Trust logo *<To be printed on site headed paper>*

**Registration Informed Consent Form**

**Study Title: Stopping anticoagulation for isolated or incidental subsegmental pulmonary embolism**

**Centre ID/Site name:**

**Registration No.:**

**Patient Initials:**

**Principal Investigator:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

***Please initial inside each box***

|  |  |  |
| --- | --- | --- |
| 1 | I confirm that I have read and understood the information sheet, dated \_ \_ / \_ \_ / \_ \_ \_ \_ version number \_\_ . \_\_ for the STOP-APE study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. |  |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used.  |  |
| 3 | I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the STOPAPE research team, representatives of the sponsor, from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research. I give permission for these individuals to have direct access to my records. |  |
| 4 | Data collected that identifies me by name, including this consent form, and contact details will be transferred from where it is collected and stored to University of Birmingham. I agree to the transfer and storage of this data. |  |
| 5 | I agree to have a leg ultrasound and for my CTPA scan to be placed on a database for review by specialist radiologists.  |  |

**Optional consents**

***Please initial inside box for each optional consent you are willing to provide***

|  |  |
| --- | --- |
| I agree for my CTPA scan to be stored at Royal United Hospitals Bath NHS Foundation Trust for the information to be used in further research studies. |  |
| I am willing to be contacted about additional STOP-APE research or other future research studies related to your PE. |  |
| I agree to take part in an interview with the STOP-APE researcher about how information was presented to me. (Note - not all patients who consent will be interviewed.) |  |
| I agree to data from my audio-recorded interview being stored at the University of Birmingham and their authorised representatives for transcription, where anonymised quotations and clips of recordings can be used for training, teaching, research, and publication purposes, now and in the future. |  |
| I understand that I am free to withdraw from the audio-recorded consultations and/or interview(s) at any time without giving a reason, and that withdrawing will not affect my legal rights. I agree to any information collected before my withdrawal being retained and used for this research. |  |

I agree for my audio recordings to be transcribed by an approved transcription company and for the transcripts of my data to be made “Controlled Access” when the study ends. I understand that this means the anonymised data will be available to other researchers who secure the necessary approvals. I understand that this means that data may be used for purposes not related to this study, but it will not be possible to identify me from these data.

*Name of Patient Date Signature*

*Name of Person taking Consent Date Signature*

**When completed: 1 for participant, 1 for Investigator Site File, 1 for the STOP-APE Trial Office, 1 original to keep in medical notes.**