



**Randomised controlled trial of Early transjugular
intrahepatic portosystemic stent-shunt in Acute Variceal
Bleeding **REACT-AVB** Trial**

<Insert Trust logo>

Consultee: Record of Telephone Declaration

Patient trial number:

Patient Name:

This sheet is to assist with the process of taking telephone declaration from the participants consultee or if not appointed, a nominated consultee.

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

<i>The researcher should initial the appropriate boxes that the consultee has agreed to.</i>		
1.	I confirm that the researcher has briefly discussed the Consultee 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.	<input type="checkbox"/>
2.	I understand that my partner's, relative's or close friend's (or the person I am representing'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.	<input type="checkbox"/>
3.	I understand that relevant sections my partner's, relative's or close friend's (or the person I am representing'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.	<input type="checkbox"/>
4.	I confirm that the researcher has discussed what will happen with my partner's, relative's or close friend's (or the person I am representing's) personal data that is collected for the REACT-AVB trial.	<input type="checkbox"/>
5.	I understand and acknowledge that data collected that identifies me and my partner, relative or close friend (or the person I am representing) by name, will be transferred from where it is collected and stored at the University of Birmingham.	<input type="checkbox"/>
6.	I agree my partner, relative or close friend (or the person I am representing) GP, to be informed of their participation in this trial.	<input type="checkbox"/>
7.	I understand that the information collected will be used for medical research only and that my partner, relative or close friend (or the person I am representing) 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.	<input type="checkbox"/>

Patient trial number:

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 providing an opinion 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.	<input type="checkbox"/>
9.	I agree to the person, I am providing an opinion for taking part in the REACT-AVB trial.	<input type="checkbox"/>

Note: The consultee on behalf of the person that they are providing an opinion for, MUST agree to all the points above in order for them to participate in the REACT-AVB Trial.

Name of Consultee:

Position: Partner Relative Close friend Nominated consultee

Date of phone call:

Time of phone call:

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 Consultee, REACT-AVB Trial Office and in medical notes.