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

<Insert Trust logo>

Welfare Attorney/Welfare Guardian/Nearest Relative Record of Telephone Consent

Patient trial number: ☐☐☐ Patient Name: .....

This sheet is to assist with the process of taking telephone consent from the participants welfare attorney (WA), welfare guardian (WG), or if these are not appointed, the participant's nearest relative (NR).

The telephone call to seek consent from any of the above will need to be witnessed by an independent member of staff.

	The researcher should initial the appropriate boxes that the WA/WG/NR has agreed to.	
1.	I confirm that the researcher has briefly discussed the Participant Information Sheet (PIS)- Welfare Attorney/Welfare Guardian/Nearest Relative, 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 the person I am consenting for's participation is voluntary and that I am free to withdraw them from the trial at any time, without giving any reason, and without their medical care or legal rights being affected. I understand that even if I withdraw them from the **REACT-AVB** trial, data collected up to the time of withdrawal may still be used.	☐
3.	I understand that relevant sections of the person I am consenting for's medical notes and data collected during the trial may be looked at by authorised 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 their taking part in this research.	☐
4.	I confirm that the researcher has discussed what will happen with the personal data collected for the **REACT-AVB** trial for the person I am consenting for.	☐
5.	I understand and acknowledge that data collected that identifies me by name and for the person I am consenting for, will be transferred from where it is collected and stored at the University of Birmingham.	☐
6.	I agree to the person I am consenting for's GP being informed of their participation in this trial.	☐

7.	I understand that the information collected will be used for medical research only and that the person I am consenting for will not be identified in any way in the analysis and reporting of the results. I understand that even if they withdraw from the trial, information already collected about them may be included in the final analysis after being anonymised.	☐
8.	I understand that the information held and maintained by NHS Digital and other central UK NHS bodies may be used to help contact the person I am consenting for or provide information about their health status. Information held and maintained by the University of Birmingham may be sent to NHS Digital and other central UK NHS bodies to link their information these organisations hold and maintain.	☐
9.	I agree to the person, I am consenting for taking part in the **REACT-AVB** trial.	☐

Note: The WG/WA/NR for the person that they are consenting for to participate in the REACT-AVB Trial MUST agree to all the points above.

Name of WG/WA/NR: ☐

Position: WG ☐ WA ☐ NR ☐

Date of phone call: ☐ DD/MM/YYYY

Time of phone call: ☐ HH/MM

Preferred method of receiving a copy of the information sheet: Email ☐ Post ☐

Email address: ☐

Postal address: ☐

Name of researcher taking consent: ☐

Signature of researcher: ☐

Name of Witness: ☐

Signature of Witness: ☐

Once completed: Original to be kept in Investigator Site File, one copy for the Welfare Attorney/Welfare Guardian/Nearest Relative Legal Representative, REACT-AVB Trial Office and in medical notes.