Delete this line, then print on Hospital/Trust headed paper with contact details of local PI

STAR Study Patient ID:			-			

PATIENT INFORMATION SHEET

ShorT stay Aneurysm Repair (STAR) Study:

A 23-hour endovascular abdominal aortic aneurysm repair pathway with evaluation of eligibility, uptake, viability, acceptability, safety and cost.

You are being invited to take part in an observational study called STAR. Before you decide, it is important for you to understand why the study is being done and what it will involve.

Please take time to read the following information carefully and discuss it with others if you wish.

- *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
- *Part 2 gives you more detailed information about the conduct of the study*

Ask us if anything is unclear, or if you would like more information. Take time to decide whether or not you wish to take part

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Thank you for reading this information sheet.

This information sheet and signed consent form must be given to the patient if they agree to take part

Part 1

Why is an aneurysm?

An abdominal aortic aneurysm (AAA) is a ballooning of the main blood vessel (the aorta) that travels down through your tummy. An AAA can grow to a large size over time, and it may burst (rupture), causing life-threatening internal bleeding.

What is EVAR?

The standard method to prevent the AAA from bursting is to re-line the aorta with a material tube that is strengthened by metal struts. This is inserted in a collapsed state, constrained by a delivery device, through the blood vessels from the artery in the groin, positioned in the aorta below the arteries supplying the kidneys and opened (deployed) under X-Ray guidance to fix it in place above and below the aneurysm. This excludes the aneurysm from the flowing blood and stops the aneurysm from expanding, reducing the risk of rupture. This is commonly known as a `keyhole' or minimally invasive approach called *Endovascular (i.e.,* inside the aorta) *aneurysm repair* (EVAR). You will have discussed this procedure with your doctor.

Why is 23-hour EVAR (or STAR) being developed?

Increasing waiting times in the National Health Service (NHS) are widely reported. Many in the NHS consider waiting times to get patients with aneurysms treated much too long for an urgent condition. The reasons for this being limitations in resources including beds and staff expertise. EVAR, to treat abdominal aortic aneurysm, has been shown to be safe and effective and does reduce the burden on health services however the length of stay in hospital is still two days or more in most patients; up till now it has not been found to be cost-effective compared to the traditional open surgical approach. COVID-19 pandemic has further restricted the resources available to get aneurysm patients treated even with keyhole techniques.

This study is designed to evaluate whether short stay EVAR (being in hospital for <24 hours for the operation) is acceptable to a wide number of patients and clinically effective. We will also study whether it is worthwhile to implement in terms of cost.

Although short stay EVAR or day case EVAR has been tried before, it has not been in any way universally accepted and so needs to be studied

scientifically. One of the main factors that has not been studied is the patient view and so satisfaction, quality of life and the patient report outcome measures will be of prime importance.

What is the intervention that is being tested?

As part of your routine care, you will be undergoing EVAR to treat your AAA. What the study is evaluating specifically, is the implementation of a protocol-driven pathway for care after the operation which aims to encourage early discharge, hence the name STAR (ShorT stay Aneurysm Repair). The pathway involves optimising all the aspects of standard routine care in EVAR to avoid inefficiencies and delays. The evaluation will include the clinical success of the operation, your recovery and satisfaction as well as cost-savings for the NHS.

Why have I been chosen?

The aneurysm that you have needs repairing and your doctor believes that the best way to repair your aneurysm is with EVAR. You have been asked to consider taking part in this study because your doctor, after reviewing your X-Ray imaging (Computed Tomography; CT scan) and assessing your overall fitness with a multidisciplinary panel, has determined that you meet the eligibility criteria to have your aneurysm repaired via a short stay pathway. Our aim is to recruit 100 patients with similar fitness levels to yours who are also requiring EVAR, to be part of our study.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive. If you decide to withdraw and do not wish for any further data to be collected about you, you should inform your clinical care team of this in order that no further follow up information is collected from your medical records.

What will happen to me if I take part?

If you decide to participate in the study, once you have given informed consent by signing the study-specific consent form, you will have a baseline

assessment by the doctor or nurse to collect some information about your medical history and current condition: this will include completing a questionnaire about your general health status. This will be done during a routine appointment at the vascular out-patients clinic before your EVAR procedure.

You will be provided with a patient information pack and your GP will also be informed of your participation in the study.

You will undergo the standard preparations for surgery, whether you participate in the study or not. As part of short stay EVAR, you will be encouraged to participate in a home-based programme to optimize your fitness for the operation. This programme will provide you with coaching, in the areas of physical fitness, respiratory exercises, nutrition, smoking and alcohol cessation and will aim to enhance your recovery after surgery. This has been proven to improve the outcomes from surgery.

You will *not* be asked to have any specific medical tests for the sole purpose of the study. There will be no additional hospital visits required because of your participation in this study. However, you will be asked to complete questionnaires about your health status and receive pre-booked telephone follow up calls from the study team at three- and six-months post treatment, as detailed in the next page.

In the short You Tube video below you can find an overview of the treatment pathway from diagnosis and workup, through admission, discharge, and follow- up. The video can be accessed at : 23-Hour EVAR - A Guide For Patients - YouTube.

The short stay or STAR pathway to repair your aneurysm is planned as follows:

1. On the day of the operation, you will arrive at hospital at a pre-arranged time. You will then undergo the standard EVAR procedure as part of your standard care. The procedure will not be changed in any way as a result of this study.

2. In the immediate period after surgery, as you are part of the study you will follow a dedicated protocol to get recovered quickly from the

operation. You will be nursed in the recovery ward and monitored. You will be reviewed by the surgical and anaesthetic teams. If they are happy with your progress at this point, all tubes and drains will be removed before returning to the ward. Here you will be encouraged to eat and drink, and mobilise early.

3. You will be expected to stay in overnight and you will be reviewed by the vascular team early the next morning. This final check will ensure any pain is well controlled, your wound sites are satisfactory, all medications are administered appropriately, and waterproof dressings are supplied for seven days. You will be given specific instructions on the follow-up arrangements.

Follow up

1. After being discharged, you will have a telephone consultation with one of the specialist team members between day 2 and 4 as part of this research. This is not offered to patients who do not participate in the study. The aim of this follow-up consultation is to ensure you are recovering as expected and that there are no post-operative complications. The team will also ensure that further follow-up arrangements are in place as well as address any issues or concerns you may have.

2. In the unlikely event that a complication relating to your aneurysm occurs at home, we urge you to attend the hospital you were treated for an urgent review. Should an ambulance not be available to you, you may be required to make your own transport arrangements. Your team will educate you on what to look out for, and we would like you to confirm that you are happy with this knowledge on the consent form.

3. You will then be reviewed in clinic after approximately 1 month with necessary scans, as part of the standard follow up care.

Data Collection

The study team will collect information about your hospital admission, the operation itself and your progress up to 15-months after your operation from routine hospital follow ups and your hospital records.

You will be telephoned to collect information about your health and quality of life and outcomes at approximately 3 and 6 months after your operation. These phone calls may take up to 30 minutes to complete. These are for the purposes of the study only. If any problems are detected, you will be referred to the clinical team.

At approximately a year after your surgery you will be expected to come back to the clinic as part of the standard care that is received after aneurysm repair. We will not ask any specific questions regarding the study at this point, although as mentioned above, the study team will monitor your progress from your medical records after your surgery.

Loss of contact

If at any point during study follow up, the team is unable to reach you for a telephone or face-to-face consultation, we will attempt to contact your next of kin, as standard practice in the NHS. Should you not wish the study team to do so, please indicate this on the informed consent form.

Loss of capacity

In the unlikely event that you lose capacity during the study period and are unable to make decisions, you will be withdrawn from the study and no further data about your care will be collected. Data already collected with consent will be retained and used for analysis.

Table 1 Table highlighting the differences between standard EVAR pathway (in blue) and the STAR pathway (in red):

Routine standard EVAR timeline								
AAA DETECTED	MDT Discussion	**Pre-assessment clinic**	Standard EVAR: [2-3 day in-hospital stay]	1 MONTH POST-OP In-person clinic follow up with CT scan	1 YEAR POST-OP In-person clinic follow up with ultrasound scan			
Short Stay Aneurysm Repair (STAR) timeline								
AAA DETECTED	MDT Discussion	**Pre-assessment clinic:** Study participants will receive multi-media guide for "Preparing for EVAR"	**Short Stay EVAR (STAR)**	DAY 2-4 POST-OP Telephone follow-up	1 MONTH POST-OP In-person clinic follow up with CT scan	3 MONTH POST-OP Telephone follow-up	6 MONTH POST-OP Telephone follow-up	1 YEAR POST-OP In-person clinic follow up with ultrasound scan
			Data collection and review of medical records up to 15 months after the procedure →					

What are the possible disadvantages and risks of taking part?

You will not be sent home unless it is safe. However, a possible disadvantage to being discharged within 24 hours of your operation is that complications not initially apparent in the first day whilst you are in hospital may not become evident until a little later, Most commonly these represent chest or urinary tract infections. These are rare, and the vast majority are something that can be managed out of hospital, with antibiotics if necessary.

We have focused on ensuring safety throughout the STAR pathway. As part of your education and engagement study pack, you will receive in-depth guidance and hence be able to fully understand the process and grasp the essence of "what is normal, and what constitutes an emergency". Furthermore, you will be familiar with the support available to you at home in the form of follow-up conversations and emergency helplines outlined above.

What if new information becomes available?

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

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

In the event where incidental findings relating to your health (i.e. medical conditions unrelated to your aneurysm) are discovered, your clinical team will ensure your GP is informed and appropriate follow up is organised with the relevant team.

What are the possible benefits of taking part?

The STAR pathway has the potential to increase satisfaction and care for recovery in a home environment and reduce complications that occur as a result of hospital care itself (for example hospital acquired infections). Furthermore, with implementation of STAR, it is possible that hospital stay will be optimised, removing delays and inefficiencies, to decrease the time spent in hospital without any compromise to patient safety. This in turn has

the potential to allow the AAA repair service to offer repair more quickly and continue despite spikes in coronavirus cases as the risk of COVID-19 infection is mitigated.

What happens when the study stops?

The STAR study will follow your recovery process after your procedure. After the study's end, you will continue to receive routine follow up care with your local vascular team. Your surveillance imaging and follow up will not be affected by the study ending.

Patient Focus Groups

Your feedback on the STAR pathway is of immense importance to us.

As we aim to better the service and ensure its viability in the NHS, we would like to invite you to partake in one of our patient focus groups after the study has concluded. These groups will take the form of a relaxed, virtual group semi-structured interview, chaired by one of the study co-ordinators. The purpose of these discussions will be to identify aspects of the pathway that worked well and perhaps ones the team can improve on. It will also give participants the opportunity to voice any ideas or concerns they may have in relation to STAR and emphasize aspects of their care which were important to them.

This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in part 2 before making any decision.

Part 2

What if something goes wrong?

You will be provided with a 24-hour emergency contact number that will give you access to advice from a trained member of your local vascular team.

The Chief Investigator and his team at the study co-ordinating centre will closely monitor the study. If there are any problems then they will be detected as soon as possible so that the study can be changed or stopped if necessary. There are several safety 'checkpoints' in place which are outlined in part 1 in order to pick up circumstances when complications arise.

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you via the Patient Advice and Liaison Service (PALS):

Delete the highlighted text and replace with details of the local PALS service

Telephone: XXX
Email: XXX
Postal Address: XXX

If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team.

How will we use information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from your medical records for this research project. This information will include the following:

- your name, NHS number, date of birth and contact details at the participating hospital (to ensure appropriate telephone follow ups).

- Your initials and date of birth at Imperial College London (Sponsor)

People will use this information to do the research or to check your records to make sure that the research is being done properly.
People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
We will keep all information about you safe and secure.
Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

Legal basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

International transfers

There may be a requirement to transfer information to countries outside the UK (for example, to a research partner). As this is optional for each participant, please let us know if you are happy for us to do so by indicating this on the informed consent form. Where this information contains your personal, pseudonymised data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

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.

- If you choose to stop taking part in the study, we would like to continue collecting information about your health from your medical records. If you do not want this to happen, tell us and we will stop.
- We need to manage your records in specific ways 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.

WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/

- or by asking one of the research team (contact details given on page 13)

COMPLAINT

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

Involvement of the General Practitioner/Family Doctor (GP):

With your permission, your GP will be kept informed of your participation in the STAR study, but otherwise all information about you and your treatment will remain confidential.

What will happen to the results of the research study?

When the study is complete, the results will be presented at high level national and international scientific conferences. They will also be published in a medical journal, and a summary of the results will be prepared in language easily understood by participants and members of the public. These will be made available via the study website and social media platforms, and hard copies can be requested from your local study team. No individual participants will be identified in any report or publication.

Who is organising and funding the study?

The STAR study is sponsored by Imperial College London. It has received funds from endograft manufacturers W.L. Gore & Associates, Inc. and Medtronic to carry out the study. The Study Coordination Centre is based at Imperial College London. Imperial College London has overall full responsibility for the coordination and conduct of the study.

Participants and individual researchers will not receive any payments, reimbursement of expenses or any other benefits or incentives, nor receive

any personal payment over and above normal salary for taking part in this research.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by an independent National Research Ethics Committee, Bromley Research Ethics Committee.

Contact for Further Information

If you have any further questions about your disease or the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the procedures involved. If you would like to learn more about this study you can contact the Study Coordinating Centre on the number/email below:

Telephone: 07376460675
Email: starstudy@imperial.ac.uk
Study website: STAR Study | Faculty of Medicine | Imperial College London
ClinicalTrials.gov Identifier: NCT052279274

More information on vascular diseases or procedures are also available from:

- **The National Institute for Health and Clinical Excellence** (NICE) is the independent organisation responsible for providing national guidance (recommendations) on whether interventional procedures are safe enough and work well enough to be used routinely in the NHS. You can read the NICE guidance on stent-graft placement in abdominal aortic aneurysms here: https://www.nice.org.uk/guidance/ta167

- **The Circulation Foundation** www.circulationfoundation.org.uk