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Participant Informed Consent / Re-Consent Form

Prospective observational study to evaluate the use of Computer aided vacuum thrombectomy within the context of intermediate and high-risk PE.

Principal Investigator: PI name

Participant Identification Number: Participant number Location number: Centre number

Please initial each statement	
1. I confirm that I have read the Participant Information Sheet PIS version; PIS date for the above study. I have had the opportunity to consider this information, ask questions and have had these answered satisfactorily.	Please Initial
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care and/or legal rights being affected.	Please Initial
3. I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from the Sponsor (University Hospitals Plymouth NHS Trust), from regulatory authorities or from the NHS organisations where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or records.	Please Initial
4. I agree for a copy of the study results to be sent to me at the end of the study.	Please Initial
5. I understand that data collected about me during the study may be anonymised and used in research reports and publications.	Please Initial
6. I understand that pseudonymised/anonymised data generated during the study will be sent outside of the UK / European Economic Area where laws protecting my personal information may be different to my own country.	Please Initial
7. I agree to my anonymised data being used for future ethically approved studies.	Please Initial
8. I agree for my contact details to be shared with Dendrite, a UK based company to send follow up questionnaires to me as required by the study.	Please Initial
9. I agree to take part in the above study	Please Initial

Localise appropriately if needed or remove the highlights and delete this text box

Name of Participant	Date	Signature
Name of Person receiving consent	Date	Signature

1 copy for participant; 1 copy in medical notes and original copy for researcher location file.