Parental Information Sheet and Informed Consent Form

Study title: A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)
Study protocol: D5290C0004
Study drug: MEDI8897, referred to throughout the document as the "study drug"
Sponsor of the study: MedImmune
Investigator: Dr Eva Galiza
Patient Name:
Patient Number:

Your child is invited to take part in this research study of an experimental drug called MEDI8897. In this study, MEDI8897 is being evaluated to determine how effective it is at preventing serious Respiratory Syncytial Virus (RSV) disease in late preterm and term infants in their first year of life. Whether your child takes part or not is completely up to you. Take the time you need to read this information and ask your study doctor any questions. You can talk to your family, friends or family doctor before you decide. If you would like your child to take part, you will be asked to sign a consent form to show that you agree for your child to take part in this study and to allow us to use your child's personal information. You will be given a copy of the information sheet and signed consent form to keep for your records and the original will stay at the study centre.

WHY ARE WE DOING THIS RESEARCH STUDY?
MedImmune, a member of the AstraZeneca group, is doing this research to find out if the experimental study drug called MEDI8897 (an antibody product, similar to a vaccine) will work and be safe for the prevention of RSV lower respiratory tract infection in infants and young children. RSV is a virus that is present in communities mostly from autumn to early spring. Infection with RSV is common in all children. In the first year of life, about half of all infants become infected with RSV. By 2 years of age, almost all children have been infected with this virus. RSV typically causes a cold-like illness in older children and adults but can cause serious disease in infants and young children. It is the most common cause of bronchiolitis (inflammation of the small airways in the lung) and pneumonia (lung infection) in infants and young children which may result in the need for hospitalisation and/or GP and hospital visits, Accident & Emergency (A&E) department visits, as well as time missed from work for the caregivers and children being absent from child care or nursery.

There are currently no medicines to prevent RSV in healthy infants who are greater than 35 weeks gestation at birth, and there are no medicines to treat child with RSV infection. Palivizumab (Synagis®) is the only EMA (European Medicines Agency) approved medicine for the prevention of serious illness caused by RSV, and its use is limited to high-risk children: preterm infants less than or equal to 35 weeks gestational age, children with chronic lung disease of prematurity (also known as bronchopulmonary dysplasia) and children with congenital heart disease. Synagis® is given by injection (like other vaccines). It is active in the body for about a month and therefore has to be given monthly to children

for about 5 months during the typical RSV season to maintain protection. Because Synagis® has to be given every month it is not feasible to give it to all healthy infants because of the significant burden on healthcare providers as well as the infants/children and their families.

MEDI8897 is not approved by any health authority, except for use in research studies like this. MEDI8897 is not an antibiotic. Like Synagis®, it is a type of antibody called a monoclonal antibody that is made in the laboratory and acts against RSV. MEDI8897 works the same as Synagis® but has changes in its structure that are expected to extend the time the antibody is active in the body against RSV. It is expected that MEDI8897 can be given once to provide protection against RSV for the entire 5 months of the RSV season. A medicine like MEDI8897 that requires fewer doses could be used to prevent RSV in all infants. The purpose of this study is to evaluate how effective MEDI8897 is at preventing lung disease caused by RSV and to evaluate the safety and tolerability of MEDI8897 in healthy infants compared with placebo (a saline solution that looks like the study drug but does not contain the active ingredient).

WHO IS ORGANISING AND FUNDING THE RESEARCH?

St George's University Hospitals NHS Foundation Trust is being paid by MedImmune to do the research. MedImmune, a member of the AstraZeneca group is responsible for your child's personal information and any results from research described in this document is owned by MedImmune, a member of the AstraZeneca group. Refer to section **'WILL MY CHILD'S TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL AND HOW WILL MY CHILD'S PERSONAL INFORMATION BE USED?'** for how your child's information will be used.

WHO WILL TAKE PART IN THIS RESEARCH STUDY?

The entire research study is planned to go on for approximately 3 and a half years. The study will include around 3000 healthy late preterm and term infants born at 35 weeks or greater gestational age and entering their first full RSV season at the time of screening. 23 babies are expected to participate from the UK. Sites in approximately 32 countries will participate in the study, and each child is expected to participate for 17 months.

WHAT WILL HAPPEN IF MY CHILD TAKES PART IN THE RESEARCH?

If you decide you would like your child to take part, your study doctor will first look at your child's medical records, ask you questions about your child's health and do tests to see if this research study is right for your child. If it is determined that this research study is right for your child, your child will be given the study drug, a single dose of MEDI8897 or placebo. Your child has a 2 in 3 chance of being given MEDI8897 as compared to placebo. The study drug your child gets is chosen at random by a computer. Neither you nor your study doctor will know if your child received MEDI8897 or placebo until the study is completed.

If your child takes part in the research, you will need to bring your child to the study site for at least 6 visits over 17 months and also be available for a number of phone calls. At any time during the study, if you take your child to any health care provider (doctor's (GP) office or clinic, Accident & Emergency (A&E) department, or hospital) for a respiratory illness, you will also need to bring your child to the study site within 2 days or as soon as possible for a follow up visit. The visits will last at least 1 hour. It may be

possible to carry out some of these visits, excepting dosing visits, at your home to make it easier for you. The study doctor and their team will discuss this with you, if required.

Visit 1: Screening (Screening and Visit 2 procedures may occur on the same day)
In order to find out if your child can take part in the study, you will bring your child to the study site for screening. At the screening visit, the following will occur to determine if he/she is eligible.

- You will be asked some general questions on your child's health and his/her medical history, including any medications he/she is currently taking.
- You will be asked if your child was breastfed, if your child attends child care or nursery, and if your child is exposed to smoking in the home.
- Your child will have a physical examination including measurement of weight, and vital signs (temperature, blood pressure, breathing rate and heart rate).
- A blood sample (by a needle stick) of about 1.5 mL (about 1/3 teaspoon) may be collected from your child. If it is not collected at the Screening Visit, it will be collected at Visit 2.

If your child can take part in the study, he/she can be given the study drug injection during this visit. If it is not possible to complete the Screening and Visit 2 procedures on the same day, you can bring him/her back to the study site to be dosed, as described below.

The use of numbing cream can be used for blood tests and/or injections given in the muscle for those study participants in countries/sites where it is routine to do so.

Visit 2: Day of Dosing (Screening and Visit 2 procedures may occur on the same day)
During this visit, your child will undergo the following procedures:

- You will be asked about any illness, doctor visits, hospitalisations, any medications your child is currently taking and problems your child may have had since the previous visit.
- Your child will have a physical examination including measurement of weight.
- Vital signs (temperature, blood pressure, breathing rate and heart rate) will be taken within 60 minutes before dosing, and at 30 and 60 minutes after dosing.
- If the Screening Visit was performed on a different day and a blood sample was not collected, a blood sample (by a needle stick) of about 1.5 mL (about 1/3 teaspoon) will be collected from your child prior to dosing.
- Your child will get a dose of study drug or placebo by injection in the thigh muscle, the same way most vaccines are given to babies.
- You and your child will need to stay at the site for at least 1 hour after your child is dosed to monitor for any allergic reactions or other problems.

Follow-up period
Your child will undergo the following procedures during the Follow-up period:

Study Visit Day 15, Day 31, Day 91, Day 151 and Day 361

- You will be asked about any illnesses, doctor visits, hospitalisations, and problems your child may be having or have had since the previous visit.
- You will be asked about any medications, vaccines, or other treatments your child may be receiving or have received since the previous visit.
- You will be asked to report any caregiver missed work days and/or child absences from child care or nursery due to a respiratory illness.
- Your child will have a physical examination including measurement of weight.
- Your child's vital signs (temperature, blood pressure, breathing rate, and heart rate) will be taken.
- On study Day 15, a blood sample (by needle stick or heel prick) of about 1 mL (about 1/5 teaspoon) will be collected from your child to measure the levels of study drug in their blood. On study Days 151 and 361, a blood sample (by a needle stick) of about 1.5 mL (about 1/3 teaspoon) will be collected from your child to measure levels of study drug and to check for an immune reaction (antibodies) to the study drug.

Over the course of your child's participation in this study (about 17 months), the total amount of blood that will be collected is about 5.5 mL (about 1 teaspoon).

Unscheduled Illness Visits

At any time during the study if you take your child to any health care provider (doctor's (GP) office or clinic, Accident & Emergency (A&E), or hospital) for a respiratory illness, you will also need to bring your child to the study site within 2 days or as soon as possible after that health care provider visit for collection of a nasal mucous sample to test for RSV. Medical records from any healthcare provider visit outside of the study site will need to be provided to the study site staff. If your child is hospitalised for a respiratory illness between study Days 1 and 361, an additional blood sample of about 1.5 mL (about 1/3 teaspoon) will be collected. Also, you should report any caregiver missed work days and/or child absences from child care or nursery due to the child's respiratory illness.

Follow-up Telephone Calls

The study site will call you 8 days after your child receives the study vaccine, then every two weeks from the time your child is dosed through to the Day 151 visit and then monthly until the final visit, Day 361, to get an update on your child's health status and to confirm if your child has had any respiratory illnesses requiring medical attention. The study site will then call you every two weeks after the Day 361 visit until the end of the study to confirm if your child has had any respiratory illnesses requiring medical attention.

Unused parts of samples for further research

MedImmune and/or collaborators might also like to use the unused parts of samples (blood and nasal mucous) for further research to find out more about possible side effects, how the study drug works, or to find out more about any disease. You do not have to agree to this if you do not want to. This does not affect participation in this study.

Questions related to respiratory illness and wheezing

The study team will ask for your permission to be contacted in the years after study completion to answer questions related to your child's health regarding respiratory illness and wheezing. The Study Doctor or

a member of his/her team will contact you for this information. The contact will occur several years after study completion.

Your child can still take part in this research study, even if you do not agree to take part in this additional research. If you decide to stop taking part in the study please tell the study doctor if you want to change your mind about using unused parts of sample(s) for further research or to be contacted to answer respiratory illness and/or wheezing questions.

You can indicate your agreement to use unused parts of samples for further research and to be contacted to answer respiratory illness and/or wheezing questions in the check boxes at the end of this informed consent form.

WHAT WILL I HAVE TO DO?

If you agree for your child to be in this research study, you must follow your child's study doctor's instructions, come to the study visits, have your child receive the study drug, and have all the tests and examinations described above.

If you cannot come to a visit, you must tell your study doctor.

Your child is not allowed to take part in any other research study with study drug or that requires procedures including blood draws while they are in this research study. If your child has any health care contact such as with a doctor or a dentist, you should tell them that your child is in this research study.

DOES MY CHILD HAVE TO TAKE PART IN THIS RESEARCH STUDY AND CAN I CHANGE MY MIND AND STOP TAKING PART?

It is entirely up to you whether to want your child to take part in this research study or not.

You can decide to stop taking part in this research study altogether at any time, but you have to tell your study doctor, who will give you more information about what will happen. You do not have to explain your reasons for stopping, but it would be helpful for us to know. Your child's usual medical care will not change if you decide not to take part or later decide to stop.

If your study doctor cannot get in touch with you during the study, he/she will try to get information about your child and your child's health elsewhere, such as searching in public registers or contacting your family doctor (GP), in accordance with local regulations, since it is important for us to know what happened to your child. If you do not want this to happen, you must tell your study doctor.

WHAT IS KNOWN FROM PREVIOUS CLINICAL STUDIES WITH MEDI8897?

MEDI8897 has been in 3 completed clinical studies; 1 in healthy adults and 2 in preterm infants. Results from the studies were reviewed by an independent safety monitoring committee, which included doctor experts on infectious diseases, and there have been no safety concerns.

In the most recent study in preterm infants of which 1447 were dosed and 968 received MEDI8897, there were significantly fewer lower respiratory tract infections in the infants who received MEDI8897 instead of placebo.

WHAT ARE THE POSSIBLE SIDE EFFECTS, RISKS AND DISCOMFORTS?

In the completed studies, no risks associated with MEDI8897 have been identified thus far. The safety profile in infants who received MEDI8897 has been similar to infants who received placebo.

However, there are always risks with taking a study drug. The study doctor will carefully check your child's health for their safety. It is important that you tell your study doctor if your child has any symptoms. In an emergency please contact your family doctor (GP) or go to a hospital Accident & Emergency (A&E) department.

As with many medications, there is a small chance that your child may have a serious allergic reaction (anaphylaxis) to the study drug. Anaphylaxis may cause a drop in blood pressure, difficulty in breathing, severe hives (swollen bumps on the skin), and sometimes death. Your doctor will monitor your child very closely for 1 hour after he/she receives the study drug and will have medications available to treat any allergic reactions that might occur. Less serious allergic reactions, such as skin rash with or without itching and swelling, may also occur within hours to days after receiving the study drug. These effects usually get better without treatment.

Although allergic reactions haven't specifically been identified as an associated risk with the study drug, every patient can respond differently to treatment. It is important for you to know what symptoms to look out for and what action to take once you've left the study site. You will be given a card with instructions to contact the site if your child experiences symptoms such as hives, itching skin or rash. If any of these signs occur in your child, you should contact the study site immediately. If your child experiences any breathing difficulty, swelling of the lips, tongue or face, or wheezing or symptoms of a serious allergic reaction, it is important that you seek emergency care immediately.

Your child's body may make an immune reaction (antibody) to this study drug. We will be testing for such antibodies during the study. It is possible that if your child has an immune response to this study drug, your child may develop joint pain and swelling, rash, fever or inflammation of your child's heart, blood vessels, nerves, and/or kidneys. Your child may also experience low platelets (cells that help the blood to clot) which can lead to bleeding in the mouth, gums, bruising, nose bleeds, and pinpoint red spots on the skin. Patients that develop these types of reactions during the course of the trial are advised to seek immediate medical help in managing their medical condition. In the most recent study of which 1447 were dosed and 968 received MEDI8897 less than 5% of the infants developed antibodies and those that had antibodies did not develop any of these immune response symptoms. If your child experiences any of these symptoms, you should seek emergency care. Your doctor will monitor your child closely throughout the study, please inform the study team of any changes to your child's condition so they can record this and arrange a visit, if needed.

Side effects usually go away, but sometimes they may not go away or may even get worse.

As with any injection, the study drug injection in the muscle may cause the area to become sore or tender, red, bruised, and swollen.

The taking of a blood sample by a needle stick may cause some discomfort. Problems with blood collection can include pain, tenderness, swelling, or bruising at the site of the needle stick.

WILL TAKING PART IN THE RESEARCH STUDY HELP MY CHILD?

For the children who receive MEDI8897, it is possible that the drug may provide protection against serious RSV disease. There is no medical benefit to your child as an individual if he/she receives placebo.

Even if there is no benefit to your child, other children may benefit from what is learned in this study.

WILL MY CHILD'S TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL AND HOW WILL MY CHILD'S PERSONAL INFORMATION BE USED?

MedImmune will act as the data controller for this study. On behalf of the Sponsor, the study doctor and research team will collect, record and use personal information about your child for the study purposes. Your child's personal information collected during the study may include sensitive information about their physical or mental health or condition, and health information about their in medical records, and other personal information such as their name, address, telephone number, race/ethnicity, date of birth and gender. Your child's privacy and their personal information will be protected using measures which follow the requirements applicable in the United Kingdom for the protection of personal information. Any information about your child that is collected during this study will remain confidential.

During the study, your child's collected personal information including their medical files may be disclosed to the Sponsor, its representatives assisting with the study research, including the central laboratory, study monitors, and to auditors, government or regulatory health authorities. Your child's medical files will be reviewed only at the hospital (or study doctor's office) in order to check the information and verify the clinical study procedures, without breaking your child's confidentiality.

All information which is collected about your child in records that leave the study centre for the purposes of medical, laboratory, statistical or regulatory activities related to the study research will be identified by your study patient number. Your child's name, address and telephone details will not be included in these records. The data collected will be stored for a minimum of 21 years, or as stated by the study Sponsor, whichever is longer.

The information from the study may be published or sent to regulatory authorities in your country or other countries where regulatory approval for the medication is required. Your child's identity will not be released except with your permission, unless necessary for the vital interests of your safety.

We use personally-identifiable information to conduct research to improve health and care. As a research company, we have a legitimate interest in using information relating to your child's health and care for research studies, when you agree for your child to take part in a research study. This means that we will use your child's data, collected in the course of a research study, in the ways needed to conduct and

analyse the research study. Your rights to access, change or move your child's information are limited, as we need to manage your child's information in specific ways in order for the research to be reliable and accurate. If you withdraw your child from the study, we will keep the information about your child that we have already obtained. To safeguard your child's rights, we will use the minimum personally-identifiable information possible.

If you wish to raise a complaint on how we have handled your child's personal data, you can contact our Data Protection Officer who will investigate the matter. If you are not satisfied with our response or believe we are processing your child's personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). You can contact the Data Protection Officer at www.astrazenecapersonaldataretention.com.

By signing the consent form, you are giving permission for the processing and use of your child's personal information for this study during the study and after the end of the study. You are also giving permission for the processing of your child's personal information or any part of it to be transferred to people and organisations (mentioned above) or to be processed and used in IT systems outside the UK, where personal data protection laws may be less strict. You can also request a copy of data transfer clauses if your personal data is shared outside the EU. Please contact the study centre in case you want to exercise these rights. The study centre will align with the Sponsor to handle your request. When we send your personal information to another country, the way we do it is either controlled by a contract approved by data privacy authorities or by MedImmune's own privacy rules which have been approved by privacy authorities (called Binding Corporate Rules).

Your study doctor may tell your family doctor about your child taking part in the study and ask them for medical information about your child.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this Web site at any time.

There is no expiration date to this statement.

WHAT WILL HAPPEN TO THE RESULTS AND THIS CLINICAL STUDY?

The results of this study may be used to learn more about the study drug and treating an RSV infection, or to develop or improve treatments for this condition in the future. The results of this study may also be published or announced. However, your child will not be identified in any publications or announcements.

The results of this study will be used to make informed clinical decisions for developing this new medication. If you want the results to be made available to you, please talk to your study doctor.

WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

The blood and nasal samples that your child donates will be used in this research study. You will not get copies of the results. If you decide that your child will stop taking part in this study, your child's personal information and samples that we have already collected will still be used in the ways that you agreed to

when your child started in the study. You can discuss with your study doctor if you do not want this to happen. We will try to destroy samples, but if the samples are no longer linked to your child, this might not be possible.

Your child's samples may be analysed or safely stored in Switzerland and the USA but will always be coded. Some samples will be destroyed when they have been used for the purpose of the study or be kept longer, up to 15 years, if you agree that the unused parts of your child's samples can be used for further research.

WILL IT COST ME ANYTHING TO TAKE PART?

Taking part in this research study will not cost you anything. You will not be paid for your child being in this research study.

Your travel, parking and reasonable expenses related to your child's participation in this study will be reimbursed and your study doctor will discuss this with you. No other compensation, such as lost wages or other damages, will be available.

WHAT HAPPENS IF MY CHILD IS INJURED WHILE IN THE STUDY?

Any compensation payable for any injury caused to your child by taking part in this study will be in line with the guidelines of the Association of the British Pharmaceutical Industry (ABPI). The Sponsor will pay for the cost of medical treatment for any injury that is directly due to treatment with the study drug or study procedure (that has been used as described in the study protocol). The Sponsor will not compensate your child where the injury has happened because a procedure has been carried out that is not in line with the study protocol or where the study doctor has acted negligently.

The Sponsor has taken out an insurance policy to cover compensation for any personal injury resulting from your child taking the study drug, provided such personal injury is not due to fault or negligence of the study doctor or his/her team.

If your child has medical insurance, please check with your child's insurance company that taking part in this study will not affect their policy.

CAN THE STUDY BE STOPPED OR CAN MY CHILD BE TAKEN OUT OF IT?

If MedImmune finds out important new information about the study, your study doctor will tell you as soon as possible, and will ask if you want your child to carry on being in the study.

Your child may be taken out of the study even if you are willing to carry on. Possible reasons for this are: your study doctor thinks it is better for your child to stop; you do not follow the study instructions; MedImmune, health authorities, the ethics or regulatory agencies decide that the study must be stopped.

WHO HAS REVIEWED THE STUDY?

All research studies are reviewed by an independent group of people, called a research ethics committee to protect your safety, rights, well-being and dignity. This study has been reviewed and has been given a favourable opinion by the South Central – Berkshire Research Ethics Committee.

It has also been reviewed and approved by the UK regulatory body, the Medicines and Healthcare products Regulatory Agency (MHRA).

The Sponsor, Regulatory Authorities or the Ethics Committee may stop the study at any time where there is good reason.

WHO SHOULD I CONTACT FOR MORE INFORMATION?

For more information please contact:

Study Doctor Name:	Dr Eva Galiza
Study Doctor Phone:	0208 725 2804
Study Nurse Name:	Fran Mabesa
Study Nurse Phone:	0208 725 2780
24-Hours Emergency Contact Name:	PIDRG Team
24-Hours Emergency Contact Phone:	07714393252
PALS/ Independent Advisor Name:	PALS team
PALS/ Independent Advisor Phone:	0208 725 2453

Information about this research study will be posted on http://astrazenecaclinicaltrials.com, https://www.clinicaltrials.gov and https://www.clinicaltrialsregister.eu/. These websites do not contain any information about your child. A short summary of the results will be added to www.trialsummaries.com when the study has ended. You can visit this website for more information or let your study doctor know if you need a printed copy. You may also get other information about your child's participation in the study from Sponsor via your study doctor.

Consent Form

Study title: A Phase 3 Randomized, Double-blind, Placebo-controlled Study to Evaluate the Safety and Efficacy of MEDI8897, a Monoclonal Antibody With an Extended Half-life Against Respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)
Study protocol: D5290C0004
Study drug: MEDI8897, referred to throughout the document as the "study drug"
Sponsor of the study: MedImmune
Investigator: Dr Eva Galiza
Patient Name:
Patient Number:

I confirm the following:

• I have read and understand the information sheet for the above study and have had enough time to think about taking part.	*Parent initial*
• I am satisfied with the answers given to all of my questions.	*Parent initial*
• I voluntarily agree for my child to be part of this research study, to follow the study procedures and to provide the information the study doctor, nurses or other staff members ask from me.	*Parent initial*
• I understand that I am free to withdraw my child from this study at any time without giving a reason and without my child's medical care or rights being affected.	*Parent initial*
• I have received a copy of this information sheet and consent form to keep for myself.	*Parent initial*
• I agree if my study doctor is not my family doctor (GP) , my family doctor may be told about my child taking part in this study and asked for medical information about my child.	*Parent initial*
• I agree to my child's samples being taken and used as described in this information sheet	*Parent initial*
• I give permission for my child's personal information to be collected and used as part of this clinical study and to be: - identified only with my child's patient ID number; - reviewed, processed and disclosed by and to the Sponsor and its authorised representatives and study monitors for the purposes described in the study protocol; - reviewed or audited by appropriately authorised organisations; - published and sent to regulatory authorities or health insurers in my country or other countries; and - transferred if required to any country, where laws protecting my child's personal information may be less strict.	*Parent initial*
• I understand I may also be contacted at a later date(s) for my permission in connection with this or any related sub study.	*Parent initial*
• I agree that medical records from any healthcare provider visit can be provided to the study site	*Parent initial*

By signing this document I agree that my child will take part in this study, as set out in this information sheet and consent form.

By signing this form you confirm the following:

- I have had time to read this information and think about the study and my questions have been answered properly.
- I agree for my child to take part in this research study.
- I have been informed on the way my child's coded personal information and samples may be collected, used, and shared as described in this document.

Additional optional consent:

I agree that my child's coded personal data can be used for other medical, healthcare or scientific related research purposes	Yes ☐	No ☐
I agree that the unused parts of my child's samples can be used for further research	Yes ☐	No ☐
I agree to be contacted at a later date after study completion to answer questions related to my child's health regarding respiratory illness and wheezing.	Yes ☐	No ☐

_____
Printed Name of child:

_____
Printed Name of father/mother or legally acceptable guardian:

_____ _____

Signature of father/mother (or legally acceptable guardian): Date and time: DD-MMM-YYYY

Investigator/Authorised Designee:

- ✓ I have fully and carefully explained the study to the person named above and confirm that, to the best of my knowledge, they clearly understand the nature, risks and benefits of taking part in this study
- ✓ I confirm that I gave them all opportunities to ask questions about the study, and that I answered all the questions they asked correctly and to the best of my ability.
- ✓ I confirm that they have not been forced into giving consent, and that they have given their consent freely and voluntarily.
- ✓ I confirm they have been given a copy of this information sheet and consent form.

Investigator Name:

Signature: Date: DD-MMM-YYYY

When signed and dated, we will give you a copy of this form.