



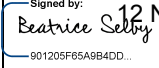
Translational Healthcare Technologies

Photon imaging for nasogastric tube location (PINGO): Participant Information Sheet – Healthy Volunteer Group

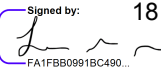
Document Reference:
THT-24-0016-PID-DD-C

Document Control Sheet

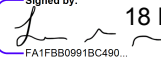
Revision History

Document number	Reason for revision	Author	Signature and Date
THT-24-0016-PID-DD-C	- Clarified that participants may request breaks between NGT placements - Clarified that healthy volunteers are part of control group	Beatrice Selby	Signed by:  12 November 2025 17:40:27 901205F65A9B4DD...
THT-24-0016-PID-DD-B	Clarified study is first in human with risks explained	Beatrice Selby	N/A - not released
THT-24-0016-PID-DD-A	Initial version	Becky Wheeler	Released 20 May 2025

Document Review

Role	Organization	Name	Signature and Date
Quality Manager	University of Edinburgh	Joanne Mair	Signed by:  18 November 2025 10:59:24 GMT FA1FBB0991BC490...
Senior Research Nurse	University of Edinburgh / NHS Lothian	Katie Hamilton	DocuSigned by:  13 November 2025 07:06:36 GMT 8BE60725CE2D405...
Trial Manager	University of Edinburgh	Beatrice Selby	Signed by:  12 November 2025 17:40:27 GMT 901205F65A9B4DD...

Document Approval

Role	Organization	Name	Signature and Date
Quality Manager	University of Edinburgh	Joanne Mair	Signed by:  18 November 2025 10:59:24 GMT FA1FBB0991BC490...
Chief Investigator	NHS Lothian	Thomas Craven	Signed by:  13 November 2025 10:31:46 GMT 2292A0C781DA4A9...

This document is valid from the date of the final signature in the table above

Participant Information Sheet (Healthy Volunteer Group)

Photon imaging for nasogastric tube location (PINGO)

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why we are doing this research and what it will involve. Please take time to read the following information carefully, and to decide if you wish to participate. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

In this study, we will collect and use information from you, your medical records, and your GP. We will only access the data necessary for the research. Your name and contact details will only be shared with a limited number of individuals if required for the study. All data will be handled securely, in accordance with privacy regulations.

At the end of the study, some data may be retained for verification purposes, auditing purposes and to support future research. Any reports produced will be anonymised to ensure that participants cannot be identified. Further details are available in the information pack.

The first three pages of this document provides a brief summary, with more detailed information in the following sections. Please feel free to contact us at any time if you require further clarification.

What is the purpose of the study?

This study aims to improve the placement of nasogastric tubes (NGTs). An NGT is a thin, flexible tube approximately 3mm wide that is placed through a patient's nose, down their throat and into their stomach. The tube allows the patient to receive nutrition and/or medication directly into their stomach.

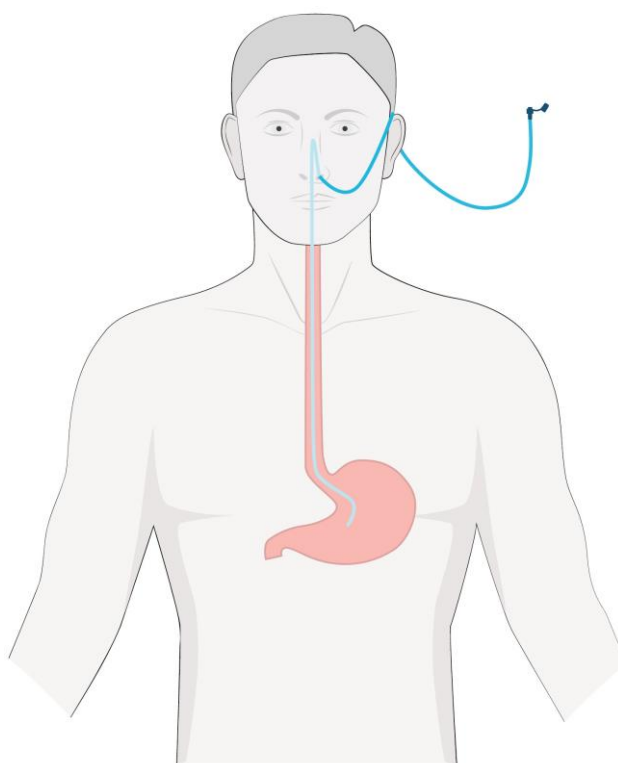


Figure 1: NGT inside a person

Having an NGT inserted is a common procedure. But if it is not inserted correctly, it can sometimes cause life-threatening complications. Currently, medical staff check the placement of an NGT inside a patient with an X-ray of the patient's chest. However, getting an X-ray can take a lot of time and delay the start of a patient's treatment.

Additionally, a chest X-ray can only be done *after* the NGT has been placed inside a patient. In other words, the current procedure cannot prevent misplacement from happening in the first place. This study looks at a technology that may be able to show the real-time location of an NGT in the patient's body *during* its insertion.

In this new technology, researchers place a thin, flexible tube called a 'light emitting fibre' inside the NGT. They then connect the fibre to a light source, and it is lit up from inside the body. A camera above the bedside detects the light from the light emitting fibre and displays images on a screen by the bedside (**Figure 2**).

This technology could help make it easier to insert an NGT, reducing cases of misplacement and the need for tests such as X-rays to check the tube's placement.

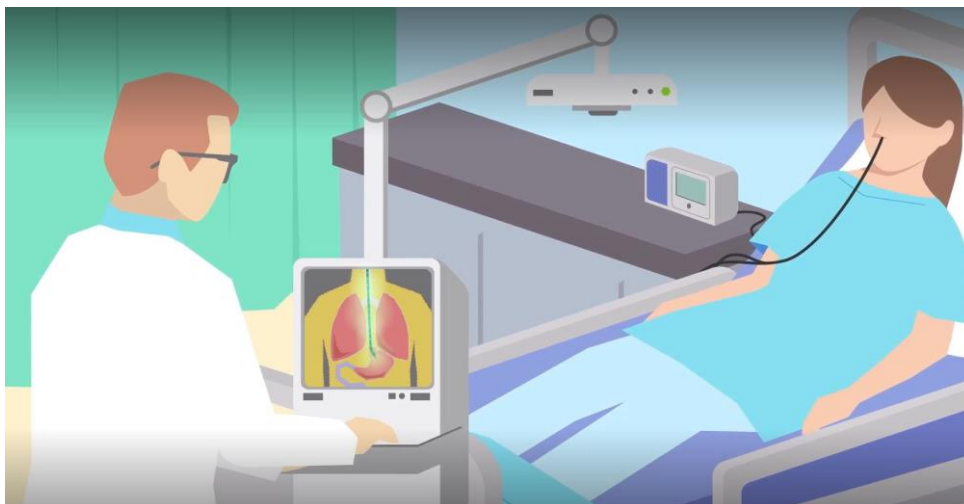


Figure 2: Study technology showing location of NGT inside person

During your initial visit, we will explain the study to you and check that you can take part. If you are eligible and decide to participate, there will be the following procedures:

- We will insert a nasogastric tube (NGT) through your nose and down into your stomach. This tube will contain a fibre that emits light.
- We will then X-ray your chest to check that the tube is in the correct place.
- We might ask you to come back up to three times to repeat those procedures if required.

Could I be eligible to take part?	
 You Must	 You Must <u>Not</u>
Be between 16 and 75 years old	Be pregnant or breastfeeding
Be in generally good health	Have struggled with the insertion of a nasogastric tube in the past

Why should I take part?
The information we will collect during this study may help make it easier to insert nasogastric tubes in the future. (You will not directly benefit from taking part in this study.)
You will be compensated for your time, travel and inconvenience.

Are there any risks to taking part?
Having a nasogastric tube inserted is a common procedure, but it can be uncomfortable.
The most common risks include sinusitis (inflammation of the sinuses) or a nosebleed.
You will not be given any experimental medicines.

Why have I been invited to take part?

You have expressed an interest in taking part in this study.

For this research, we are recruiting healthy volunteers, like you, to have an NGT inserted, this is also known as a control group. We are also approaching patients who are going to have an NGT placed as part of their routine clinical care.

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. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will happen if I take part?

Consent and Screening

You will have been in touch with the clinical research team to note your interest in the study and they will have asked you for some information to be able to arrange an appointment. This information sheet will have been emailed or posted to you. At the initial face-to-face appointment at the Clinical Research Facility within the Royal Infirmary of Edinburgh, you will be given a copy of this information sheet to read and keep. A clinically trained member of the research team will discuss the study with you, allowing you time to ask any questions you may have. If, after reading the information sheet and discussing the research study, you decide that you wish to take part, we will ask you to sign a consent form.

Once the consent form has been signed, the research team will confirm if you are eligible. This is done by a physical examination where your pulse rate, blood pressure, peripheral oxygen saturations, and temperature will be recorded. We will also record your height and weight, and calculate your Body Mass Index (BMI). With your consent, your medical record may also be reviewed.

If you are a female of child bearing potential (typically aged between 16-50), we also need to confirm that you are not pregnant. A pregnancy test will be carried out on a urine sample and repeated at each visit (if applicable). Confirmation of your eligibility will be added to your medical record.

All screening and research procedures will take place at the Clinical Research Facility in the Royal Infirmary of Edinburgh. A map and contact details are enclosed.

We will ask you to eat a light breakfast prior to 7 a.m. on procedure days. Consent and the first procedure may be on the same day. If so, you will be advised of this when arranging your visit for screening and consent.

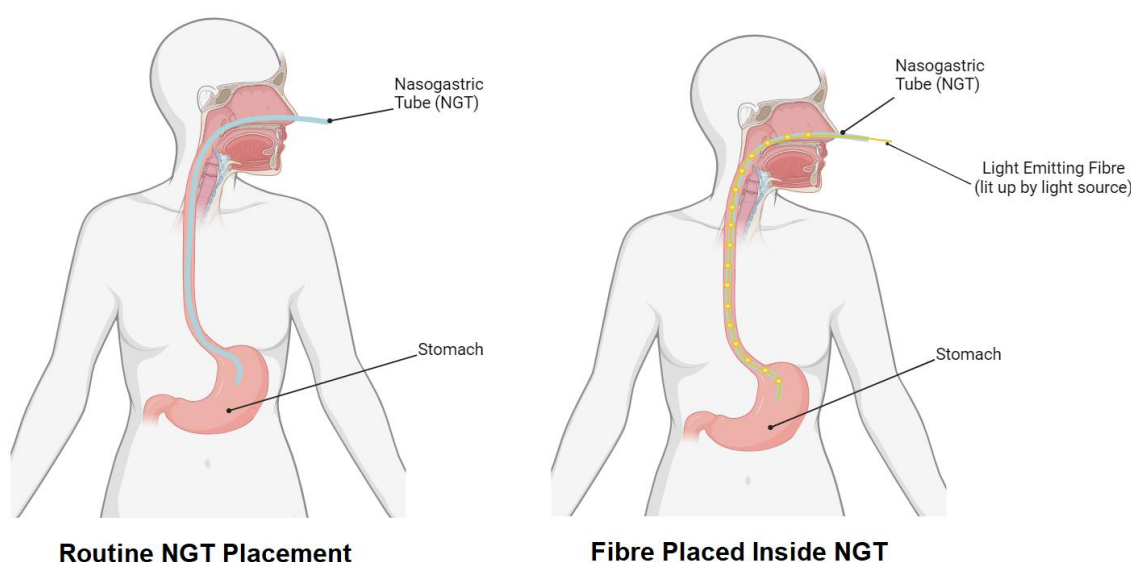


Figure 3: View of a routine NGT placement in the stomach (left) and the light emitting fibre placed inside the NGT (right)

During the Procedure

Once it has been confirmed that you are eligible to take part in this study, a clinically trained member of the research team will place a standard clinical NGT for our research. When placing the NGT, you will be asked to remain in an upright sitting position. The tube is then inserted through the nose, passed down the throat, and into the stomach (**Figure 3: Left**). During this procedure, you may be asked to swallow or have something to drink to help the movement of the tube into the stomach. We may also use water to help lubricate the NGT. Once in place, the end of the NGT will be secured to your nose and cheek with some adhesive tape.

In case the NGT is inserted and found to be in the incorrect position, it will be reinserted with a new NGT and new fibre, if you agree to this.

Once the NGT has been placed, if possible, a small amount of fluid will be sucked up from the NGT and tested with pH paper. The thin, flexible light emitting fibre will then be fed down the NGT

(**Figure 3: Right**). The end of the light emitting fibre is then connected to our imaging device, which is located by the bedside.

Our imaging device has a camera that will be positioned above you, a screen that will display the live images from the camera, and a light source. Once the light emitting fibre is connected to the imaging device, the light source will be turned on. This will shine light through the fibre. These lights are picked up by the camera above you which will display images and videos on the screen of the real-time location of the fibre and NGT inside the body.

To make sure we get accurate imaging readings, we may place a small metal sheet close to you (e.g., under your chin) whilst carrying out the procedure.

Once our imaging device has captured images of the fibre and the NGT's location in the body, the light source is switched off, the fibre is removed from inside the NGT, and the imaging device will be moved away from the bedside. The NGT is left in place. You will then have a chest X-Ray to confirm where the NGT is inside your body. The research team will then compare the results from the X-ray to the results produced by our technology (the imaging device and the light emitting fibre).

After the X-Ray, the NGT will be removed.

The whole procedure will take around 60 minutes. If at any point you wish for the procedure to halt, you can advise the clinical team and this will happen.

After the Procedure

After the X-Ray, a member of the research team will conduct an assessment including clinical questioning (asking how you are feeling), a physical examination, and recording of vital signs. The research team will give you an emergency contact card to keep with you until your final visit. The card will include an out-of-hours telephone number for the study team in case you need to contact them in case of any non-urgent medical questions or concerns.

If there are no clinical concerns after this assessment, you will be invited to provide ongoing consent to repeat the study procedure up to three more times. You are welcome to ask for breaks between placements and placements can be deferred to subsequent days if preferred. If you feel you cannot repeat the procedure, you can withdraw from the study at any point without giving a reason.

Repeat Procedure

If you consent, repeating the research procedure starts with another recording of your vital signs, followed by the placement of another NGT, and another pH test of fluid taken from the NGT. Then the flexible light emitting fibre will be inserted down your NGT, lit up by the light source, and images will be taken with the imaging device's camera. As before, the light emitting fibre will then be removed and you will have a chest X-ray to confirm the position of the NGT. After the chest X-ray, your NGT will be removed and you will have a physical examination from a clinically trained member of the research team.

We may ask for your consent to repeat the NGT placement and measurements up to three times. This means you could undergo the research procedure a maximum of four times. This will be over the space of seven days. As a result, you could be asked to visit the Clinical Research Facility at the Royal Infirmary of Edinburgh several times over the course of these seven days. You are welcome to ask for breaks between placements and placements can be deferred to subsequent days if preferred. You may repeat the NGT placement and measurements several times within a day, depending on how you feel. After the last placement of each day, if there are no concerns after the physical examination, you will be sent home.

Eating a normal meal after the removal of the final NGT for that particular day is permitted.

We estimate about an hour per research procedure, including the placement and measurements. However, you should allow a full day for the visit (to finish by 5pm). You will be reimbursed for your time up to a maximum of £600.00, depending on the length of time you spend at the Clinical Research Facility undertaking the research procedures. You will receive £300 for consent and initial procedure. If you are not able to tolerate 4 NGT placements during this visit and if you are willing to return another day for further placements, you will receive further reimbursement for your time and inconvenience.

If taking part in this research results in additional out of pocket expenses, we are also able to cover your travel costs such as reasonable bus/taxi fares and car parking fees. This will be in addition to reimbursing you for your time.

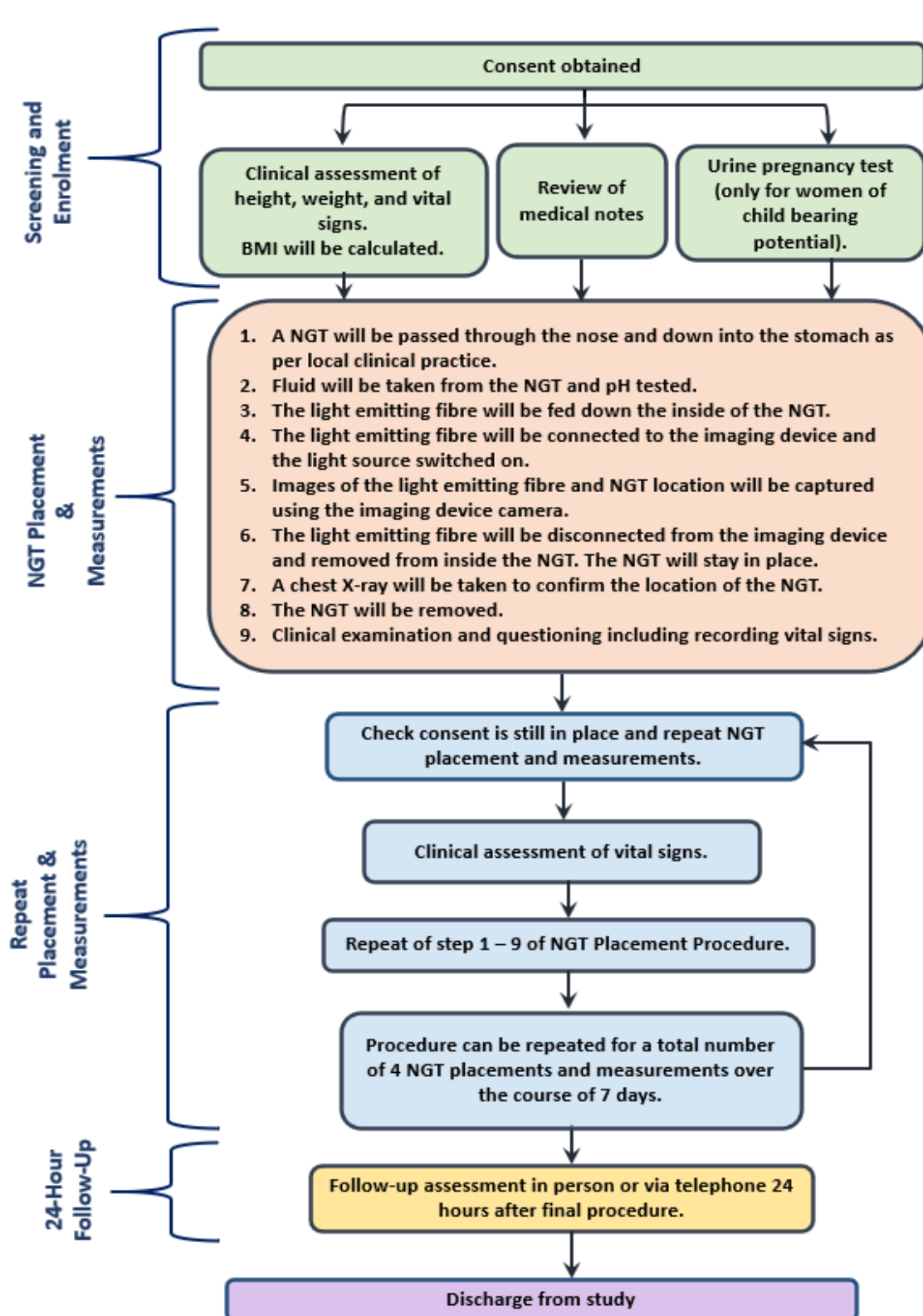
The research team will attempt to contact you a maximum of five attempts if required for arranging your next appointment or conducting your follow-up visit.

Discharge from the Study

After completion of the final X-ray and clinical assessment, you will be discharged from the Clinical Research Facility by a clinically trained member of the research team.

24 hours after the final procedure, you will have a follow-up assessment. This will be via telephone. This is to check how you are feeling after the procedure and if you have any side effects. Completion of this assessment marks the end of your involvement in the study.

The process of study involvement is outlined in **Figure 4** below.



Summary of the research procedure/involvement

Is there anything I need to do or avoid?

On the day of the procedure, you may have a light breakfast before 7 a.m. You will be provided with refreshments at the end of the procedures at the Clinical Research Facility before you leave for the day. You may drink between procedures on the day.

In preparation for the procedure, you may wear your usual clothes but we request that you wear a thin, light-coloured layer (e.g., white t-shirt) because thick, dark layers can affect the imaging picture. You will not need to remove any jewellery.

What are the possible benefits of taking part?

While there is no anticipated benefit to taking part in this study, we hope the information gained from this study will provide evidence for the future development and use of our optical technology which will reduce the complications arising from misplaced NGTs for patients in the future.

The results of this study may be used for the future commercial development of a new medicinal product, treatment or test. Your participation in this study will not entitle you to benefit financially from the commercial development of the product, treatment or test.

What are the possible disadvantages of taking part?

This is early-stage development of the technology. That means that this is the first time our optical technology has been used for this purpose on living human participants, also known as a 'first in human' study. This means it is the first time the device has been tested on living humans. It is possible that some participants could have side effects that we do not know about yet and you are encouraged to report anything that is troubling you. However, all the technology used in this study has undergone extensive pre-clinical testing. The flexible, light emitting fibre we use has already been approved for use in humans.

There are some risks associated with the placement of the NGT itself rather than the use of the flexible light strip. The most common risks related to the placement of NGTs are discomfort, sinusitis, or a nosebleed. These usually resolve when the NGT is removed. Another, more serious complication is aspiration. Aspiration refers to when fluid or stomach contents are inhaled into the lung. This can happen during insertion of the NGT or if the NGT is misplaced into the patient's lung instead of their stomach. This can cause coughing and wheezing, and in some cases, pneumonia. The risk of aspiration from NGT placement is low, occurring in a very small percentage of procedures, but that includes cases where medication or nutrition is incorrectly administered.' We will not be using the NGT placed in

this study to administer anything so the risk of this is reduced even further. In the unlikely event that there are any issues during the procedure, these will be handled as per usual clinical care.

If you take part in this study you may have up to 4 chest x-rays. This will be extra to those that you would have if you did not take part in the trial. This procedure uses ionising radiation to form images of your body. Ionising radiation can cause cell damage that may, after many years, turn cancerous. The dose you will receive by taking part in this study is equivalent to approximately 7 days natural background radiation. This represents a risk of 1 in 500,000. The natural population risk of developing cancer is 1 in 2.

During the course of a chest X-ray, we may discover an incidental finding (something that can be seen on the X-ray that is not part of the study). If we have any concerns, we will contact your GP who will follow this up. This is unlikely to occur but is a possibility.

What if there are any problems?

If you have a concern about any aspect of this study, please contact the study research team on 0131 651 8294 or Pingo@ed.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the normal NHS Complaints Procedure.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence, you may have grounds for a legal action for compensation against the NHS Board involved. You may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

You can stop being part of the study at any time, without giving a reason. Your decision to withdraw from the study will not affect the standard of any treatment you receive now or in the future. If you do decide to withdraw from the study, all data and information collected to date will be retained by the research team. 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 change the data we hold about you.

What happens when the study is finished?

Following completion of the 24-hour follow-up assessment with the research team, your involvement in the study will end.

The research team will not be able to provide individual research results. Should you wish to find out more about the overall results of the study, please contact the research team on 0131 651 8294 or Pingo@ed.ac.uk

All study data will be retained at the University of Edinburgh Institute for Regeneration and Repair (IRR) and archived securely in accordance with Sponsor requirements for 15 years as per MRC guidance. When the minimum retention period has elapsed, study documentation will not be destroyed without prior permission from the Sponsor.

Your de-identified personal data may be shared with funders, collaborators, commercial companies, and publicly available resources. This may include collaborators out with the UK. With your consent, we may also use your de-identified data in other studies to improve the development of the technology.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage. For details on what data will be held about you and who will hold and store this information please refer to the 'How will we use information about you?' section below.

With your permission, we shall inform your GP in writing that you have taken part in this study.

How will we use information about you?

We will need to use information from you, your medical records, and your GP for this research project.

We will collect your **Community Health Index (CHI) number**, which is a unique identifier used in Scotland for healthcare purposes. The CHI number is considered personal identifiable information and is being collected for the administration of this study. This information will remain within the NHS (Lothian Health Board) and will not be shared externally.

Other personal identifiable information collected will include:

- Name
- Date of birth
- Weight, height, and calculated BMI
- Telephone number
- Email address
- Home address

- Registered GP surgery
- Signed consent form

This information will be used to conduct the research and verify records to ensure the study. This data will be stored for 12 months after the end of the study.

Individuals who do not need to know your identity will not have access to your name or contact details. Instead, your data will be assigned a unique code to protect your privacy.

Your information will be stored securely at the University of Edinburgh Institute for Regeneration and Repair (IRR). Digital records will be stored on a password-protected, database hosted by the University of Edinburgh, while paper records will be securely stored within the Clinical Research Facility within NHS Lothian in a locked area.

To ensure the study is conducted properly, we will ask for your consent to allow responsible representatives from the Sponsor and NHS Institution to access your medical records and study-related data where relevant to your participation. The Sponsor is responsible for the overall management of the study, including providing insurance and indemnity.

As part of the study, you will undergo one X-ray per nasogastric tube (NGT) placement to confirm its position. A consultant radiologist will review each of these X-rays. If our research uncovers any new findings that may be relevant to your clinical care, we will share this information with your GP, but only with your consent.

International Transfers

We may share data about you outside the UK for research related purposes for:

- Publications
- Future device development or commercialisation

If this happens, we will only share the data that is needed. We will also make sure you cannot be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following types of organisations:

- Scientific research journals for publication
- Medical device development companies or investors wishing to examine the validity of the device for future use in clinical practice

We will make sure your data is protected. Anyone who accesses your data outside the UK must follow our instructions so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- We do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says.

Once the study is completed, we will retain some data to verify the results. All reports will be anonymised to ensure participants cannot be identified.

We will retain your study data for a maximum of 15 years, after which it will be fully anonymised and securely archived or destroyed.

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. 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.

If you agree to take part in this study, you will also have the option to allow the research team (within the sponsoring organisation) to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study. Your verbal consent may then be sought to pass your contact details to another research team within the University of Edinburgh and/or NHS Lothian. Agreeing to be contacted does not oblige you to participate in further studies.

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

You can find out more about how we use your information

- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email or calling one of the co-sponsor data protection officers.

Data Protection Officer contact information:

University of Edinburgh
Data Protection Officer
Governance and Strategic Planning
University of Edinburgh

NHS Lothian
Data Protection Officer
NHS Lothian
Waverley Gate

Old College
Edinburgh
EH8 9YL
Tel: 0131 651 4114
dpo@ed.ac.uk

2-4 Waterloo Place
Edinburgh
EH1 3EG
Tel: 0131 465 5444
Lothian.DPO@nhs.net

What will happen to the results of the study?

It is our intention that the results of the study will be published in scientific/medical journals and presented at medical and scientific meetings.

You will not be identifiable from any published results.

Your pseudo-anonymised personal data will only be shared with the study research team at the University of Edinburgh and Heriot-Watt University (to store the device images, BMI and trial subject ID number). With your consent, we may wish to share pseudo-anonymised (your trial subject ID number) data with funders, collaborators, commercial companies and publicly available resources. No identifiable data will be shared.

Who is organising and funding the research?

The University of Edinburgh and NHS Lothian are sponsoring this study and are responsible for the overall management of the study and providing insurance and indemnity. The study is funded by The UKRI Medical Research Council, led by Dr Thomas Craven at the University of Edinburgh, in collaboration with Associate Professor Michael Tanner at Heriot-Watt University, and will take place in the Clinical Research Facility at the Royal Infirmary, Edinburgh.

Who has reviewed the study?

The study proposal has been reviewed by a number of the research team at the University of Edinburgh and Heriot Watt University.

Patients and members of the public have contributed to the development of this study by providing valuable feedback on our advertising materials and study documents.

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from Dulwich London REC. NHS Management Approval has also been given.

The UK regulator for medicines and medical devices (Medicines and Healthcare Products Regulatory Agency, MHRA) have also reviewed and authorised this study.

Researcher Contact Details

If you have any further questions about the study, please contact the study team:
Pingo@ed.ac.uk

The lead clinician is Dr Thomas Craven and he can be contacted at
Thomas.Craven@ed.ac.uk

Independent Contact Details

If you would like to discuss this study with someone independent of the study, please contact Dr Adam Marshall at adam.marshall@nhs.scot

Complaints

If you wish to make a complaint about the study please contact:

Patient Experience Team – NHS Lothian

Mainpoint
102 Westport
Edinburgh
EH3 9DN

By telephone: 0131 536 3370 (open Mon-Fri, 9am to 2pm)

By email: LOTH.Feedback@nhs.scot

Certificate Of Completion

Envelope Id: 8C4AD177-D96D-459C-A6C0-6F66A74C6E3A

Status: Completed

Subject: Complete with Docusign: THT-24-0016-PID-DD-C PINGO Healthy Volunteer PIS V3.0 18Jul2025.docx

Source Envelope:

Document Pages: 18

Signatures: 6

Envelope Originator:

Certificate Pages: 5

Initials: 0

Beatrice Selby

AutoNav: Enabled

Edinburgh Clinical Trials Unit

Envelopeld Stamping: Enabled

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IP Address: 81.131.24.52

Record Tracking

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12 November 2025 | 17:32

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Security Level: Email, Account Authentication (None)

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Signature Adoption: Pre-selected Style

Using IP Address: 81.131.24.52

Timestamp

Sent: 12 November 2025 | 17:39

Viewed: 12 November 2025 | 17:40

Signed: 12 November 2025 | 17:40

Electronic Record and Signature Disclosure:

Not Offered via Docusign

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Clinical Project Manager

The University Of Edinburgh- Translational

Healthcare Technologies Group

Security Level: Email, Account Authentication (None)

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Signature Adoption: Uploaded Signature Image

Using IP Address: 192.41.125.253

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Resent: 13 November 2025 | 17:38

Resent: 18 November 2025 | 10:56

Viewed: 18 November 2025 | 10:59

Signed: 18 November 2025 | 10:59

Electronic Record and Signature Disclosure:

Accepted: 03 November 2025 | 16:13

ID: 6b99852f-6af4-4e70-9a8b-024b67507b7d

Katie Hamilton

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Senior Research Nurse

Security Level: Email, Account Authentication (None)

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Signature Adoption: Pre-selected Style

Using IP Address: 81.157.85.97

Signed using mobile

Sent: 12 November 2025 | 17:39

Viewed: 13 November 2025 | 07:06

Signed: 13 November 2025 | 07:06

Electronic Record and Signature Disclosure:

Accepted: 30 October 2025 | 11:42

ID: bbd371d2-b97a-4701-aa27-445e55b0fa96

Tom Craven

Thomas.Craven@ed.ac.uk

Dr

Royal Infirmary of Edinburgh

Security Level: Email, Account Authentication (None)

Signed by:

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Signature Adoption: Pre-selected Style

Using IP Address: 62.253.82.243

Sent: 12 November 2025 | 17:39

Viewed: 13 November 2025 | 10:31

Signed: 13 November 2025 | 10:31

Electronic Record and Signature Disclosure:

Accepted: 13 November 2025 | 10:31

ID: 4113065d-2b2d-41b7-b0ce-4c636d621b15

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Intermediary Delivery Events	Status	Timestamp
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Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	12 November 2025 17:39
Envelope Updated	Security Checked	18 November 2025 10:56
Certified Delivered	Security Checked	13 November 2025 10:31
Signing Complete	Security Checked	13 November 2025 10:31
Completed	Security Checked	18 November 2025 10:59
Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

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You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:

To contact us by email send messages to: mucactcopd@ed.ac.uk

To advise The University Of Edinburgh MucAct COPD Trial of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at mucactcopd@ed.ac.uk and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

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To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to mucactcopd@ed.ac.uk and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

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To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

- i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;
- ii. send us an email to mucactcopd@ed.ac.uk and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

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The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: <https://support.docusign.com/guides/signer-guide-signing-system-requirements>.

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