Randomised controlled trial of EArly transjugular intrahepatiC porTosystemic stent-shunt in Acute Variceal Bleeding REACT-AVB Trial

<Insert Trust logo>

RECOVERED CAPACITY: PATIENT INFORMED CONSENT FORM

Patient trial number: ☐☐☐ Principal Investigator: .....

	Please "initial" inside each box to confirm consent	
1.	I confirm that I have read (or had read to me) and understood the Patient Information Sheet, version number ___ ○ ___ dated ___ ___ /___ ___ ___ / ___ ___ ___ ___ for the **REACT-AVB** trial. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw from the trial at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that even if I withdraw from the **REACT-AVB** trial, data collected up to my time of withdrawal may still be used.	☐
3.	I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the **REACT-AVB** trial research team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research.	☐
4.	I have read (or had read to me) and understood the information in the Patient Information Sheet about what happens with my personal data collected for this trial.	☐
5.	I agree to my GP being informed of my participation in this trial.	☐
6.	I understand and acknowledge that data collected that identifies me by name, on the Informed Consent Form, will be transferred from where it is collected and stored at the University of Birmingham.	☐
7.	I understand that the information collected will be used for medical research only and that I will not be identified in any way in the analysis and reporting of the results. I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised.	☐
8.	I understand that the information collected about me will be used to support other related research in the future, and may be shared anonymously with other researchers.	☐
9.	I understand that the information held and maintained by NHS Digital and other central UK NHS bodies may be contacted to provide information about my health status using my NHS number/ Community Health Index (CHI) or Health & Care number (H&C). Information held and maintained by the University of Birmingham may be sent to NHS Digital and other central UK NHS bodies to link my information these organisations hold and maintain.	☐

Patient trial number: ☐☐☐

10.	I agree to take part in the **REACT-AVB** trial.	☐

To participate in the **REACT-AVB** Trial you MUST consent to all the points above and **initial** the corresponding boxes.

If you are the patient completing this form, please provide your signature below

Name of Patient (Printed)	Signature	Today's date

Witness is only required if patient is physically unable to sign the form but has the capacity to give consent. By signing below:

I witnessed accurate reading of the consent form to the potential patient, who could ask any questions and got satisfactory replies. I confirm they gave their consent freely.

Name of patient (Printed)	Name of Witness (Printed)	Signature	Today's date

Person taking consent, please provide your signature below

Name of Person taking Consent (Printed)	Signature	Today's date

Once completed: Original to be kept in Investigator Site File, one copy for the patient, REACT-AVB Trial Office and in medical notes.

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