

<u>R</u>andomised controlled trial of <u>EA</u>rly transjugular intrahepatiC por<u>T</u>osystemic stent-shunt in <u>A</u>cute <u>V</u>ariceal <u>B</u>leeding <u>REACT-AVB</u> Trial

## CONSULTEE DECLARATION FORM

Patient trial number:

Principal Investigator:

	Please "initial" inside each box to confirm consent		
1.	I confirm that I have read and understood the Consultee Information Sheet, version number•dated// for the <b>REACT-AVB</b> trial. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.		
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 <b>REACT-AVB</b> trial, data collected up to the time of withdrawal may still be used.		
3.	I understand that relevant sections of 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 <b>REACT-AVB</b> 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 have read and understood the Consultee Information Sheet about what happens with my partner, relative or close friend (or the person I am representing) and the personal data collected for the <b>REACT-AVB</b> trial.		
5.	I understand and acknowledge that data collected that identifies me by name and my partner, relative or close friend (or the person I am representing's) will be transferred from where it is collected and stored at the University of Birmingham.		
6.	I understand that the GP of my partner, relative or close friend (or the person I am representing) will be informed of their participation in this trial.		
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.		



8.	I understand that the information held and maintained by NHS Digital and other central UK NHS bodies may be used to help contact my partner, relative or close friend (or the person I am representing) 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.	In my opinion, my partner, relative or close friend (or the person I am representing) would have no objection to taking part in the <b>REACT-AVB</b> trial.	

For your partner, relative or close friend (or the person you are representing) to participate in the **REACT-AVB** Trial you MUST **initial** all the above in the corresponding boxes.

Name of patient (Printed)	Relationship of Consultee to patient	
Name of Consultee (Printed)	Signature	Today's date
	[]	
Name of Person Taking Consent (Printed)	Signature	Today's date

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