*Insert Header with institution’s name or institution’s letterhead*

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*[Insert site name]*

|  |  |
| --- | --- |
| **Title** | **High Power Short Duration (HPSD) versus Lower Power Longer Duration (LPLD) Atrial Fibrillation Ablation in Posterior Left Atrium and Hyperthermic Effects on EsophAgeal Tissue : the HiLo HEAT Study**  |
| **Short Title** | HiLo HEAT  |
|  |  |
| **Project Sponsor** | Alfred Health  |
| **Coordinating Principal Investigator /** **Principal Investigator** | Professor Peter Kistler *Principal Investigator*  |
| **Associate Investigator(s)** | *[Associate investigators (s)]*  |
| **Location**  | *[Location]*   |
| **HREC Reference/ ID** | HREC/58589/Alfred- 2019 |
| **Local Project Number** |  |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have Atrial fibrillation (AF) and your treating doctor has proposed that you have a catheter based AF ablation procedure to treat this. From here on, the term AF ablation in this consent form refers to catheter based AF ablation.

The research project is comparing the safety and effectiveness of two different power settings used when performing AF ablation in the back wall (posterior wall) of the left upper chamber (atrium) of the heart

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

Atrial fibrillation (AF) is the most common disorder of heart rhythm. It is caused by abnormal, uncoordinated electrical impulses in the heart’s upper left chamber (also known as the left atrium), and may produce palpitations, fatigue, breathlessness, and pulse irregularity. It is also an important cause of stroke and heart failure.

Correction of normal heart rhythm using medications is generally difficult, and “AF ablation” has emerged has an important alternative strategy. This is a minimally invasive procedure which is done under general anaesthesia (you will be asleep for the procedure). Whilst you are under anaesthesia, we will place a ultrasound probe down your foodpipe (transesophageal probe) to check the heart function and make sure there is no clot in the heart chambers. We will then place catheters (long thin tubes) through your right groin, up the blood vessels, and into the right upper chamber (right atrium) of the heart. We will then use the catheters to enter the left atrium of the heart, where AF occurs, by making a small puncture through the wall (septum) that separates the right from the left atrium. Once we are in the left atrium, we will use specialised instruments, delivered through these catheters, to burn tissue in the left atrium which has caused you to have atrial fibrillation. We use various measures to ensure your safety during the procedure: we will give you blood thinners to ensure that no clot forms in your heart chambers during the ablation. We will also put a temperature monitoring probe down your foodpipe (esophagus) to monitor the temperature in the foodpipe during the ablation. The foodpipe sits right behind the heart. The typical duration for an AF ablation procedure is around 3 hours, including time to administer the general anaesthesia to you, and also to wake you up from the anaesthesia.

Whilst AF ablation is safe, there is a small risk of complications from it. As mentioned above, the food pipe sits behind the heart, next to the back wall of the left atrium. Applying heat energy around the left atrium back wall can cause heating-related injuries to the esophagus. Ways of reducing the risk of heating-related injuries include reducing the heating energy at the back wall and reducing the ablation time – this is called lower power longer duration [LPLD] ablation. In addition, a temperature probe is placed into the esophagus to monitor for temperature rises early.

Recent research has shown that the use of high power and short duration (HPSD) ablation in the back wall of the left atrium can actually improve the effectiveness of ablation, and significantly reduce the length of time of the procedure and patients’ exposure to X -ray radiation (X-ray radiation is used routinely in AF ablation to visualise the heart and the catheters used in the ablation). HPSD ablation has also been shown to have low complication rates, including heating-related injury to the esophagus.

However, we need more data to confirm the safety of HPSD ablation, especially with regards to heating-related injury to the esophagus.

Hence this study is designed to compare HPSD ablation with the conventional LPLD ablation in the back wall of the left atrium and the effect on heating-related injury rates.

The results of this research will be used by the study doctor David Chieng to complete his Doctorate of Philosophy (PhD) degree

**3 What does participation in this research involve?**

You are going to undergo a cardiac procedure as part of your routine care, called AF ablation. An explanation of the procedure has already been described above (see page 2). You will have to sign a standard *[Institution]* procedural consent form for the AF ablation. This research consent form is used to enrol you into this research study

Participation in this project will involve collection of data during your routine procedure and during your routine follow-up visits over a period of twelve months. During the procedure, we will be collecting information including the ablation power settings, temperature changes in the esophagus, the amount of radiation exposure, and the procedural time. During your follow up we will be collecting information on medication changes, any recurrence of AF, any complication from the procedure, and questionnaire information.

If you are eligible and you decide to participate in this study, your consent will be obtained before any study assessments are performed.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random).

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions

Once you are enrolled, you will be randomly allocated to have ablation on the back wall of the left atrium performed with either :

* conventional lower power longer duration (LPLD) approach, with power set at 25 Watts ; or
* the high power short duration (HPSD) approach, with power set at 40- 50 Watts.

With each ablation we aim to achieve a specific target which tells us that the amount of energy delivered is sufficient enough. This target is known as the ablation index, or lesion index (depending on which 3D mapping system is used on the day of your ablation)

You will have a 1 in 2 chance of receiving the HPSD setting for your ablation

A multisensor temperature probe (Circa Scientific, S-Cath) will be placed in your esophagus throughout the ablation to monitor for any temperature rise. If there is a significant temperature rise at an ablation spot, we will stop the ablation for that spot, and wait for the temperature in the esophagus to normalize. We will then continue with ablation at a different spot.

The duration of an AF ablation procedure using the conventional lower power longer duration ablation approach is on average 3 hours. Using the high power short duration approach, the duration of the procedure will be shorter, down to about 2 hours.

Following the ablation, you will undergo an endoscopy procedure within 24 hours of the ablation procedure to look for the presence / absence of heating-related injury to the esophagus. This will be performed under sedation at the gastroenterology department at the *[Institution].* An endoscopy is a non surgical procedure which is used commonly to examine a person’s digestive tract. With endoscopy, a flexible tube with a light and camera attached to it is passed through your mouth, down the throat, and into the foodpipe (esophagus) and stomach. The procedural doctor (he/ she is called a gastroenterologist) can see pictures of your esophagus and stomach on a big colour TV monitor and can assess for any abnormality.

If you do not have any heating-related injury, we will still place you on a standard dose of a stomach-acid suppressing medication called a proton pump inhibitor (PPI) for 1 month. This is a routine prevention measure that we use in all patients having AF ablation.

However, if you have heating-related injury, we will:

* place you on a higher dose (double dose) of the proton pump inhibitor, Depending on the severity of the heating related injury you may be advised by the gastroenterologist to undergo a repeat endoscopy to check for complete healing i.

In the highly unlikely scenario where there is perforation of your esophagus, or where an abnormal connection exists between the esophagus and the left atrium (atrio-esophageal fistula), you may be required to undergo further procedure(s) / surgery to fix the complication.

We will also organise for a MRI (magnetic resonance imaging) of the brain the day after the ablation to look for any evidence of silent stroke (asymptomatic cerebral infarction), which means stroke with no obvious symptom. MRI stands for magnetic resonance imaging. A MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans.

We will ask you to lie on a table inside the MRI scanner. The scanner will record information about your brain. It is very important that you keep very still during the scanning. When you lie on the table, we will make sure you are in a comfortable position so that you can keep still. The scanner is very noisy and we can give you some earphones to reduce the noise. Some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing on a call button provided to you. The brain MRI should take about 1 hour to perform.

There are no proven long-term risks related to MRI scans as used in this research project. MRI is considered to be safe when performed at a centre with appropriate procedures. However, the magnetic attraction for some metal objects can pose a safety risk, so it is important that metal objects are not taken into the scanner room.

We will thoroughly examine you to make sure there is no reason for you not to have the scan. You must tell us if you have metal implanted in your body, such as a pacemaker or metal pins

You will be followed up for 12 months after your ablation. You will have routine clinic reviews at the *[Institution]* arrhythmia clinic at 3 months and at 12 months after your ablation. During your reviews we will :

* Perform an ECG
* Discuss about your symptoms and concerns
* Perform a physical examination
* Review your medications and make changes as needed

Your heart rhythm will be monitored after the ablation to look for any AF recurrence.

In most cases we will supply you with an Alive Cor device, which is an electronic rhythm monitoring device that is linked with your smartphone. You place your fingers over the device for 1 minute to record the ECG. You will be required to send your ECGs via email to us, twice a day every day for 12 months after your ablation. We will analyse your ECGs every day to look for any AF recurrence.

If the use of the Alive Cor device is not possible, we will arrange for you to wear an external heart rhythm monitor for 24 hours, every three months ( 4 times in total).

You will also be requested to complete the Atrial Fibrillation and Effects on Quality of Life (AFEQT) questionnaires at 6 and 12 months following your ablation. This will take 5 minutes to complete and will help us to better understand the impact of AF and the ablation procedure on your quality of life and physical functioning.

**4 What do I have to do?**

We will need to monitor your heart rhythm to look for any AF recurrence. In most cases we will supply you with an Alive Cor device. As described above, this is a quick and non invasive way to check your heart rhythm. In general it takes about 1 minute to record the ECG on your smartphone. You will be required to send your ECGs twice a day to us, every day for 12 months after your ablation. If the Alive Cor is not possible, then we will organise for you to have a 24 hour Holter monitor. The holter monitor is a small portable device with 3 ECG leads which are attached to your chest using stickers. This can be taken off for showers. During the 12 month follow up, you will have the 24 hour Holter monitor every 3 months, so in total 4 times over the duration of the study. There are no restriction on existing medications or diet if you enter the study.

**5 Other relevant information about the research project**

This study will involved a total of 88 participants. We are expecting to recruit [*Number]* participants from *[Institution]*. This research has been initiated by Prof. Peter Kistler at Alfred Health,.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

**6 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with *[Institution]*.

**7 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

If you decide *not* to participate, you will still undergo your AF ablation procedure, using the conventional lower power longer duration (LPLD) ablation on the back wall of the left atrium.

**8 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may includeclose contact with the research team for the duration of the trial and thereafter if ongoing management is required and timely follow up with a single doctor for the duration of the study. You will be contributing to the advancement of the field and help the wider community.

**9 What are the possible risks and disadvantages of taking part?**

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you

Risks associated with AF ablation

|  |  |
| --- | --- |
| Common risk (less than 5% or 5 in 100) | minor bruising at the puncture site |
| Uncommon risks (1 to 5% or 1 to 5 in 100) | major bruising or swelling at the groin puncture sitechest paindevelopment of another arrhythmiadamage to the heart muscle or valveclots in the leg with pain and swellingprolonged chest pain taking weeks to resolve due to inflammation of the membrane sack around the heartstroke with long-term disability |
| Rarely (less than 1% or 1 in 100) | narrowing of the veins from the lungs to the heart causing breathlessnessdamage to the phrenic nerve that controls the diaphragm (breathing muscle)Atrio-esophegeal fistuladeath  |

Risk of heating related injury to the esophagus ( as diagnosed on endoscopy)

Heating related injury of the esophagus, as diagnosed on endoscopy post ablation, varies in presentation from mild redness (erythema) of the surface of the esophagus, to superficial and deep ulceration, and in the worst cases to perforation of the esophagus and abnormal connection between the heart and esophagus (atrioesophageal fistula). The risk of any heating related injury is approximately 11% (11 in 100), which mostly consisted of mild redness with no long term consequences. The risk of ulceration is low at 1-5% or 1 to 5 in 100, and atrio-esophegeal fistula is extremely uncommon with a risk of <3 in 10000.

Risk associated with endoscopy procedure

|  |  |
| --- | --- |
| Common risks (less than 5% or 5 in 100) | nausea and vomitingdizziness (especially when you start to move around after the procedure) muscle aches and pains |
| Uncommon risks (1 to 5% or 1 to 5 in 100) |  vomit in the lungs causing pneumoniadamage to your teeth or jaw due to the presence of instruments in your mouth. |
| Rarely (less than 1% or 1 in 100) | accidental hole (perforation) in the oesophagus/ stomachbacteraemia ( infection in the blood stream) |

Risks associated with general anaesthesia

These days, whilst anaesthesia is generally very safe there are some risks associated with anaesthesia. The most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare. The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team.

If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team. In addition, you may prefer to suspend or end your participation in the research if distress occurs.

Special risk with high power short duration ablation

There is no special risk associated with high power short duration ablation. A theoretical concern previously had been of potentially increased esophageal thermal injury with high power short duration ablation. However current evidence suggest that high power short duration (HPSD) ablation has similar risk of heating related injury to conventional lower power longer duration (LPLD) ablation. In particular, a recent large study had shown that the risk of atrioesophageal fistula in HPSD ablation to be 3 in 10000 cases.

Risk associated with ionising radiation

This research study involves exposure to a very small amount of radiation if you require a pre-MRI safety screening X-ray examination (such as an orbital X-ray) prior to your MRI scan. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 0.01 mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure. The risk is believed to be minimal. Have you been involved in any other research studies that involve radiation? If so, please tell us. Please keep information contained within the Participant Information and Consent Form about your

exposure to radiation in this study, including the radiation dose, for at least five years. You will be required to provide this information to researchers of any future research projects involving exposure to radiation.

**10 What will happen to my test samples?**

There will be no sample collected from this study for research purposes

**11 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project, you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

**12 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. Your study doctor will explain to you which treatments or medications need to be stopped while you are involved in the research project.

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

**13 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the researchers up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

**14 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as

* Unacceptable side effects
* One treatment shown to be more effective than the other

**15 What happens when the research project ends?**

After the study ends, you will be followed up by your treating doctor regularly as before.

At the conclusion of the study, the information will be gathered and written up as a manuscript and published in a peer reviewed journal. This information will be freely available to the public. If you are keen to know the result and conclusion of the trial, please ask your treating doctor.

**Part 2 How is the research project being conducted?**

**16 What will happen to information about me?**

By signing the consent form, you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project.

Any information obtained in connection with this research project that can identify you will remain confidential. Your information will be recorded as per usual practice within this hospital / health system.

You will be assigned a unique number for this trial to protect your privacy. This unique number will then be used to record all your study information in the study database. The database is for the purpose of this study only. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. The database will be hosted and managed by the Alfred Health.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form, you agree to the study team accessing health records if they are relevant to your participation in this research project.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by *[Institution]* and the Alfred Hospital, the institution relevant to this Participant Information Sheet. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. The results will be presented as a group and not individually.

Your study information may be used for future research related to this project. By signing this consent form you agree to the study team using your de-identified study information for future research related to this project.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant Australian and Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law. The data will be stored indefinitely at Alfred Health

**17 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

**18 Who is organising and funding the research?**

This research project is being conducted by Alfred Health with Professor Peter Kistler as the principal investigator..

**19 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Alfred Health – the Alfred Hospital Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**20 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects) you can contact the principal study doctor on +613 9076 3352 or any of the following people:

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are (please quote project number 638/19):

**Complaints contact person**

|  |  |
| --- | --- |
| Name  | *[Name]* |
| Position: | *[Position]* |
| Telephone: | *[Phone number]* |
| e-mail:  | *[Email address]* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

|  |  |
| --- | --- |
| Reviewing HREC name | Alfred Hospital Ethics Committee |
| Position | HREC Executive Officer |
| Telephone | +613 9076 3619 |
| Email | research@alfred.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | **High Power Short Duration (HPSD) versus Lower Power Longer Duration (LPLD) Atrial Fibrillation Ablation in Posterior Left Atrium and Hyperthermic Effects on EsophAgeal Tissue : the HiLo HEAT Study** |
| **Short Title** | HiLo HEAT  |
|  |  |
| **Project Sponsor** | Alfred Health  |
| **Coordinating Principal Investigator/****Principal Investigator** | Professor Peter Kistler *Principal Investigator*  |
| **Associate Investigator(s)** | *[Associated Investigator(s)]* |
| **Location**  | *[Location where the research will be conducted]* |
| **HREC Reference/ ID** | HREC/58589/Alfred- 2019 |
| **Local Project Number** |  |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to *[name of institution]* concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| Declaration - for participants unable to read the information and consent formWitness to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \* Witness is not to be the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | **High Power Short Duration (HPSD) versus Lower Power Longer Duration (LPLD) Atrial Fibrillation Ablation in Posterior Left Atrium and Hyperthermic Effects on EsophAgeal Tissue : the HiLo HEAT Study** |
| **Short Title** | HiLo HEAT  |
|  |  |
| **Project Sponsor** | Alfred Health  |
| **Coordinating Principal Investigator/****Principal Investigator** | Professor Peter Kistler *Principal Investigator*  |
| **Associate Investigator(s)** | *[Associated Investigator(s)]* |
| **Location**  | *[Location where the research will be conducted]* |
| **HREC Reference/ ID** | HREC/58589/Alfred- 2019 |
| **Local Project Number** |  |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

|  |
| --- |
|  |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

|  |
| --- |
|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.