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RESTORE - INFORMATION SHEET FOR PARENT(S)/GUARDIAN(S)

Study Title:	A randomised trial of surgery versus no treatment to RESTORE cardiopulmonary function in severe pectus excavatum
IRAS ID:	331910
Study Doctor:	If you have any questions about this study, please talk to your study doctor or nurse. *<Full name of principal investigator, title, institutional affiliation, address, phone number>*
Study Sponsor & Data Controller:	*South Tees Hospitals NHS Foundation Trust*
Participant ID:	*<INSERT, IF AVAILABLE>*

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SUMMARY You are being asked for consent for your child to take part in a research study. This section provides an overview of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide more detail.	
WHY IS THIS RESEARCH BEING DONE?	Pectus Excavatum (PE), also known as funnel chest, is a condition where the ribs and breastbone (sternum) grow inwards forming a dent in the chest. People with severe PE, can have symptoms such as breathlessness, dizziness, fainting and pain with exercising. This can be very restrictive in daily life. Treatment for PE includes surgery, which lifts the sternum up, which relieves these symptoms. High-quality data showing that the surgery improves physical health and heart-lung function is limited. The purpose of this study is to see how surgery to treat PE affects a participant's ability to be physically active. We will also look at how much this costs the National Health Service (NHS) overall.
WHAT HAPPENS TO THEM IF I AGREE TO TAKING PART IN THIS RESEARCH?	Your child already has a diagnosis of severe PE and you might have been told that they are eligible for surgery. In this research study there are two different parts and if you have already been told that your child is eligible for surgery you and your child can choose for them to take part in one part or the other. If you haven't been told that they are eligible for surgery then they can go into the second part of the trial. Option (1), AN OBSERVATIONAL GROUP: Your child will go ahead as normal with their scheduled surgery. We will collect some data from their medical notes and ask them to complete some questionnaires. After surgery, we will follow-up with them about their health for a period of up to 4 years. During this time, they will be asked about their health, to do exercise tests and to complete questionnaires. Option (2), A TRIAL: Your child will be allocated to undergo surgery as soon as possible (within 3 months) or with a year's delay. This delay provides us with data to compare how effective surgery is in improving physical health. The group they are allocated to will be chosen randomly by a computer (like tossing a coin). There is equal chance of being allocated to each group. Your child's health will then be followed up for a period of up to about 3-4 years. During this time, they will be asked about their health, to do exercise tests and to complete questionnaires.
COULD BEING IN THIS RESEARCH HARM THEM?	The research involves standard surgical procedures for treating PE. The health risks for your child are the same whether they have these procedures as a participant in this research study or outside of the research study. The most common surgical complications are pain and minor wound infections. More rarely they may require repeat chest drains, suffer deeper wound infections or movement of the bars placed in chest during surgery (Nuss operation only) displacement needing hospital treatment and very rare complications include more major damage to the heart or lungs, blood clots and extremely rarely the possibility of life-threatening complications. As a follow-up to the surgery they may have a follow-up CT scan and chest X-rays which expose them to a small amount of radiation.
YOUR PERSONAL DATA	In this research study we will use information from your child and their medical records. We will only use information that we need for the research study. We will

	let very few people know their name or (your) contact details, and only if they really need it for this study. Everyone involved in this study will keep the data safe and secure. We will also follow all privacy laws. At the end of the study, we will save the data for 5 years in case we need to check it and for future research, after which it will be destroyed. We will make sure no-one can work out who your child is from the reports we write. The information pack tells you more about this.

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1. WHY AM I RECEIVING THIS INFORMATION SHEET?

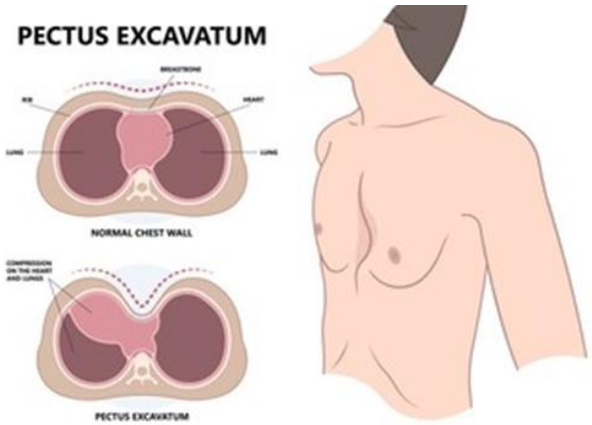
You are being asked to consider this research study as your child has severe or very severe Pectus Excavatum (PE) and they experience significant symptoms as a result.

Your child is currently under the age of 16, therefore we are approaching you as their parent/guardian (as well as your child). Before deciding whether you agree to your child taking part (if that is also their wish), it is important for you to understand why the research is being conducted and what it will involve. Your child may want to discuss the study with you. There is also a simplified information sheet provided for them.

This information sheet tells you about the study. Please take your time to read it carefully, and a member of the research team will also go through this with you. Then ask your doctor or nurse if anything is not clear or if you would like more information. If you decide to join the study and later you or your child change your minds, they will be able to stop at any time without giving a reason.

If you or your child decides not to take part in this study, they will still get their standard medical care.

2. WHY IS THE STUDY BEING DONE?



Pectus Excavatum (PE), also known as funnel chest, is a condition where the ribs and breastbone (sternum) grow inwards forming a dent in the chest. It is a condition which can occur at or soon after birth, although for most it occurs during a growth spurt (at around 11-14 years). For most people with PE there is no significant impact on health; however, people with severe PE, the narrowing of the chest cavity can affect how the heart and lungs work, causing symptoms such as breathlessness, dizziness, fainting and pain with exercising. This can be very restrictive in daily life. Surgery for PE lifts the sternum away from the heart, which relieves these symptoms. There are two types of surgery. One is called Nuss and one is called Ravitch. Both types are included in this study and the surgeon will discuss these with you and your child to help you decide which is the best type for your child.

In England, funding for surgery for PE is very limited because there is not enough high-quality data showing that the surgery improves physical health and heart-lung function. The purpose of this study is to see how surgery to treat PE affects a participant's physical ability and heart function. We will also look at how much this costs the health service overall.

There will be 300 participants across up to about 12-15 hospitals in the United Kingdom taking part.

We will ask 100 participants to take part as an observational group for the study; these are people with very severe PE, who have been assessed by a national team of pectus experts and who are eligible for NHS-funded surgery.

We will also compare 200 other people with severe PE in two treatment groups: the first group of 100 people will have early surgery (within 3 months) and the second group of 100 will have surgery after being followed-up for a year first (this part of the study is a randomised-controlled trial).

All three groups will be followed-up for 3-4 years after surgery.

It is entirely up to you and your child to decide whether they should take part in this study or not and you can do this at any time prior to your child's surgery, as long as the study team have an opportunity to collect some data from your child. If your child wants to take part in the randomised part of the study then the study team would need to know prior to any standard care surgical slot being allocated to them. Your and your child's choice will not affect their ongoing care or any future medical care.

3. WHAT HAPPENS IF THEY TAKE PART IN THE STUDY?

If your child chooses to take part with your agreement, we will need to collect a set of baseline data from them and their medical records, including exercise tests, and they will be asked to complete a set of questionnaires, to document their PE. The questionnaires will cover aspects of their physical fitness, quality of life, physical and mental wellbeing and use of healthcare resources. Where available, we will take existing data from their ongoing care; however, where, for example, their exercise tests are more than 6 months old, we might ask them to repeat the tests. This is because they are at the age where their growth might change their exercise ability.

OPTION 1 - OBSERVATIONAL GROUP

If your child, with your agreement, chooses to take part in the observational group, their surgery and after care (which should include a low-radiation dose CT scan) will take place as planned and we will collect data from their medical records.

They will then be followed up at 6 and 12 months, and then at approximately 3 years after surgery. If they undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at approximately 3 years, will be timed to be at least 6 months after bar removal. All post-surgery visits will collect data from them about their health and they will be asked to complete the same set of questionnaires as at baseline. At 12-months and 3-years they will be asked to perform an exercise test too.

OPTION 2 - TRIAL OF EARLY OR LATE SURGERY

If your child, with your agreement, chooses to take part in the randomised-controlled trial, you will be asked if you are willing to travel to another hospital(s) for treatment and which one(s). This is because capacity for treating pectus and surgery is limited across England, so you might also prefer to see a team at another hospital to be included in the trial sooner. You will also be asked if there is a preference for the type of surgery for your child to have (Nuss or Ravitch). The treatment group they will be allocated to, will be decided by chance (like tossing a coin), the chance that they are allocated to the early or late surgery group will be 50% or 1 in 2. You will be told as soon as possible which group they have been allocated to:

Early-surgery group

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If your child is allocated to the early-surgery group, their surgery will take place within 3 months of allocation.

They will follow routine after care which should include a low-radiation dose CT scan and we will collect data from their medical records.

They will then be followed up at 6 and 12 months, and then at approximately 3 years after surgery. If they undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at approximately 3 years, will be timed to be at least 6 months after bar removal.

All post-surgery visits will collect data about their health and they will be asked to complete the same set of questionnaires as at baseline. At 12-months and 3-years they will be asked to perform an exercise test too.

Late surgery group

If they are allocated to the late-surgery group, they will be contacted at 6 and 12 months after the date of allocation and asked to complete some questionnaires.

At 12 months, they will also be asked to perform an exercise test.

Their surgery will then take place within 3 months of this date and they will follow routine after care which should include a low-radiation dose CT scan and we will collect data from their medical records.

They will then be followed up at 6 and 12 months after surgery, they may also be contacted at approximately 3 years after surgery. The 3-year follow-up will depend on when they enter the trial and we will be able to let them know well in advance whether this will take place or not. Also, if they undergo the Nuss procedure, then we expect bar removal to be at approximately 2.5-3 years after surgery. The final follow-up at ~3 years, must also be timed to be at least 6 months after bar removal.

As for the other groups, all post-surgery visits will collect data about their health and they will be asked to complete the same set of questionnaires as at baseline. At 12-months and 3-years (if this goes ahead) they will be asked to perform an exercise test too.

The team is also interested in understanding any surgery preferences and you and your child will be invited to take part in a survey at 16 months after allocation.

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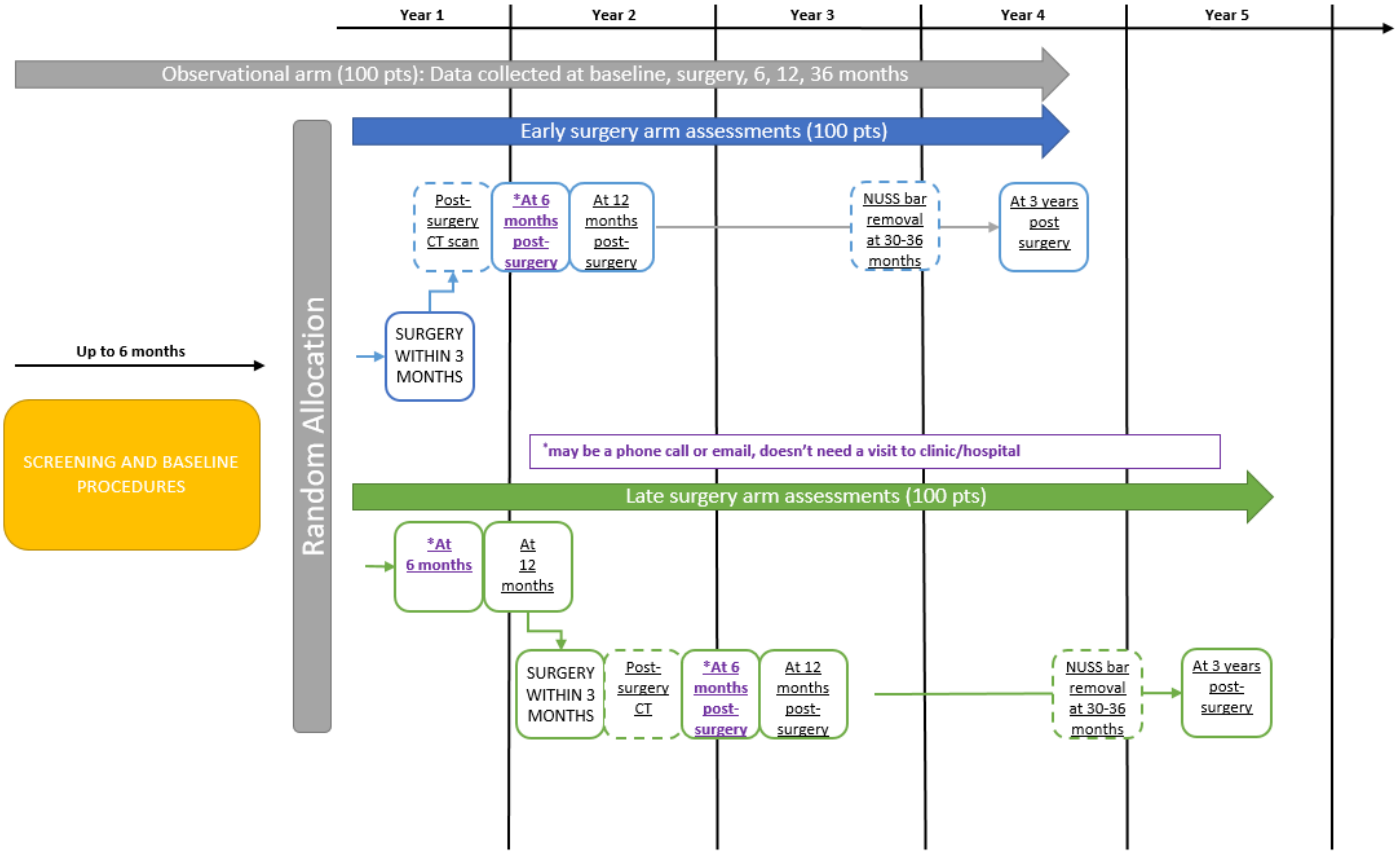
THEIR JOURNEY THROUGH THE STUDY



Highlighted in purple text with a * in the scheme above, are those times where your child won't need to visit the hospital if you and they are happy to enter their data online or have a phone call instead. We estimate this will take between 40 to 60 minutes to complete questionnaires and provide medication usage information. Some of the questionnaires ask similar questions, and there may appear to be overlap, but it is important for our study that all of the questionnaires and questions within them are completed for all patients. If your child wants to complete the questionnaires online, we will need an email address to send the links to. We will send the questionnaires in batches, so your child can take a rest between completing them, similar to if they are completed on paper.

Some follow-ups will need your child to go to a hospital site/clinic, which could take a couple of hours to complete. If your child is in the observational group, or allocated to the early surgery group they will need to attend hospital/clinics between 4 and 6 times, of which, 2 times would be purely for the study. Their involvement could last around 3.5 years.

If your child is allocated to the late surgery group they will need to attend hospital/clinics between 5 and 7 times, of which, 3 times would be purely for the study. Their involvement could last around 4.5 years. If any baseline assessments need to be repeated, it may need another visit or two at the start.

You are responsible for making sure your child attends all study visits scheduled by the study team. If you need to reschedule any visits, please contact your study team.

At each visit and between visits, you and your child should let your study team know if there are any new symptoms, or your child's health or condition changes. Please also let your study team know as soon as

possible if your child is admitted to hospital. If your child sees another doctor, please tell this doctor they are taking part in this study and that they can contact the study team for information.

If your child turns 16 at any time whilst taking part in this study, we will ask them if they want to continue to take part. If they agree, they will need to sign the consent document themselves.

We may also need access to your child's scans (CT scan, echo, etc) to confirm clinical details and we are asking for your consent for this. We would also like to keep these scans for future research, if you agree.

Please speak to your study team right away if you have any concerns or questions.

4. ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

If your child has very severe PE and is already eligible for surgical treatment whether or not you take part in the study, there is no additional benefit to them in taking part in this study.

However, we know that the information collected in this study will help doctors and the NHS learn more about the impact of surgery on people with PE, and this in turn may help future patients.

If your child's PE isn't in the very severe category, then it is expected that the surgery will improve their condition. The surgery will be available to you free of charge (paid for by the NHS). However, with any surgery there are risks and possible complications (see section below for more detail on the possible risks).

5. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART? WILL THERE BE ANY COMPLICATIONS?

As with any surgery, there are risks of complications, including bleeding, infection and problems with the anaesthetic.
With pectus surgery specifically, the risks of possible complications are:

- prolonged pain is a common occurrence
    - about 1 in 10 people, may experience significant pain and need to take painkillers for more than 6 weeks
- wound infection is a common experience
    - about 1 in 10 people, may suffer minor wound infections needing dressings or antibiotics
- bar(s) moving out of place
    - about 1 in 100 people having the NUSS procedure may experience movement of bars placed in chest
    - you might need chest X-rays to check the placement of the bars, X-rays use small amounts of ionising radiation
- less common is bleeding, fluid building up near the lungs, deep infection needing intravenous antibiotics or the removal of the bar(s) and lung inflammation
    - each of these complications might occur in fewer than 1 in 200 people
- 1 in 1000 people may experience some damage to the heart
- 4 people in 100,000 might die

If your child has very severe PE and takes part in the randomised-controlled trial, there is a potential of delay to their surgery. This might have an impact on their health.

We will be collecting some personal data, with this is a risk that your child's confidentiality might be breached, despite us keeping it as safe and secure as we can. In Section 7 of this information leaflet we tell you more about how we handle information we collect.

Important information about pregnancy

Girls of childbearing age may be asked to perform a pregnancy test as part of standard care prior to surgery and CT scans. If your child becomes pregnant during the study, please inform the study doctor immediately. Surgery, CT scans and the exercise test would pose a significant risk to any pregnancy so these would not be carried out during pregnancy. Information about the pregnancy and the outcome will be collected.

6. WHAT PROCEDURES WILL BE DONE IN THIS STUDY?

Study Procedures(s) Glossary	**Description text**	**Risks**
Surgery 	Your child will undergo either the Nuss or Ravitch operations. Your child's surgeon and care team will discuss this with you in detail.	As described above
Cardio-Pulmonary Exercise Test (CPET) 	A Cardiopulmonary Exercise Test (CPET) is used to assess exercise capacity and investigate the response of the heart and lungs. Your child should wear clothing and shoes comfortable for exercising in. Your child will be asked to exercise, on an indoor static bike. They will be encouraged to exercise for as long as they can whilst their body's response is recorded. To track their heart during exercise, sticky patches called electrodes will be put on their chest. Their chest will be cleaned with alcohol and if needed shaved in some areas for this. An inflatable cuff will be placed on their upper arm to measure blood pressure and a facemask to check your lungs. A pulse oximeter (probe) will be placed on their finger to assess blood oxygen levels. These will not hurt. All your child's study CPET assessments will be done at the same hospital/clinic.	The risk for CPET is the same as for mild-moderate exercise, the number of patients who develop symptoms is low (1:1000). From our experience, due to the nature of the test occasionally patients may feel lightheaded We will be monitoring your child closely during the test, with continuous ECG, blood pressure and oxygen measurements. If they develop significant symptoms, we will stop the testing.
Questionnaires 	They will be asked to complete 9 questionnaires up to 6 times during the course of the study. The questionnaires will be about: - Their health and level of activity - Their quality of life – including how well they get about doing daily activities - How they are feeling, how they feel about their condition and how they look - What health services have recently used and how much time and money have been spent using them (you might need to help with these questions) As well as directly with a study team member, they will be able to complete these questionnaires online or over the phone, whichever they prefer.	They may feel uncomfortable with completing some of the questionnaires. Should any of their answers be of concern to the study team, you and their GP will be contacted to assess their needs and help provide psychological support.
General health interview	They will be asked at each follow-up generally about their health, medications they are taking and any complications or additional hospital visits that they	No risks

	might have had since the last time the team contacted them. If they prefer, they will also be able to answer these questions online.	
Low-radiation CT scan 	If you take part in this study you will have low-dose CT scans of your chest after surgery (there may also be the need for a scan before surgery if no recent scans are available). A CT scan is part of routine care after pectus surgery, but a pre-surgery scan would be extra to those that you would have if you did not take part. There may also be a need for standard chest x-rays to check the placement of the bars (Nuss procedure), or assess for possible complications. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information.	Ionising radiation may cause cancer many years or decades after the exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study will increase the chances of this happening to you to about 0.03% (0.06% if you also require a pre-surgery scan).

7. WHAT ARE MY RIGHTS AS A STUDY PARTICIPANT?

What if something goes wrong?

If you or your child think there has been damage to your child's health as a direct result of participating in this study, you must tell your study team as soon as possible. In the event that something does go wrong and your child is harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against South Tees Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

You and your child will be told if any new information becomes available that may affect your decision to continue to take part in the study. You and your child will be asked to sign a form if you agree to continue with their participation. Sometimes, new information may also mean that they will no longer be able to continue in this study. If this happens, your study doctor will discuss this with you and your child.

If you or your child want to complain about how researchers have handled their information, you should contact the research team. If you are not happy after that, you can contact the Data Protection Officer. The research team can give you details of the right Data Protection Officer. If you are not happy with their response or believe they are processing your data in a way that is not right or lawful, you can complain to the Information Commissioner's Office (ICO) (www.ico.org.uk or 0303 123 1113).

What happens if I or my child don't want to carry on with the study?

You and your child can completely stop study participation at any time, without giving a reason, but we will keep the information that we already have.

You and your child can also choose to only partly withdraw, for example, where you or your child might not want direct contact with the study team, but are happy with completing questionnaires online.

How will we use information about your child and how will it be kept confidential?

We will need to use information from your child and their medical records for this research project, this will include their personal data.

The following types of personal data collected in the study, will include:

- Information to arrange their participation in the study such as their (and your) name, address, telephone number, email address.
- Information such as their date of birth, sex at birth, postcode, ethnicity.

- Health information such as medical history, medical conditions, results of their exercise tests, results of imaging (like CT scans).

Data collected for the study is "coded". This means any information that could directly identify your child, like their name, is removed by the hospital study team and replaced by a code. This code is usually a number. A separate list that matches the code to who they are is kept by the hospital study team (separate from coded data). If you and your child choose to use the electronic system to answer the questionnaires, then we will need to keep a personal email address with the study data.

Your child's records at the hospital will remain "un-coded" and contain data that can directly identify them. If you and your child prefer to have surgery at another hospital, their name and (your) contact details will be shared with a national coordinator who will make the arrangements for transfer and their uncoded data will also be passed on to the new hospital teams. The national coordinator will be based at South Tees Hospitals NHS Foundation Trust.

Apart from the hospital study teams and national coordinator, only a small group of people from the sponsor can see the un-coded data to make sure the study is done properly. These people must keep the data private. People who do not need to know who your child is will not be able to see their or your name, their NHS number or any contact details.

Your and your child's data are protected by UK data privacy laws (UK GDPR and the Data Protection Act 2018). As the Sponsor of this study, South Tees Hospitals NHS Foundation Trust is the data controller for this study. This means that we, as South Tees Hospitals NHS Foundation Trust researchers, are responsible for looking after the information and using it properly. We will use the minimum personally-identifiable information possible. We will keep identifiable information about your child for 5 years after the study has finished, unless you and your child provide your additional consent to a longer-term follow-up after the end of the study. If you do agree to the longer-term follow-up, then we will keep your child's information for another 5 years after the end of the follow-up period.

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 they took part in the study.

We will keep all information about you and your child safe and secure.

Who receives the coded data?

The coded data will be provided to the research team, who include people at other NHS institutions and UK universities.

Anyone your child's data is shared with must protect it in the same way as described in this Information Sheet.

What are your choices about how your child's information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you or your child see or change the data we hold about them.

Where can you find out more about how your child's information is used?

You can find out more about how we use your child's information:

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

- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team

Will I receive any financial reimbursement, expenses or compensation?

You and your child will not be paid for taking part in this study and your child's surgery and medical care will not cost you anything.

We are able to help with travel costs (up to £40 for each visit) when your child return to hospital/clinic for the repeat exercise test (at 12 months after allocation for the late-surgery group and at 12 months and 3 years after surgery).

If you and your child choose to have surgery at another hospital, we are also able to help support some travel and accommodation costs for them and a carer (e.g., you, your partner or another adult), please discuss this with the study team.

Who is organising and funding the study?

Funding has been provided by the National Institute for Health and Care Research Health Technology Assessment (HTA) Programme. South Tees Hospitals NHS Foundation Trust is organising this study and known as the 'Sponsor'.

Who has approved the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee which is there to protect participants' safety, rights, wellbeing and dignity. This project has been reviewed and was given a favourable review by the East of Scotland Research Ethics Committee.

What happens with the study results?

A description of this study will be available on www.isrctn.com

No information will be published that can identify your child.

After the whole study is finished and the data have been analysed, we will report our findings to the funder, to the National Institute for Health and Care Excellence (NICE) and to a number of professional surgical societies and present at surgical conferences. We will also work with our Patient Advisory Group (PAG) and the patient representatives on the research team to decide on the best way to let patients and the public know about the results.

How have patients and the public been involved in this study?

There are two patient representatives on the funding application team and they will continue to remain involved with the study. They have helped to develop the question and how we might answer it in the design of the study, with the two treatment groups, the assessments and the follow-up periods.

The patient representatives have also been involved with reviewing this Participant Information Sheet.

Will my General Practitioner (GP) be informed of my participation?

Your child's GP will be notified that they are taking part in this study. Your child's GP may be approached to provide further information about their health during the course of this study, this might be in asking for results of blood tests or the results of other tests.

8. FURTHER INFORMATION AND CONTACT DETAILS:

(Form to be on headed paper)

Please contact <ENTER STUDY TEAM DETAILS>

Thank you for reading this information and considering taking part in this study.