



**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 CONSENT FORM

Patient trial number:

Principal Investigator:

		<i>Please "initial" inside each box to confirm consent</i>
1.	I confirm that I have read and understood 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.	<input style="width: 60px; height: 40px;" type="text"/>
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.	<input style="width: 60px; height: 40px;" type="text"/>
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.	<input style="width: 60px; height: 40px;" type="text"/>
4.	I have read and understood the PIS- Welfare Attorney/Welfare Guardian/Nearest Relative about what happens with the personal data collected for the REACT-AVB trial for the person I am consenting for.	<input style="width: 60px; height: 40px;" type="text"/>
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.	<input style="width: 60px; height: 40px;" type="text"/>
6.	I agree to the person I am consenting for's GP being informed of their participation in this trial.	<input style="width: 60px; height: 40px;" type="text"/>
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.	<input style="width: 60px; height: 40px;" type="text"/>
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.	<input style="width: 60px; height: 40px;" type="text"/>

Patient trial number:

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

Please note, for the person that you are consenting for to participate in the **REACT-AVB** Trial you **MUST initial** all the above in the corresponding boxes.

I confirm that I am the Welfare Attorney or Welfare Guardian for:

Name of patient (Printed)

Name of Person giving Consent (Printed)

Signature

Today's date

OR:

I confirm that I am the Nearest Relative for:

Name of patient (Printed)

Relationship of Legal Representative to patient

Name of Person giving Consent (Printed)

Signature

Today's date

Name of Person Taking Consent

Name of Person Taking Consent (Printed)

Signature

Today's date

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