**STOP-APE: Stopping anticoagulation for isolated or incidental subsugemental Pulmonary Embolism**

**Healthcare Professional Information Study and Audio-recording Consent Form**

You are being invited to take part in an interview as part of a research study. Before you decide if you are willing to be interviewed it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with colleagues if you wish. Ask us if there is anything that is not clear or if you would like more information.

## What is the purpose of the interview study?

The purpose of the interview is to find out about healthcare professionals’ views on acceptability and potential consequences of a no treatment approach for subsegmental pulmonary embolism. This will help us to identify specific issues that are affecting recruitment and improve the recruitment process.

## Why have I been chosen?

We hope to interview about 30 healthcare professionals caring for patients who are taking part in the STOP-APE trial.

## What do I have to do?

We are asking you to be interviewed by a qualitative researcher at a time and place that is convenient to you. The interview will be conducted either face-to-face or via telephone or video call. We expect each interview to last up to an hour. The interviews will be audio recorded on to a secure audio recording device.

## Do I have to be interviewed?

We will telephone you to invite you to take part in an interview. It is up to you to decide whether or not to take part. If you decide to take part we will ask you to sign the consent form at the end of this sheet. If you decide to take part you are still free to withdraw at any time and without giving a reason.

## Will my taking part in this study be kept confidential?

All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and social care research and will be kept strictly confidential. University of Birmingham is the Sponsor for this study. The University of Birmingham will act as the data controller for this study. This means that the University of Birmingham are responsible for looking after your information and using it properly.

## How will we use information about you?

We will need to use information from you for this research project. This information will include your full name and telephone contact number. The recordings will be made on an encrypted device (password protected). The recording will be transcribed by a transcription company which has been approved for transcription of medical data. People who do not need to know who you are will not be able to see your name or contact details. Your data will be allocated a unique study number instead. Access to this data will be restricted to members of the research team at University of Birmingham. We will keep all information about you safe and secure. You will never be identified in any publications but we may quote your words. All audio-recordings will be kept for 10 years after the end of the study and then destroyed. Documentation and data from this part of the study will be securely stored at the University of Birmingham for 10 years.

All information collected by the Sponsor will be securely stored at the University of Birmingham on paper and electronically and will only be accessible by authorised personnel. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or audit the data collection process. In the Trial Office, you will be identified by a unique study number.

Under no circumstances will you be identified in any way in any report, presentation or publication arising from this or any other study. All individuals who have access to your information have a duty of confidentiality to you.

## What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your data in specific way for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the University of Birmingham has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below.

Legal Services

University of Birmingham

Edgbaston

Birmingham, B15 2TT

You can also find out more about how we use your information at [www.birmingham.ac.uk/privacy](http://www.birmingham.ac.uk/privacy).

## Where can you find out more about how your information is used?

You can find out more about how your information is used from [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/) and by reading the information available here [**www.hra.nhs.uk/patientdataandresearch**](http://www.hra.nhs.uk/patientdataandresearch)**.**

If you are worried about any part of this study or have a complaint, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to complain formally, then the normal National Health Service complaints mechanisms will be available to you: please ask to speak to [insert local details of independent advice service as per local trust policies] or you can contact the trial office at stopape@trials.bham.ac.uk or telephone 0121 415 9120. If you would like more information on your rights, would like to exercise any right or have any queries relating to our processing of your personal data, or if you wish to make a complaint about how your data is being or has been processed, please contact:

**The Data Protection Officer, Legal Services, The University of Birmingham, Edgbaston, Birmingham B15 2TT
Email: dataprotection@contacts.bham.ac.uk
Telephone: +44 (0)121 414 3916**

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| ***This form should be completed by the participant.*** | ***Please initial each box:*** |
| 1. I confirm that I have received enough information, about this research to make an informed decision and have had the opportunity to ask questions. These questions have been answered clearly and satisfactorily.
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| 1. I agree to take part in an in-depth audio-recorded interview and for this recording to be transcribed by a transcription company.
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| 1. I agree for my audio recording and anonymised transcripts to be stored at the University of Birmingham by authorised members of the research team.
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| 1. I understand that my data may be looked at by authorised representatives of the NHS Trust, Sponsor organization and regulatory authorities where applicable to check that the research is being done correctly. I consent for these authorised individuals to have access to my data.
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| 1. I understand that I am free to withdraw from the study at any time without giving a reason and that withdrawing from the study will not affect my legal rights.
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| 1. I agree to take part in this study.
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Name of participant Signature Date

**When completed: 1 for participant, 1 for Investigator Site File, 1 for the STOP-APE qualitative researcher.**