may need access to personal information about me generated at the study site or collected by the study team for the study and any	

other research. I agree that they may have access to my personal information.	
6. I do not give up any of my legal rights by signing this consent document. I have been told that I will receive a signed and dated copy of this document.	
7. I agree to take part in the study described in this document.	

_____

Printed name of participant

_____

Signature of participant Date of signature§
(If no legally acceptable representative is used)

_____

Printed name of legally acceptable representative Relationship
(if applicable)

_____

Signature of legally acceptable representative Date of signature§
(if applicable)

Person Obtaining Consent:

_____

Printed Name of the Person Conducting the Consent Discussion

_____

Signature of the Person Conducting the Consent Discussion † Date of signature

†The investigator, or an appropriately qualified and trained person designated by the investigator to conduct the informed consent process, must sign and date the consent document during the same discussion when the participant signs the consent document.

Consent for Participant Who Cannot Read:
The study participant has indicated that he/she is unable to read. One or more members of the study team read the consent document to the study participant, discussed it with the study participant, and gave the study participant an opportunity to ask questions.

_____

Printed name of impartial witness ‡

_____ _____

Signature of impartial witness Date of signature§

☐ Not applicable (*Check this box if the Signature of an impartial witness is not required. Signature of an impartial witness is required if the participant or the participant's legally acceptable representative cannot read.*)

§Participant/legally acceptable representative/impartial witness must personally date their signature.

‡ Impartial Witness: A person, who is independent of the study, who cannot be unfairly influenced by people involved with the study, who attends the informed consent process if the participant or the participant's legally acceptable representative cannot read, and who reads the informed consent and any other written information supplied to the participant. *See* Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance.