** A randomised controlled trial to investigate clinical and cost effectiveness of Amiodarone vs Beta Blockade for new onset atrial fibRillation in icU - a Pragmatic sTudy**  **Trial**

<Insert Trust logo>

|  |  |
| --- | --- |
|  | **Record of Telephone Declaration** |

Patient trial number: Patient Name: ………………………………………………………

**This sheet is to assist with the process of taking telephone declaration from the participant’s legal representative.**

**The telephone call to seek consent will need to be witnessed by an independent member of staff.**

|  |  |
| --- | --- |
|  | *The researcher should initial the appropriate boxes that the legal representative has agreed to.*  |
|  | I am willing to act as a legal representative for my relative/friend/patient. |  |
|  | I am able to do this because I am (please see page 3):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |
|  | I confirm that the researcher has discussed the Legal Representative Information Sheet, version number \_\_\_ • \_\_\_ dated \_\_\_ \_\_\_ /\_\_\_ \_\_\_ \_\_\_ / \_\_\_ \_\_\_ \_\_\_ \_\_\_ for the **ABBRUPT** trial. I have had the opportunity to consider the information and ask questions, and have had these answered satisfactorily. |  |
|  | It is my belief that my relative/friend/patient would not object to being included in this research project. I am not aware of any previously expressed contrary opinion. |  |
|  | I understand that if, at any time, I consider that my relative/ friend/ patient would object to being included in this trial, I can inform the ABBRUPT Research Team who will withdraw them from the trial immediately. I do not need to give a reason and my relative’s/friend’s/ patient’s medical care or legal rights will not be affected. I understand that data collected up to their time of withdrawal may be used. |  |
|  | I understand that relevant sections of my relative’s/friend’s/ patient’s medical notes or information related directly to their participation in this trial may be looked at by responsible individuals from the sponsor, regulatory authorities and research personnel where it is relevant to their taking part in research. I give permission for these individuals to have access to their records. |  |
|  | I understand that information collected that identifies my relative/ friend/ patient by name, e.g. Consent Forms, will be transferred from where it is collected and stored at the University of Birmingham during the trial and then at a specialist, secure archiving facility, in compliance with current regulations, after the trial. I agree to the transfer and storage of this information. |  |
|  | I understand that my relative’s/friend’s/patient’s GP will be informed of their participation in the ABBRUPT Trial and may also be contacted by members of the ABBRUPT Research Team for information about their health specific to the ABBRUPT Trial. |  |
|  | I agree to my friend/relative/patient continuing to take part in the ABBRUPT Trial. |  |
|  | I understand that the information collected about my friend/relative/patient may be used to support other related research in the future  |  |
| **Note: The legal representative on behalf of the person that they are providing consent for, MUST agree to all the points above in order for them to participate in the ABBRUPT Trial.****Points 11 and 12 below are OPTIONAL; please only initial these boxes if you agree to the following:** |
|  | I agree that blood samples taken from my friend/ relative/ patient can be stored for future biochemical tests to help understand new onset atrial fibrillation. These samples will be taken and stored on the understanding that the investigations are for medical research only and the results will be kept confidential. Any trial on this material is subject to Research Ethics Committee approval. I understand that these samples will be analysed in research laboratories outside this hospital, within the UK.  |  |
|  | If my relative/ friend/ patient is transferred to another hospital for further treatment, relating to their illness, I consent for the ABBRUPT Research Team to contact the hospital where they are receiving treatment, to request some information about their health specific to the ABBRUPT Trial. |  |

Name of Legal Representative:

Position: Friend Relative Patient

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Date of phone call:

 H H / M M

Time of phone call:

Preferred method of receiving a copy of the information sheet: Email Post

Email address:

Postal address:

Name of researcher taking consent:

Signature of researcher:

Name of Witness:

Signature of Witness:

# Additional information regarding legal representatives

# *Who can act as a personal legal representative for the purposes of obtaining consent for research participation?*

A carer/relative/friend who is willing to act on their behalf. Ideally it should be the person with the closest personal relationship with the potential subject who is capable him or herself of giving consent or the doctor who is primarily responsible for the treatment provided to the participant, provided he/she is NOT connected with the trial.

In legislation, being connected with the trial is defined as being:

* 1. The sponsor of a trial
	2. A person who is involved in the trial management.
	3. An investigator for the trial
	4. A health care professional who is a member of the trial team
	5. A person who provides health care under the direction or control of the investigator, whether in the course of the trial or otherwise.

If the doctor is connected with the conduct of the trial, the health care provider responsible for the care of the patient must nominate someone who can act as a legal representative of the person concerned.

***What does a personal legal representative do?***

A personal legal representative consents to participation in medical research on behalf of a person who cannot consent for themselves. Deciding what the person would have wanted should take into account:

* the person’s values and preferences
* their physical and psychological health and well-being
* their quality of life
* their spiritual and religious welfare

Prior to reaching a decision on whether to give or withhold consent, the personal legal representative must be fully aware of the type of research, its purpose, risks, inconveniences and implications of the trial. A personal legal representative has the right to withdraw consent to participation.

# *Who can act as a professional legal representative for the purposes of obtaining consent for research participation?*

A person independent of the trial, who is the doctor primarily responsible for the medical treatment provided to that adult. Or a person nominated by the relevant healthcare provider

**Once completed: Original to be kept in Investigator Site File, one copy for the Legal Representative, one copy to the ABBRUPT Trial Office and one copy in the patient’s medical notes.**