Participant Information Sheets and Consent Form

A Randomised Controlled Trial of Antenatal Melatonin Supplementation in Fetal Growth Restriction for Fetal Neuroprotection.

Project Sponsor	Monash Health, VIC, Australia
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Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this clinical trial (research project) because you are pregnant and your baby has been identified as having fetal growth restriction (FGR).

This Participant Information Sheet/Consent Form tells you about the research project. It will explain what participation involves. Knowing what is involved will help you decide if you would like to take part in the research, or not.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

Participation in this research is voluntary. If you don't wish to take part, you don't have to.

You will receive the best possible care whether or not you choose to take part.

If you decide you want to take part in the research project you will be asked to sign the Consent Form. By signing it you are telling us that you:

- understand what you have read
- consent to take part in the research project
- consent to have the tests and treatments that are described
- consent to the use of your personal and health information as described.

You will be given a copy of these Participant Information Sheets and signed Consent Form to keep.

2 What is the purpose of this research?

The researchers are undertaking this research project in order to look at the use of *melatonin* as a way of protecting the developing brain of a baby with fetal growth restriction (FGR) during pregnancy.

FGR is a condition of pregnancy where the fetus (baby) does not grow at the rate that would be expected for their gestation. There are many causes of FGR, but the most common cause is because the placenta is not working as well as it should. When compared to a placenta from a pregnancy that does not have FGR, a placenta from an FGR pregnancy is different. A placenta from a FGR affected pregnancy may not receive or transport oxygen as easily to the fetus. This results in lower oxygen levels and the development of what is known as '*oxidative stress*' within both the FGR placenta, as well as within the FGR baby's body. *Oxidative stress* is believed to be harmful to a FGR baby's developing brain. For FGR babies during pregnancy, *oxidative stress* is one of the reasons why, after they are born, some FGR babies can have problems with their development and need extra support, especially if they were also born very early (preterm). For example, compared to those who did not have FGR, infants and children who had FGR are more prone to have poorer neurodevelopmental outcomes such as: learning disabilities, cerebral palsy and behavioural disorders. While not every baby who has FGR will be affected in this way, we know that FGR does increase the risk of these conditions occurring.

At this time, there are no treatments which can minimise, or even prevent, the adverse effects of oxidative stress on the developing brain of a FGR baby during pregnancy.

Previous work at Monash Health and Monash University, Australia has shown that *melatonin*, a naturally occurring hormone and powerful anti-oxidant, maybe useful as a potential treatment to protect the FGR baby's developing brain from *oxidative stress* during pregnancy. Therefore, a team of senior medical and scientific researchers have designed this research project. The aim of the research project is to find out if *melatonin* can reduce the effects of *oxidative stress* and **PROTECT** the baby's brain during pregnancy and ultimately lead to improved immediate and long-term (2-3 years) neurodevelopmental wellbeing for the baby after it has been born. This study started enrolling women in Australia in 2019 and over 300 women and their babies across Australia and New Zealand will take part.

Melatonin has previously been used in small, preliminary safety studies in FGR and pre-eclampsia (high blood pressure in pregnancy); in these studies 26 pregnant women received melatonin. While the results from both of these studies were encouraging, *melatonin* has not been used in a large, randomised, research project specifically for the purpose of fetal neuroprotection during pregnancy. Therefore, the use of *melatonin* in this research project is regarded as 'experimental'.

3 Who has reviewed the research project?

This research project has been reviewed and received ethical approval from the New Zealand Health and Disability Ethics Committee. This study has also been reviewed and approved by the hospital where you are taking part.

This project will be carried out according to the *National Ethical Standards for Health and Disability Research and Quality Improvement (2019)*. These have been developed to protect the interests of people who agree to participate in human research studies.

4 What does participation in this research project involve?

If you agree to participate in this research project, it will involve the following:

Consent

- We will ask you to read the Participant Information Sheet and sign the Consent Form.

Randomisation

- Using randomisation, we will allocate you into **one** of the two study groups: either to receive *melatonin* tablets **or** to receive tablets that do not contain any *melatonin* ('a placebo').

To make sure that all the information obtained from the research project is reliable and the best it can be, we have chosen to undertake the research project as a *randomised controlled trial (RCT*). The RCT is regarded as the best way to test drugs, such as *melatonin*, for a specific purpose. The RCT method uses a process called 'randomisation' (selected by chance by a computer) to allocate patients to the different study groups. Randomisation tries to make sure that the patients in each of the study groups are similar, and at the end of the research project, it allows us to interpret the results in a fair and accurate way.

The randomisation method of allocation means that you have an equal chance of being placed in either group. So as not to influence the results, neither you, the people caring for you or the researchers are able to choose the group that you are placed into. Neither you nor the doctors/midwives caring for you will know which tablets you are receiving.

Trial Intervention

- The intervention for this trial is tablets containing either: *melatonin* 10mg or 'a placebo', i.e. a tablet(s) that looks the same but does not contain any melatonin. Taking part in the research project will require you to take the tablets three times a day, by mouth, until you have given birth.

- We will ask you to keep a record of all the tablets you have taken and to also make a note of how the tablets make you feel.

Maternal blood sample collection

We would like you to allow us to collect some blood from you, at these time points:

- The first blood sample(s) will be collected from you before you take any of the trial tablets.
- Further blood samples will be collected at 48 hours (+/- 24 hours) and at 14 days (+/- 2 days) after you have started taking the trial tablets.
- Around the time of birth, a further blood sample will be collected from you.

These blood samples will check your blood count, liver and kidney function. During your pregnancy blood samples maybe undertaken regularly (e.g. daily, alternate days, weekly) as part of your routine clinical care and where possible we will use the results of your routine blood tests. If you have FGR and preeclampsia most of the samples will be part of your routine care, except for the blood sample at 48 hours which will be additional. If you have FGR only most of the blood samples will not be part of your routine care and will be additional for this research project. Each blood sample will not exceed 20mL of blood (just over one tablespoon). This volume of blood can safely be collected from you without risk of harm to you or your baby.

Participant (maternal) surveillance

- Fortnightly

- Take and record your blood pressure
- Record your weight
- Test your urine i.e. urinalysis (dipstick) to look for protein in your urine

It is likely that this monitoring would be performed regardless of your involvement in the study as part of your routine clinical care. We will use this routine data.

Ultrasound scans and Doppler waveform studies

All pregnancies with FGR will be closely monitored using ultrasound scans and Doppler waveform studies, and this will not change with your participation in the research project.

The ultrasound and Doppler studies that are a necessary component of the research project will include:

- On the day of recruitment
  - Ultrasound scan to measure your baby's growth

Thereafter, *at least*:

- *Fortnightly (i.e. every 2 weeks)*
  - Ultrasound scan to measure your baby's growth
  - Ultrasound scan to measure the amniotic fluid ('waters') around your baby and a Doppler waveform study to measure the blood flow in different blood vessels in your baby and within the umbilical cord.
  - Doppler waveform study to measure the blood flow in your uterine (womb) arteries.

In addition:

- Permit us to record the information (measurements) from any other ultrasound scans and Doppler wave forms studies that are performed as part of your routine, clinical care during pregnancy.

Ultrasound scans and Doppler studies are undertaken as part of routine clinical care in a pregnancy with fetal growth restriction (FGR). It is likely these scans would be performed regardless of your involvement in the study (and may need to occur more frequently depending on the clinical situation).

Collection and use of information about you and your baby

- To assist us to understand and present the results from our research project we will need to collect relevant information from your health records and those of your baby with regard to: your health, pregnancy (including ultrasound and Doppler studies), birth and postnatal period and then subsequently, your child up to 2.5 years (+/- 6 months) of age.

- Permit us to use the final, combined, results (only) from all the participants in this research project in the planning of future, related research projects for which Ethics Committee approval will be sought and obtained.

Follow-up of your baby/child

➢ General assessment

For one week after birth, we would like to record your baby's wellbeing. This will include asking you to keep a daily record of their sleep and feeding patterns. We can review your baby's feeding charts or, if you prefer, we can give you a form and you can complete the information in collaboration with hospital staff. Should your baby go home before they are one week of age, we will ask you to record their sleep-feed cycles.

➢ Neurological assessments

The purpose of the research project is to find out if the administration of *melatonin* to the mother during pregnancy, protects the developing brain of her baby. Therefore, it is important that we are able to complete some neurodevelopmental assessments on your baby after they have been born. These assessments will include:

- General Movement Assessment (GMA): a non-invasive measure of spontaneous infant movements will be carried out using video recordings, these are simply performed on a mobile phone. For the research project, the GMA will be performed twice. The first time will be around the date your baby would have been due. The second time will be around 3 months (± 2 weeks), corrected age. We aim for the 3 month assessment to be done at home.

  If your baby has already gone home when the first GMA is due we will ask you to make one visit back to the hospital in order to undertake these studies.

- Bayley Scales of Infant and Toddler Development III (Bayley-III): performed around 2.5 years (± 6 months), corrected age. The Bayley-III assesses developmental functioning of infants, including assessment of, for example, movement, thinking and

response to situations around them.

GMA assessment is not currently in routine clinical use at this hospital. All GMAs will be collected using the Baby Moves App (Murdoch Children's Research Institute) and assessed by assessors blinded to treatment group. As these tests are not part of usual care in New Zealand, results will not be disclosed to you or the health care professionals responsible for your and your baby's clinical care.

The results of the 2.5 year (+/- 6 months) neurodevelopmental assessments performed on your child will be discussed with you. Should there be any concerns, this will be explained with you and ongoing care will be arranged with the appropriate services.

We will collect your baby/child's health and wellbeing data, for example hospital admissions, until they are 2.5 years (+/- 6 months).

Inform your General Practitioner (GP)/lead maternity carer (LMC)

- We will send a letter to your GP (family doctor)/lead maternity carer (LMC) to inform them that you have taken part in this clinical trial.

5 Do I have to take part in this research project?

No, you do not. Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the research project at any stage.

Your decision whether to take part or not, or to later withdraw from this research project, will not affect your routine treatment, or your relationship with those treating you.

If you decide to take part, you will be given this Participant Information Sheet and Consent Form to sign, and subsequently, a signed copy of these documents to keep.

6 What are the alternatives to participation?

If you choose not to take part in the study you will be offered the standard care provided for pregnancies complicated by FGR. You do not have to take part in this research project to receive treatment at this hospital. *Melatonin* will not be offered to women not taking part in this study.

7 What are the possible benefits of taking part?

There may be no clear benefit to you or your baby from your participation in this research project. The study is designed to find out whether the use of *melatonin* will improve neurodevelopmental wellbeing for babies with FGR. However, we do not know if it will make a difference. Some women find the additional surveillance provided as part of a clinical trial is reassuring, and we hope that the findings from the research project may change, and

improve, the care of mothers with a FGR pregnancy in the future.

8 What are the possible risks and disadvantages of taking part?

- Melatonin

Melatonin has previously been tested in pregnant women in research projects and in women undergoing assisted reproduction, e.g. IVF (in vitro fertilization) procedures. Researchers at Monash Health have previously used *melatonin* in two other, small studies as a potential new treatment for mothers who had problems in their pregnancies, such a pre-eclampsia (high blood pressure in pregnancy) and FGR. These mothers received *melatonin* at similar doses to this trial. In those other studies women took melatonin for many days, or weeks. No side effects or adverse effects of melatonin on either a mother or her baby has been reported.

Animal studies to specifically investigate harmful effects of the use of melatonin during pregnancy have not shown any damage to the mother or fetus. These animal studies have used doses of *melatonin* that would be equivalent to 100-times higher than the dose that we use in this study. As a result of this, *melatonin* has been assigned a TGA (Therapeutic Goods Administration Australia) category B3. This category is used for drugs which have been taken by only a limited number of pregnant women, where an increased risk of harm to the fetus has not been seen. Drugs in the B3 category have either limited animal safety data or have shown evidence of an increase in fetal damage in animal studies with an unclear significance to humans.

Melatonin has an excellent safety profile. As with any other medicine it can cause adverse reactions. The most common adverse reactions are drowsiness, headache, nasopharyngitis (congestion in the nose and throat), back pain, and joint pain.

As with any medication, there may be side effects caused by *melatonin* administration that the clinical staff caring for you do not expect or do not know about. Tell your doctor or midwife and the research team caring for you immediately about any new or unusual symptoms that you get.

If you are taking any medications, please tell a member of the research team, because some types of medication should not be combined with *melatonin* and as a result you would not be eligible to take part in this research study.

- Maternal blood sample collection

The total volume of blood that you are being asked to provide to this research project will not cause you harm. Wherever possible we will try to collect blood samples at the same time as blood is being taken for your routine clinical care, or from an intravenous cannula ('line') if one is in place.

Having a blood sample taken may cause you some discomfort or bruising. Sometimes, the blood vessel may swell, blood may clot in the blood vessel, or the area could become inflamed. Rarely, there could be a minor infection or bleeding. If this happens, it can be easily treated.

- Ultrasound scans and Doppler waveform studies

Both ultrasound and Doppler waveform studies have a strong safety record. For women who have a baby with FGR, frequent ultrasound scans and Doppler studies are an integral component of routine, clinical care. No adverse event from ultrasound in pregnancy has been reported.

- Follow-up of your baby/child

There is a chance that we may identify an abnormality during the MRI scan that you would not otherwise have known about, this might affect insurance for your baby in future. We do not anticipate any risks to you or your baby/child related to the GMA or 2.5 year neurodevelopmental assessments. The results of the MRI and 2.5 year neurodevelopmental assessments performed on your baby/child will be discussed with you by your treating doctors. Results will be provided to you and if any concerns are identified, these will be discussed with you and ongoing care arranged with the appropriate services.

- Other

As with any research project, there may be additional risks that the researchers do not expect or do not know about.

9 What if new information arises during this research project?

Sometimes during the course of a research project, significant new information becomes available about the treatment that is being studied. If this happens, the researchers will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your research doctor will make arrangements for your regular health/clinical care to continue. In some cases you may be asked to review and sign an updated Participant Information Sheet and Consent Form.

If, on receiving new information, your research doctor considers it to be in your best interests to withdraw you from the research project they will explain the reasons and arrange for your regular health/clinical care to continue.

10 Can I have other treatments during this research project?

It is important to tell the researchers about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell the researchers about any changes to these during your participation in the research project.

11 What if I withdraw from this research project?

Participation in this research project is entirely voluntary. If you decide to withdraw from the project, please notify a member of the research team. You may be asked to sign the Withdrawal of Participation Form to confirm this, but it is not a requirement that you complete this. Your withdrawal from this research project will in no way affect your routine clinical care, your relationship with those treating you, or your relationship with the researchers.

If you do withdraw your consent during the research project, the researchers will not collect any additional personal information from you. Although you should be aware that any personal information that may have already been collected will be retained and form part of the research project final results. This is necessary to ensure that the results of the research project can be measured properly and to comply with the law. If you do not want the researchers to do this, you must tell them before you join the research project.

12 Could this research project be stopped unexpectedly?

It is unlikely this research project will be stopped unexpectedly but it would be stopped if:

- We discovered that participants in the research project were being compromised in any way.
- The sponsor of the research project, Monash Health, makes a request for the research project to stop.

13 Can I find out the results of the study?

If you would like to know the results of the study and whether you received *melatonin* or placebo we will send you a summary of the findings once this is complete (this is not expected to occur until 2024).

14 Other relevant information about the research project

Additional costs
There are no additional costs associated with participating in this research project, nor will you be paid. All the trial tablets i.e. *melatonin or* placebo and investigations that are required to be performed as part of this research project, will be provided to you free of charge. If you have to attend additional visits for the purpose of this research project your parking costs and/or travel costs will be reimbursed.
At the end of the Bayley-III assessment around 2.5 years of age, your child will be offered a small gift to thank them for taking part.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the Consent Form, you consent to the collection and use of and any relevant information about you and your baby/child, that is required for the conduct of this Ethics Committee approved research project.

Any information collected about you will only be disclosed to the researchers, with your permission, except as required by law. Any information will always be disclosed to them in a de-identified form, that is without your personal details, for example: name, initials, date of birth, address, telephone number or hospital record number being attached to it.

Any information obtained in connection with this research project that can identify you will remain confidential. This information will be stored in a locked filing cabinet and password-protected database, accessible only by the research team that have been approved by an Ethics Committee.

After the research project has been completed, the information will be securely stored for a minimum of 25 years by the principal investigator, as currently recommended by the National Health and Medical Research Council (NHMRC) and Monash Health HREC, Australia. After this time, all the information will be disposed of in a secure and confidential manner.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor, Monash Health or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant named research personnel and regulatory authorities as noted above.

- Information about your participation in this research project will be recorded in your hospital records.
- A letter will be sent to your GP (family doctor) and lead maternity carer (LMC) to

inform them that you have taken part in this research project.
- It is anticipated that the results from this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

16 Compensation

If you or your baby are injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you/they were injured in an accident at work or at home. This does not mean that a claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If the claim is accepted, you will receive funding to assist in your or your baby's recovery.
If you or your baby have private health or life insurance, you may wish to check with the insurer that taking part in this study won't affect your or your baby's cover.

17 Who is organising and funding the research?

This research project is being conducted in several hospitals across Australia and New Zealand and has been initiated by Professor Euan Wallace, Carl Wood Professor and Head of Department of Obstetrics and Gynaecology, Monash University. It is being led by Doctor Kirsten Palmer, Monash Health and Monash University. Professor Wallace and Doctor Palmer are working with a multi-disciplinary team of Monash Health and Monash University, senior medical and scientific researchers, who are all recognised experts in their respective fields. The project has been funded by several, different research awards made to the researchers for the purposes of furthering research into fetal growth restriction (FGR) and fetal neuroprotection. These include awards from: Equity Trustees, Monash University, The Cerebral Palsy Alliance and the National Health and Medical Research Council (NHMRC), Australia.

No member of the research team will receive a personal financial benefit from your involvement in the research project (other than their ordinary wages).

18 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you would like any further information concerning this research project, or if you have any medical problems which may be related to your involvement in the project (for example, any side effects) you can contact your local study doctor or research midwife (contact details on page 1).

You may wish to have a friend, family or whānau support person to help you ask questions and understand the study.

Māori data, data produced by Māori or that is about Māori, is acknowledged as taonga. If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact He Kamaka Waiora (Māori Health Team) by telephoning +64 9 486 8324 ext 2324.

If you have any queries or concerns regarding your rights as a participant in this study, you may wish to contact an independent health and disability advocate:

Freephone: 0800 555 050 Freefax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:
Phone: 0800 4 ETHICS Email: hdecs@health.govt.nz

This study has been reviewed and received ethical approval from the Northern B Health and Disability Ethics Committee, reference 20/NTB/137. This study has been reviewed and approved by your local hospital.

Consent Form

A Randomised Controlled Trial of Antenatal Melatonin Supplementation in Fetal Growth Restriction for Fetal Neuroprotection.

Project Sponsor	Monash Health
Principal Investigators	Professor Euan M. Wallace and Doctor Kirsten Palmer
Location	Middlemore Hospital, Counties Manukau Health
Local Investigator	Dr Chris McKinlay

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I have been given sufficient time to consider whether or not to take part in this research project.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to use a legal representative, whānau/family support or a friend to help me ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and I understand that I am free to withdraw at any time during the research project without it affecting my future health care.
- I consent to the research staff collecting and processing my/my baby's information, including information about my/my baby/child's health.
- I understand that my General Practitioner (GP)/lead maternity carer (LMC) will be informed of my participation in this research project.
- I understand that I will be given a signed copy of this document to keep.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.
- I understand my responsibilities as a study participant.

Please complete:

I wish to receive a summary of the results from the study. *Please note a significant delay may occur between data collection and publication of the results.*	Yes ☐	No ☐

Name of participant (Please PRINT): _____

Signature:_____ **Date:**_____

Declaration by senior researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of the senior researcher (Please PRINT): _____

Signature:_____ **Date:**_____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.
Note: All parties signing the consent section must date their own signature.

Consent Form (baby/child)
To be completed after birth

A Randomised Controlled Trial of Antenatal Melatonin Supplementation in Fetal Growth Restriction for Fetal Neuroprotection.

Project Sponsor	Monash Health
Principal Investigators	Professor Euan M. Wallace and Doctor Kirsten Palmer
Location	Middlemore Hospital, Counties Manukau Health
Local Investigator	Dr Chris McKinlay

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes, procedures and risks of the research described in the project.
- I have had an opportunity to use a legal representative, whānau/family support or a friend to help me ask questions and I am satisfied with the answers I have received.
- I freely agree for my baby/child to participate in this research project as described and I understand that I am free to withdraw my baby/child at any time during the research project without it affecting the future health care of my baby/child.
- I consent to the research staff collecting my baby's health data (including electronic health data) up to 2.5 years (+/- 6 months) of age.
- I understand that my baby's General Practitioner (GP) will be informed of my baby/child's participation in this research project.
- I understand that I will be given a signed copy of this document to keep.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my baby's/child's relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I understand that my participation in this study is confidential and that no material, which could identify my baby/child personally, will be used in any reports on this study.
- I understand the compensation provisions in case of injury during the study.
- I know who to contact if I have any questions about the study in general.

Name of participant (baby/child) (Please PRINT): _____

Name of Parent/Guardian (Please PRINT): _____

Signature of Parent/Guardian: _____ **Date:**_____

Declaration by senior researcher†
I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of the senior researcher (Please PRINT): _____

Signature: _____ **Date:**_____

† A senior member of the research team must provide the explanation of, and information concerning, the research project. Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation

A Randomised Controlled Trial of Antenatal Melatonin Supplementation in Fetal Growth Restriction for Fetal Neuroprotection.

Project Sponsor	Monash Health
Principal Investigators	Professor Euan M. Wallace and Doctor Kirsten Palmer
Location	Middlemore Hospital, Counties Manukau Health
Local Investigator	Dr Chris McKinlay

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with the researchers.

Name of Participant (please PRINT):

Signature: **Date:**

In the event that the participant's decision to withdraw is communicated verbally, the researcher will need to provide a description of the circumstances below.

Declaration by the senior researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of the senior researcher (Please PRINT):

Signature: **Date:**

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.