(Form to be on headed paper)

RESTORE - PARTICIPANT INFORMATION SHEET AND ASSENT FORM

FOR 12-16 YEAR OLDS

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>*

(Form to be on headed paper)

PART 1 – TO GIVE YOU INFORMATION ABOUT THE STUDY

1. WHY AM I RECEIVING THIS INFORMATION SHEET?

We are asking whether you would be interested in taking part in a research study.

Before you decide if you would like to join in, it is really important that you understand what the study is about, why the study is being done and what it would involve for you.

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, ask as many questions as you want to.

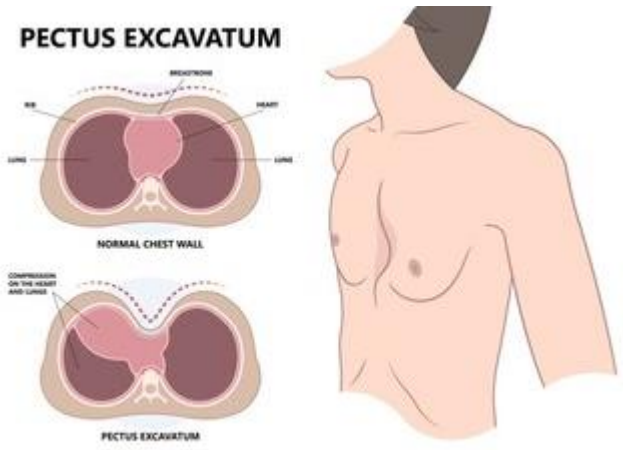
Thank you for reading this.

2. WHY IS THE STUDY BEING DONE AND WHY AM I ASKED TO TAKE PART?

We are inviting you to take part because you have severe or very severe pectus excavatum (PE).

PE, also known as funnel chest, is where the ribs and breastbone grow inwards forming a dent in the chest.

As you might already know and experience yourself, people with severe PE, can suffer from being breathless, dizziness, fainting and pain with exercising. This can stop them doing lots of things in daily life.



Surgery, which lifts the breastbone up, can help with these effects, but we don't have enough good data to show that surgery does make people feel better and more active. This is why this research is being done.

.

3. WHAT HAPPENS IN THE STUDY?

There will be 300 people, from the age of 12 and upwards in the study, the study will go on for about 5 years. The 300 people will be split into 3 groups.

- Group 1: 100 people who have very severe PE, are already going to have surgery and don't want to wait any longer.
- Group 2: 100 people who will have surgery as soon as possible.
- Group 3: 100 people who will have surgery after 1 year.

Groups 2 and 3, are for people with severe PE or very severe PE who don't mind waiting for surgery. Whether they are in Group 2 or 3 will be chosen randomly for them by a computer (like tossing a coin) and there's an equal chance of being in Group 2 or 3.

(Form to be on headed paper)

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

4. DO I HAVE TO TAKE PART IN THE STUDY?

No, you don't. It is your choice whether you want to take part and you can always change your mind at any time.

5. WHAT HAPPENS TO ME IF I TAKE PART?

First study visit

a) You will meet with your care team where you can ask any questions about the research. To confirm you are happy to take part, you sign this form.

b) Then we will ask you some questions about your health and medications, we'll take data from your medical notes, including from any scans you will have had and exercise tests. If you prefer you can provide this information by completing some questionnaires either online or on paper.

c) If your exercise tests were more than 6 months' ago we might ask you to repeat them, because things can change a lot in 6 months for younger people.

d) We will ask you to complete a number of questionnaires online, or on paper. You can do these with or without help from the study team or your parent(s)/guardian. If you are happy to complete the questionnaires online, we will ask for an email address so that we can send you them to complete online in the future. Some of the questionnaires ask similar questions, but it is important for our study that all of the questionnaires and questions within them are completed for all patients. We will email the questionnaire links in batches, so you can take a rest between completing them, similar to if you complete them on paper. It may take up to an hour to complete a set of questionnaires.

Surgery and timing of it

- If you are in Group 1, you'll have your surgery as planned and we will collect some data from your notes.

- If you choose to take part in Groups 2 and 3, we will then put your details in a computer and the computer will choose whether you will have surgery soon or after a year.
    - If you are in Group 2, your surgery will take place within 3 months.
    - If you are in Group 3, you will be asked the same questions and to do the same questionnaires in 6 and 12 months' time. At 12 months you will also be asked to do another exercise test. Your surgery will be arranged within 3 months of this.

After surgery

For all three groups, you should have a scan after surgery (like you have had before) and anytime up to 6 months afterwards, to look at how well the surgery went, we will collect that data if it's available.

We will then ask you health questions and to do the same questionnaires at 6 months, one year and three years after surgery. As for the first study visit, if you are happy to do these on a computer, we can send you an email with a link to a webpage to answer these questions and questionnaires.

At one and three years after surgery we'll also ask you to do an exercise test.

The team is also interested in understanding if there's a type of surgery you might prefer, so you will be invited to take part in a survey at 16 months.

6. WILL TAKING PART IN THE STUDY HELP ME?

You will have surgery in this study, which is expected to help your PE.

The information we collect in this study will help doctors and the NHS learn more about how surgery helps people with PE. We hope that this may help future patients with PE.

7. WILL TAKING PART IN THE STUDY HURT ME?

You will be having surgery to help your PE. Surgery has risks, and for this type of surgery there are some things that might happen and the most common things are:

- It might hurt for a long time after surgery
- Your wound might get infected and you might need to take antibiotics or need dressings
- If bars are put in, then these might move about and you might also need to have X-rays to check them

As part of your surgery follow-up, you should have a CT scan, which uses X-rays. X-rays can cause cancer in the long-run but the radiation used is very low.

WHO SHOULD I ASK IF I HAVE FURTHER QUESTIONS?

The questions and questionnaires might make you feel uncomfortable. If your answers makes us worry about you, we will have to let your parent(s)/guardian and your GP know.

If you have any questions, talk to your parent(s)/guardian or to the research team at:

<INSERT STUDY TEAM CONTACT DETAILS>

THANK YOU FOR READING THIS FAR. IF YOU ARE STILL INTERESTED, PLEASE GO TO PART 2.

(Form to be on headed paper)

PART 2 – MORE DETAIL THAT YOU NEED TO KNOW IF WANT TO TAKE PART

1. WHAT IF SOMETHING GOES WRONG?

Tell us if there's a problem and we will try and sort it out. Or talk to your parent(s)/guardian and they can contact the study team too.

If it's about your data, you or your carer can also contact the hospital data protection officer, and the study team can give you those details, or you can complain to the Information Commissioner's Office www.ico.org.uk (0303 123 1113).

2. WHAT IF I DON'T WANT TO DO THE RESEARCH ANYMORE?

Just tell us or your parent(s)/guardian(s) at any time. If there's just a part you don't want to do anymore (like the questionnaires), but you're fine to do the exercise tests, that's ok too. You will still continue to have the same care for your condition from your normal care team.

3. WHAT IF NEW INFORMATION COMES ALONG?

Sometimes in the time it takes to do a study, new information comes up. If this happens, we'll let you know about it and we will discuss whether you still want to carry on in the study.

4. WILL MY INFORMATION BE KEPT PRIVATE? WILL ANYONE ELSE KNOW I AM TAKING PART?

The people in our research team will know you are taking part, as will the doctors looking after you whilst you are in hospital. We will only tell those that need or have a right to know, like your parent(s)/guardian(s) and your GP and study team members helping to make arrangements for your care.

We will keep all information about you safe and secure.

5. WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

When the study has finished, we will present our findings to other doctors, and put the results in medical publications and websites that doctors read. In these results, people will not know that you took part in the research.

6. WHO HAS APPROVED THE STUDY?

Before any research is allowed to start, it has to be checked by a group of people called a Research Ethics Committee. They make sure the research is fair and safe. This research study has been reviewed by the East of Scotland Research Ethics Committee.

Thank you again for your time in reading this information and thinking about taking part in this study.

(Form to be on headed paper)

IRAS ID:	331910
Centre No.	
Study Title:	A randomised trial of surgery versus no treatment to RESTORE cardiopulmonary function in severe pectus excavatum
Study Doctor:	Full name of principal investigator, title, institutional affiliation, address, phone number
Study Sponsor & Data Controller:	*South Tees Hospitals NHS Foundation Trust*
Participant ID:	

		Please circle the answer you agree with:
1.	Do you understand what this research study is about?	YES / NO
2.	Have you asked all the questions you want?	YES / NO
3.	Have you had your questions answered in a way you understand?	YES / NO
4.	Are you happy to take part?	YES / NO

If any answers are NO, then please don't write your name below.

If you do want to take part, please write your name below:

Your name:	Date:	

The person who explained this research to you needs to sign too:

Their name:	Date:	Signature:

When completed: 1 copy for participant; 1 copy for researcher site file; 1 copy to be kept in medical notes.