University Hospitals of Leicester NHS

NHS Trust

ASSENT FORM

Assent by relative to participation in a clinical trial

Title of Project:

CESAR: Conventional ventilation or ECMO for Severe Adult Respiratory failure: A Collaborative Randomised Controlled Trial

PATIENT NAME: _____ Please initial the boxes

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐

2. I understand that my relative's participation in this trial is voluntary and that he/she is free to withdraw at any time, without giving any reason, without his/her medical care or legal rights being affected. ☐

3. I understand that sections of my relative's medical notes may be looked at by responsible individuals from The CESAR Trial or from regulatory authorities where it is relevant to my relative's participation in research. I give permission for these individuals to have access to my relative's records. ☐

4. I understand and acknowledge that the investigation is designed to add to medical knowledge. I acknowledge that the purpose of the investigation, the risks involved from drugs or other procedures, and the nature and purpose of such procedures have been explained to me by discussion with the doctor caring for my relative. I have had the opportunity to discuss these matters with them. ☐

5. I have received a written explanation of these matters. ☐

6. I agree for my relative to take part in the above study and believe that my relative would not object to taking part in the study. ☐

Name of relative/next of kin who is giving assent	Date	Signature
_____	_____	_____
Name of assenting doctor	Date	Signature
_____	_____	_____
Name of assenting nurse	Date	Signature
_____	_____	_____

Please make 2 copies of this form. Send 1 copy to the CESAR Data Co-ordinating Centre, file 1 copy in the CESAR folder and keep the original with the patient's note.