**ABBRUPT Trial**

**CONSENT FORM FOR A LEGAL REPRESENTATIVE**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Patient Trial Number:** ii I ii I ii I ii | | **Please initial each box to confirm consent ↓** | | |
| **1.** | I am willing to act as a legal representative for my relative/ friend/ patient | |  |
| **2.** | I am able to do this because I am (please see page 3): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  |
| **3.** | I confirm that I have read and understood the Legal Representative Information Sheet, version **ii ii . iLii** dated\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ for the above trial. I have had the opportunity to think about the information, ask questions and have had these answered to my satisfaction. | |  |
| **4.** | 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. | |  |
| **5.** | 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. | |  |
| **6.** | 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. | |  |
| **7.** | 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. | |  |
| **8.** | 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. | |  |
|  |  | |  |
| **9.** | I agree to my relative/ friend/ patient continuing to take part in the ABBRUPT Trial | |  |
|  |  | |  |
| **10.** | I understand that the information collected about my friend/relative/patient may be used to support other related research in the future. | |  |
|  |  | |  |
|  |  | |  |
|  | **Your relative/ friend/ patient may only continue to participate in the ABBRUPT Trial if you have consented to points 1-10 above and initialled the corresponding boxes. Points 11 and 12 below are OPTIONAL; please only initial these boxes if you agree to the following:** | |  |
| **11.** | 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. | |  |
| **12.** | 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. | |  |

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| --- | --- | --- | --- | --- |
|  |  | | | |
| Name of patient |
|  |  |  |  |  |
| Name of legal representative |  | Date |  | Signature |
|  |  |  |  |  |
| Name of person receiving consent |  | Date |  | Signature |
| By signing this form, I confirm that I witnessed the remote consent process. The legal representative confirmed verbally that all of their questions had been answered and they agreed for the patient to participate in this study on the patient’s behalf. | | | | |
| Name of witness  (witness only required if legal representative is physically unable to sign) |  | Date |  | Signature |

***Original to be filed in the Investigator’s Site File; 1 copy for patient; 1 copy to be kept with patient’s hospital record; 1 copy to be sent to BCTU***

# 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.

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