<Enter Institution / hospital header where the Research Study is carried out or print on headed paper>

Parental Information Sheet and Informed Consent/Permission Form

PROTOCOL NUMBER: GE-045-401

Short Title:	**Sonazoid™ for Contrast-Enhanced Ultrasound Liver Imaging in Paediatric Patients**
Protocol Number:	**GE-045-401**
IRAS ID:	**1007450**
Sponsor Name:	**GE HealthCare Ltd.**
Study Doctor:	**<insert name>**
Hospital Address:	**<insert address>**
Study Related Telephone Numbers:	
Daytime Telephone No.	**<insert number>**
24 Hour Telephone No.	**<insert number>**
Participant Number: **(To be handwritten by site)**	

1. Study Title

A Phase 4, Multicentre Study to Evaluate Safety and Efficacy of Sonazoid™ for Contrast-Enhanced Ultrasound Liver Imaging in Paediatric Patients.

2. Introduction

We are inviting you to consider allowing your child to participate in a study at <institution / hospital>. Your child's participation in this study is voluntary. You are free to say no, and to withdraw your child from the study at any time, without giving a reason. Your child's medical care or legal rights will not be affected.

Please read this information and Consent/Permission form carefully. Your child's study doctor or study nurse can answer any questions you may have. If you agree to allow your child to join the study, you will be asked to sign and date the Parental Informed Consent/Permission Form at the end of this document. A copy of this document will be given to you to take home.

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3. What is the purpose of the study?

This is a medical-scientific research study. The purpose of this study is to look at how the imaging agent Sonazoid™, can be used to accurately diagnose and distinguish the difference between untreated benign and malignant masses in the livers of patients under the age of 18.

Sonazoid™ is a diagnostic imaging agent which is a product given to patients before or during an imaging procedure such as ultrasound to make the pictures clearer for the doctor.

The study will enrol participants under the age of 18 who have been previously diagnosed with one or more untreated abnormal masses in the liver called Focal Liver Lesions (FLL).

Another purpose of this study is to see if Sonazoid™, which has been shown to be safe in adults, is also safe for use in younger patients under the age of 18 when carrying out ultrasound of the liver. Sonazoid™ is already approved for use in adults in several countries. The use of Sonazoid™ with ultrasound may give doctors more confidence in diagnosing benign versus malignant liver masses in patients under the age of 18.

Sonazoid™ powder is mixed with water for injection and shaken gently before being injected into a vein. The dose of Sonazoid™ will be calculated based upon your child's body weight. Following injection, Sonazoid™ is quickly distributed in blood vessels throughout the body including those in the liver. The injected Sonazoid™ reflects and scatters ultrasound waves and will help your child's doctor to see normal and tumour associated blood vessels in the liver.

After an initial ultrasound examination with no enhancement (no injected product), a dose of Sonazoid™ will then be injected and a second ultrasound examination will be performed. Images for both ultrasound examinations will be collected and compared.

Study overview:

This study plans to enrol up to 50 participants under the age of 18 at hospital sites in Europe. This study is an open-label study, meaning that everyone will receive the study product, Sonazoid™. Your child's participation in this study is expected to last up to 3 weeks.

4. Why has my child been invited?

Your child must meet certain requirements to take part in this study. If your child does not meet the requirements, the study doctor or study nurse will tell you why.

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Your child has been invited to take part in this study because he/she is scheduled to have or has had a liver imaging procedure as part of their routine care.

It is up to you and your child (wherever possible) to decide to join the study. We will explain the study and go through this information sheet with you. If you agree for your child to take part, we will then ask you to sign this Consent/Permission form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign, or acknowledge with their thumb print, a separate assent form with you, if they want to.

You will be given a copy of the information sheet and the signed Consent/Permission and assent forms to keep for your records.

You are free to withdraw your child from the study at any time, without giving a reason. This will not affect the standard of care your child receives.

If your child does not want to take part in the research, his/her decision will prevail, and he/she will not participate.

5. What will happen to my child if he/she takes part?

An overview of study procedures is shown below:

1) The Research doctor or nurse approaches you with information about the study for your child.

You and your child will have the opportunity to discuss the study with your child's doctor, and you can also discuss the study with your family and friends.

2) If you and your child are interested and willing to participate in the study you will be invited to attend a screening visit.

3) You and your child attend a screening visit **(up to 2 hours for this visit):**

- You sign parental consent form
- Your child signs assent form (if able)
- Demographic information
- Medical/Surgical history
- Review of any medication your child is taking
- Physical examination and vital signs
- Blood and urine samples
- Ultrasound (**without** Sonazoid™)
- Pregnancy test (if required)
- Egg allergy testing if status unknown

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If your child meets all the study criteria of this screening visit they will be eligible to go to the next part of the study which is the imaging visit.

4) You and your child attend an ultrasound imaging visit with Sonazoid™ within 14 days of the screening visit, and these visits could be on the same day.

(up to 5 hours for this visit):

- Check study criteria again (if required)
- Demographic information
- Review of any medication your child is taking
- Vital signs
- Pregnancy test (if required)
- Ultrasound (**without** Sonazoid™)
- Sonazoid™ injection
- Ultrasound (**with** Sonazoid™)immediately after injection and 20 mins later
- If the ultrasound image is not clear enough, your child may need a second injection with Sonazoid™ and another ultrasound.
- Four hours after injection, your child will receive a physical exam, vital signs will be checked, and blood and urine samples taken
- The site where your child was injected will be checked for any adverse reaction

5) You will receive a follow-up phone call the day after the imaging visit and another follow-up phone call 3 days after the imaging visit.

END OF STUDY

6. What do I have to do?

As a parent of a child participating in this study, you are responsible for the following:

1. Attending the clinic as required, and/or notifying the study doctor if you and your child will not be able to attend.
2. Giving correct information about your child's medical history and current health conditions.
3. Telling your child's study doctor of any issues that may occur during this study.

4. Telling your child's study doctor if your child has participated, or is currently in, other studies.
5. Telling your child's study doctor or research study staff if you change your mind about your child's participation in the study.
6. Being available for the follow-up telephone calls 24 hours and 72 hours after the imaging visit.

Your child will be able to continue to take their regular medication or other prescribed or over-the-counter drugs.

You will be able to stay with your child in the examination room while the study activities are taking place. Your child cannot be in this study if they were involved in any other drug or device studies (within 30 days prior to receiving Sonazoid™).

7. What are the possible benefits of taking part?

Your child's participation in this study will not benefit them directly. The study drug being used in this is study is being tested to see if it can help with disease diagnosis. It is not a treatment or therapy that may make your child feel better, but their participation may help to improve understanding of the medicine used in the study which may benefit patients in the future.

For some patients participating in this study, there might be a benefit relating to characterisation of their liver masses and/or detection of new masses in their liver.

8. What are the possible risks / discomforts?

Risks Associated with the Study Drug

The study drug Sonazoid™ has been shown to be safe for use in adults and there are no reasons to expect that there will be greater safety concerns in patients under the age of 18 who will take part in this study. The study doctor will ask you about your child's medical conditions and decide if there is any extra precaution required while administering Sonazoid™.

Sonazoid™ can cause side effects in some patients. The information about side effects is from the use of the Sonazoid™ in adults. Adverse reactions to Sonazoid™ are usually non-serious. Reported adverse reactions following the use of Sonazoid™ were mild to moderate with subsequent full recovery. The most commonly noted adverse reactions were headache, injection site pain, diarrhoea, nausea, vomiting, abdominal pain, transient altered taste, and fever.

A risk consideration involves patients with a hypersensitivity to eggs or egg products. Sonazoid™ may contain trace amounts of egg proteins. Rarely, hypersensitivity reactions to egg or egg

proteins (including symptoms of skin rashes, difficulty breathing, swelling of the mouth or throat, hypotension or shock) may occur.

Please inform your study doctor or study nurse if your child experiences a side effect or a medical event during the study. Additional information about them and the event will be collected from you directly or your child's medical records. This information may be helpful to better understand the safety of the medicinal product. The information will not include any details that would identify your child and will use just the unique study number assigned to them.

Risks Associated with the Procedures

There are also possible risks and discomforts from the procedures your child may experience during the study. These include:

Placing of a catheter for blood draws in one arm and one for medication administration in the other arm: The risk of placing a catheter includes discomfort around the injection area with possible pain, bruising and/or, bleeding. This can also in rare cases cause infection, fainting or nerve damage. The volume of blood collected will not exceed the international ethics and regulations guidance and should be less than 10 ml (one to two teaspoons).

If other conditions (e.g. disease or health risk) were to be discovered as a result of the study, your doctor will advise or refer your child to the most appropriate standard of care physician.

Risks to the Unborn Child

a) Female of Childbearing Potential

Because so far it is not clear or known whether participation in this study could cause harm to unborn or nursing children, women who are pregnant, breast-feeding or plan to become pregnant during the research study period, cannot participate in this study.

A pregnancy test may be necessary to confirm that your daughter is not pregnant before her participation in this study. If your daughter suspects that she may be pregnant after administration of Sonazoid™ it is advised that the study doctor is informed immediately.

<u>If your child is a female of childbearing potential:</u>

Females of childbearing potential who are sexually active with a non-sterile male partner must use an acceptable method of contraception (as defined below) from at least 30 days before being enrolled in the study and 30 days after receiving Sonazoid™.

Your daughter must be advised to use at least one of the following forms of birth control during this research study.

a) Be sexually inactive/abstinent

b) Be surgically sterile (e.g., bilateral tubal occlusion, hysterectomy)
c) Have an intrauterine device (IUD)
d) Surgical sterilization of your daughter's partner (e.g., vasectomy)
e) Use combined (oestrogen and progestogen containing) hormonal contraception methods including oral (e.g., the pill), intravaginal or transdermal contraceptives
f) Use progestogen-only hormonal contraception methods associated with inhibition of ovulation, including oral, injectable or implantable contraceptives

Acceptable but not highly effective birth control methods that result in a failure rate of more than 1% per year include:

- Progestogen-only oral hormonal contraception, where inhibitions of ovulation is not the primary mode of action
- Male or female condom with or without spermicide
- Cap, diaphragm or sponge with spermicide

The study doctor will need to confirm with you and your child what method of birth control your child is using, if applicable. If at any time during this study you think your daughter might be pregnant, or later learn that your daughter was pregnant, during the study, you must contact the study doctor immediately for further instructions about your daughter's participation in this study and what to do next.

b) For Males

There might be risks to your son's unborn child that we are not aware of if your son's partner becomes pregnant during the study. Because of this, your son must not participate in this study if he and his partner plan to become pregnant during the study period. By signing and dating this Consent/Permission form, you confirm that to the best of your knowledge your son and his partner are not planning a pregnancy during this research study.

Your son must be advised to use at least one of the following forms of birth control at least 30 days before starting this study and until 30 days after receiving the study drug:

a) Be sexually inactive / abstinent
b) Be surgically sterile (e.g., vasectomy)
c) Male condom with or without spermicide

Or your son's partner must use at least one of the following forms of birth control during this study:

a) Be surgically sterile (e.g., tubal ligation, hysterectomy)
b) Use hormonal methods including oral contraceptives (e.g., the pill)
c) Have an intrauterine device (IUD)
d) Female condom with or without spermicide
e) Cap, diaphragm or sponge with spermicide

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If at any time during this study you think your son's partner might be pregnant, or later learn that your son's partner became pregnant during your son's participation in the study, you must contact the study doctor immediately for further instructions about what to do next.

In this situation your son's partner will be asked to give their voluntary written Consent/Permission for any pregnancy related follow-up that may be required.

Unexpected Risks

There is always a chance of unexpected risks. Throughout the study, we will follow and update safety information. If we learn new information that could affect your child's safety or their willingness to continue, we will notify you and possibly ask you to sign a new Consent/Permission form.

9. What are the alternatives for diagnosis or treatment?

The current standard of diagnosis method for liver masses is ultrasonography, contrast-enhanced CT, or MRI. If you have any questions about alternative care, its risks and benefits, it is important that you ask the study doctor for more information.

10. Compensation for injury

GE HealthCare has an insurance policy in place to cover this research study.

The sponsor will provide compensation for any injury caused by taking part in this study in accordance with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). The Sponsor will pay compensation where the injury probably resulted from:

- A drug being tested or administered as part of the trial protocol;
- Any test or procedure you received as part of the trial.

Any payment would be without legal commitment. (Please ask if you wish more information on this). We would not be bound by these guidelines to pay compensation where the injury resulted from a drug or procedure outside the trial protocol or where the protocol wasn't followed.

If you believe your child has suffered injury or illness that may be related to his/her participation in this study, please contact your child's study doctor, immediately.

If your child has private Medical Insurance prior to your participation, you should check with your child's insurance company, whether your child's participation should be reported and any impact this might have.

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11. Expenses and payments

It is important that you understand that your child will not be paid to be a participant in this study and that there will not be any additional cost to you/your child as a result of being in the study. Examinations and medical fees directly associated with this study will be paid the Sponsor.

You will be reimbursed for the cost of your child being in the study (e.g., transportation associated with hospital visits).

12. What will happen if I don't want my child to continue participating in the study?

If you choose not to allow your child to participate in this study, or if you wish for your child to leave the study at any time, your child's medical benefits, rights and interests will not be changed in any way.

If you decide to withdraw your child, or your child decides to withdraw, from the study, please tell your study doctor, and the study doctor will discuss with you the best way to stop your child's participation in this study.

Your child may be asked to leave the study if they need other medical treatment or if there are safety concerns, if you/your child does not follow study procedures and instructions given by the people doing the study, if your child becomes injured or ill during the study, or for other unforeseen reasons determined by the Sponsor and/or people and doctors involved with the study.

If you withdraw your consent, no new information or biological samples will be taken from your child. The data already obtained at the time of consent withdrawal from previous testing on samples will continue to be kept only in an anonymized form. You may ask to delete your child's data and destroy your child's samples; however, this request is subject to certain exceptions and will be assessed as necessary to comply with applicable legal or regulatory requirements; or as necessary to maintain the integrity of the study.

13. Involvement of the general practitioner

With your approval, your child's personal physician/general practitioner may be informed of his/her participation in this study by the study doctor, who may ask them for medical information about your child.

14. What will happen to the results of the study?

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The information collected (including diagnostic images / pictures) of this study will be recorded and analysed, and a report may be written and submitted to regulatory authorities. The report will not contain any information that would allow individuals to be identified. If the results are published or presented at scientific meetings, your child's identity will not be revealed.

15. What if relevant new information becomes available?

If new information becomes available that might affect your willingness to allow your child to participate in the study your child's study doctor will discuss it with you and your child. If you decide to stop your child's participation in the study, your child's study doctor will arrange for your child's normal medical care to continue. If you decide to continue to allow your child to participate in the study, you may be asked to sign an updated Parental Information and Consent/Permission Form.

On receiving new information your child's study doctor might consider it to be in your child's best interests to withdraw him/her from the study. They will explain the reasons and arrange for your child's medical care to continue.

If the study is stopped for any other reason, you will be told why, and your child's continuing care will be arranged.

16. What happens when the study stops?

After the study is completed, your child's participation ends. Your child's doctor will continue his/her treatment according to the standard guidelines for his/her condition.

This study or the study treatment may be stopped without your consent/permission.

Reasons why the Sponsor can stop the study or put the study on hold include:

- The imaging agent has been shown not to work.
- The imaging agent has been shown to work and there is no need for the study to continue.
- Decisions made in the business or commercial interests of the Sponsor.
- Decisions made by the Regulatory Authorities or Ethics Committees.

Reasons why the study doctor can stop your child's study treatment include:

- Taking part in the study is not in the best interests of your child.
- Your child is having bad side effects.
- Your child needs to get other treatments for their medical condition that the study does not allow.

17. What will happen to any samples my child gives?

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While your child is in this study, blood and urine sample(s) will be taken. These samples will only be used for medical research to support this study. Reports about research conducted with your child's samples might be put in your child's health/medical record and will be kept confidential to the best of our ability within the law.

- Samples will be coded (your child's name will be replaced with a subject identification number) to protect your child's identity, before being transferred from the clinic to the laboratory where they will be tested.
- Samples will be sent to a laboratory for testing, research use and storage purposes. Samples being collected will be sent to the local hospital laboratory.
- No samples will be kept after completion of the study.

18. Who is organising and funding the study?

This study is sponsored and being paid for by GE HealthCare.

The hospital/institution, <institution / hospital>, will be paid for the work involved in including your child in this study.

19. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in <institution / hospital> by the institutional ethics committee.

20. How will your child's confidentiality be respected, and the privacy of your child's personal information maintained?

The study site will record basic personal details about your child, including your child's name, contact details, gender, height, weight and racial origin (to be used only for clinical purposes), as well as information on your child's medical history, and clinical data collected about your child's participation in the study. The following people may also access these records on-site:

- Study monitors and auditors, who may work for GE HealthCare or its authorized agents, who check that the study is being performed correctly and that the information collected about your child is accurate;
- National and international regulatory authorities involved in keeping research safe for participants;
- Clinical trial recruitment company if your child was referred to the study by such a company, for analytical purposes and so they may be compensated.

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To ensure privacy, your child's name and other directly identifying information will not be attached to records or samples released to GE HealthCare and its service providers for research purposes. Instead, your child will only be identified by a code. Only the study doctor and authorized personnel will be able to connect this code to your child's name, by a list that will be kept securely by the study site for 25 years. Your child's date of birth and initials may also be recorded to help identify your child's study record.

Your child's coded data will be forwarded to GE HealthCare and its service providers for activities related to the study e.g. laboratory analysis. A list of companies to whom your child's coded information is transferred is available from the GE HealthCare via your study doctor.

Under the Data Protection Act 2018, GE HealthCare makes important decisions on how your child's information collected for the research project are used and disclosed and is responsible as controller for ensuring that the rules of this law are followed. The study site will have similar responsibility in respect to the handling of data in your child's medical files at site.

To the extent there is no conflict with the purpose of the study, you have the right to access, through your child's study doctor, all the information collected about your child and, if applicable, ask for corrections. You may have the additional rights to object to how your child's information is being handled, request deletion of your child's data, or restrict aspects of the processing of your child's information.

You also have the right to complain about how your child's information is handled to a supervisory authority that is responsible for enforcing data protection law. In the UK, this is the Office of the Information Commissioner.

Recipients of your child's information may be in countries that do not provide the same standard of legal protection for your child's information as in the United Kingdom, raising the risk that you and your child will not be able to enforce the above rights and recipient organisations may not be legally required to fully secure your data. Certain international recipients of your child's information may have signed special contracts to provide legal protection for your transferred information (e.g. so called "Standard Data Protection Clauses"). In any event, all parties involved in the study are required to maintain your confidentiality.

Your child's information is collected, used and disclosed in the interest of GE HealthCare conducting scientific research. You are asked to provide permission to various uses and disclosures of your child's information at the end of this form.

If your child should withdraw from the study, data collected prior to your child's withdrawal may still be processed along with other data collected as part of the study. Normally no new information will be collected for the study database unless you and/or your child specifically consent to that.

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However, the law does require that any side-effects you may suffer are documented. You and your child have the right to require that any previously retained samples are destroyed.

This study may only be performed by collecting and using personal information on study participants as described in this form, therefore your child may only participate in the study if you agree to the collection and use of your child's information as described here.

If you have any questions, comments or complaints about how your information is handled in this study, or wish to obtain a copy of the Standard Data Protection Clauses, you should firstly contact your child's study doctor who will be able to direct your query where appropriate to staff responsible for data protection at GE HealthCare or the site, including the site Data Protection Officer.

A description of this study will be available on https://www.clinicaltrialsregister.eu/ as required by EU law and also on https://www.clinicaltrials.gov. These websites will not include information that can identify you or your child. At most, the web site will include a summary of the results. You can search these websites at any time.

21. Where to get my questions answered during the study?

You have the right to get updates about the progress and other information about this study. Some information may not be available until after the study is complete. If you have questions, please contact your child's study doctor.

If you have additional questions about the study or your child's rights, or your child experiences a research-related injury, use the details provided in the table below.

Question Type	Contact Information	Phone	Email
Questions about the study or if you need help (**Emergency Contact**)	First Last, MD, PhD (Principal Investigator)	PI Phone Number	
Questions or requests specifically about the handling of your child's personal information by GE HealthCare	GE HealthCare's Data Protection Officer	N/A	Privacy.GEHC@gehealthcare.com

You also have the right to contact and log complaints with the local supervisory authorities *Information Commissioner's Office ICO in UK (https://ico.org.uk/).*. However, we encourage you to first contact the individuals named above.

Your child will be given a Clinical Study Participant card on the day your child is enrolled on the study. He/she should keep this with him/her at all times during their participation in this research

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study. This can be provided to any doctor or nurse caring for your child in an emergency so that they are able to contact your child's study doctor, or in the case that your child's study doctor cannot be reached, they will be able to speak to a doctor working for the Sponsor to get more information / advice about your child's participation in this study.

Thank you for considering allowing your child to participate in this study.

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PARENTAL INFORMED CONSENT FORM

Study Title:	A Phase 4, Multicentre Study to Evaluate Safety and Efficacy of Sonazoid™ for Contrast-Enhanced Ultrasound Liver Imaging in Paediatric Patients.
Protocol Number:	GE-045-401
Sponsor Name:	GE HealthCare Ltd.
Participant Number:	

Parent/Guardian Initials

1.	I confirm that this study has been explained to me and that I have read and understood the information sheet for this study. I have also had the opportunity to ask questions and these have been answered satisfactorily. I know that I can ask more questions any time today or in the future.	
2.	I confirm that my child does not have an egg allergy or if their egg allergy status is uncertain, I consent to my child having an egg allergy test prior to being allowed to participate in this study.	
3.	I have had time to consider the information and whether I wish to allow my child to take part in the study.	
4.	I consent to allow my child to participate in the study as it is described. I understand that my child's participation is voluntary and that I am free to withdraw him/her at any time, without giving any reason, without his/her medical care or legal rights being affected in any way.	
5.	I consent to my child's general practitioner (GP) being informed of my child's participation in the study and consent to the sharing of information between the study doctor and my child's GP.	
6.	I understand that relevant sections of my child's medical notes and data collected during the study, may be looked at by individuals from GE HealthCare, from regulatory authorities or from the NHS Trust, where it is relevant to my child taking part in this research. I give my permission for these individuals to have access to my child's records.	

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7.	Study data, including your child's coded medical information, may be retained and later used for further research into your child's medical indication, unless you object.	
8.	Study data may be transferred to other countries for study purposes, including countries not providing the same standard of legal protection for your child's personal information as in the United Kingdom.	
9.	I consent to be contacted by the study team 24 hours and 72 hours after my child received Sonazoid™ for follow-up.	
10.	I understand that a description of this clinical study and a summary of the results will be available on http://www.ClinicalTrials.gov/ and https://www.clinicaltrialsregister.eu/. These web sites will not include information that can identify my child, and I understand that I can search these web sites at any time.	
11.	I understand that study data and results with my child's personal identifiers removed may be used, in or outside the Sponsor or its group of companies, for any purpose, including, without limitation, scientific publications, presentations at scientific meetings or tradeshows, product development, marketing and/or educational material. Such uses will not be restricted in time.	
12.	I consent to my child's taking part in this study.	

Signatures

Person to sign	**Printed Name** **(PERSON SIGNING TO COMPLETE)**	**Date** **(PERSON SIGNING TO COMPLETE)**	**Signature**
Patient's Parent/Guardian			
Patient's Parent/Guardian			
Legal representative ***(if required)***			

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Person to sign	**Printed Name** **(PERSON SIGNING TO COMPLETE)**	**Date** **(PERSON SIGNING TO COMPLETE)**	**Signature**
Impartial Witness** ***(if patient is unable to read or write)			
Person Obtaining Consent (e.g. Physician)			

**Impartial Witness is defined as "A person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject or the subject's legally acceptable representative cannot read, and who reads the informed consent form and any other written information supplied to the subject" according to ICH E6 R2.*

*1 signed **original** for Investigator Site File (**ISF**);*

*1 **copy** of signed original **to the Patient's parent / guardian***

***1 copy** for participant Medical Record (if required by local regulations or guidance)*

SIGNATURE PAGE

Date / Name	Justification / Role
Signed By: Meghna Gill Date of signature: 29-Apr-2024 13:28:48 GMT+0000	Justification: Approved Role: Project Management
Signed By: David Thompson Date of signature: 30-Apr-2024 09:56:52 GMT+0000	Justification: Approved Role: Medical Director

This is a representation of an electronic record that was signed electronically in accordance with GxP guidelines and controls. The information above is a valid manifestation of the electronic signature(s) and is legally binding