Participant Information Sheet

Study title: **Breathing perception and its relationship to anxiety**
Measuring the effects of antidepressants on behaviour

Locality: Dunedin

Ethics committee ref.:
20/CEN/168

Sponsor (if applicable): *University of Otago*

Lead investigator: Dr Olivia Harrison

Contact phone number: 03 479 8818

You are invited to take part in a study evaluating changes in mood and other assessments in response to pharmacological treatment of anxiety. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Anxiety is a major clinical health problem and anxiety disorders are the most common mental health disorders in New Zealand. Many of the symptoms due to anxiety occur in our body, such as having a racing heart or being short of breath. There is also some

evidence that anxiety may alter our ability to perceive these symptoms in our body, and this may negatively affect how we are able to cope with body symptoms.

One treatment that is known to typically improve anxiety symptoms is a type of drug called serotonin re-uptake inhibitors (SSRIs, e.g. citalopram, sertraline). Therefore, the main goal of this study is to understand how this type of treatment changes our mood, as well as general perceptions of our body and the rest of the world. This information will help us understand how the treatment works, and how we can best use it in the future to help people cope with their anxiety.

If you choose to participate in this study, one of our research team will check that you meet the study criteria and you will have the opportunity to ask any questions you might have before agreeing to participate. This can be done in person or over the phone. If you then enroll in the study, you will complete one initial testing session to measure your current levels of mood and body perception (full details can be found below). Following this visit, and after 6 weeks of taking your SSRI treatment (prescribed by your doctor), we will ask you to come back and repeat the same measurements you performed in the first study visit, so that we can assess what has changed from the beginning of the study.

This study has been checked and approved by an Ethics Committee, and it is funded by the Royal Society of New Zealand in association with the University of Otago. Full contact information is provided at the end of this form if you have any questions about the study – we would be happy to discuss these with you.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

To participate in this study, you need to meet the following inclusion criteria:

- Have a prescription from your doctor for a course of an SSRI to help with your anxiety
- Be between 18 and 45 years of age
- Have full colour vision (i.e. not colour-blind)
- Not suffering from any chronic medical disorders, including any current or past history of a severe brain injury or breathing disorder e.g. severe asthma, chronic obstructive pulmonary disease etc.
- No past or current diagnoses of schizophrenia, bipolar disorder, drug addiction or psychosis
- For women only: Not pregnant or breastfeeding

We will assess these criteria during the screening process (either in person or over the phone). Both visits will happen at the School of Pharmacy Clinic on Great King Street Street. The actual time you will be involved in the study is approximately 8 weeks, with 1 measurement visit at the beginning (week 1), a treatment period (weeks 2-7) and 1 measurement visit at the end (week 8).

At visit 1 you will come to the School of Pharmacy Clinic for a set of baseline measurements. This session will last approximately 4 hours, and will involve:

- Reading the study documents and signing the consent form (you are free to ask any questions at this time and at any point during the study)

- You will then be asked to complete a range of questionnaires to measure various aspects of your psychology and personality.
- In one of the tasks, we will then ask you to perform a very short test to measure how strong your breathing muscles are, so that we can adjust our other breathing tasks to suit you.
- For the breathing task that measures learning, where you will be presented with shapes on a screen that will be associated with small increases in the resistance to your breathing, and you will be asked to answer questions using a button box. You will always be able to breathe without maximal effort, and we will run a practice for the task before we begin so that you can see what the breathing resistance feels like. You will be able to easily remove the breathing system whenever you like if you become uncomfortable, or would like to take it off. You will be able to breathe at all points – there are no occlusions in the breathing task. In addition, measures such as your heart rate and breathing rate may be monitored and recorded. This task will take approximately 40 minutes.
- A second breathing task involves an experiment to measure how sensitive you are to very small changes in your breathing, where you will breathe through a mouthpiece connected a breathing system. We will ask you to tell us whether or not you could observe a very small change in the resistance to your breathing during the experiment, and how confident you are of that perception. The duration of this task will be about 30-60 minutes.
- We will also run a similar experiment to measure how sensitive you are to very small differences in pictures presented on a screen. This task will be carried out on a computer, and will take about 10 minutes.
- Finally, we will run another task on the computer where you will be asked to respond to pictures of faces. The task will take about 10 minutes.
- You will be able to take as many breaks as you like during the session.

After you have completed 6 weeks of your treatment, you will be invited back to repeat all of the procedures from visit 1, so that we can assess how your treatment changed your mood and the results from these tasks.

Notes for before experimental visits:

- In the 24 hours prior to the study experiment you are not allowed to consume any alcohol.
- If you should fall ill shortly before the experiment (even if you do not deem it seriously ill, e.g. a cold), we would ask you to please contact the experimenter immediately, so that we may evaluate whether participation is possible or useful.
- Please bring to the study experiment a valid ID card (identity card or driving license).

For women of childbearing age (“Not in menopause yet and last menstruation less than 12 month ago, not surgically sterilized, ovaries and/or uterus not surgically removed”) participating in the experiment: For security reasons we have to ask whether a pregnancy might be possible. In case of any doubt, participation is only possible when a mandatory pregnancy test has been carried out.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

What are the possible benefits? You may find that both your general health and anxiety symptoms improve or disappear over the course of the study, or you may not experience any improvement.

What are the side-effects? There are no known side effects from any of the tasks performed in the study.

What are the risks for me? There are no known risks from participating in the study, however possible short-term side effects of the SSRIs include an initial increase in anxiety and nausea, dizziness, headache, drowsiness, insomnia, nervousness, agitation, and sexual dysfunction and other issues can occur. The continuation of your treatment will be decided between yourself and your physician, independent of the study.

Reproductive Risks: While there are no proven risks to pregnant women or unborn babies when using SSRIs, to ensure maximal safety we will not include any participants who are pregnant or breastfeeding. If you are female and not sure if you could be pregnant, you will be required to undergo a pregnancy test prior to commencing the study. If you do become pregnant whilst participating in the study, you should advise study staff immediately - you must not continue in the study if you become pregnant.

WHO PAYS FOR THE STUDY?

There will be no cost to you to participate in this study. The study is being paid for with funds from the Royal Society of New Zealand and the University of Otago.

To recognize the actual or reasonable costs involved with participating in this project, all participants will be reimbursed $150 in total. You are free to withdraw from the study at any time, and if you choose to discontinue the study (please see full details below under 'What are my rights?') you will be reimbursed proportionately. *It is the study participant's responsibility to correctly account for tax on the receipt of any cash payment.*

WHAT IF SOMETHING GOES WRONG?

If you are injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

If you feel you are becoming more anxious over the course of the study, we are here to help. Contact details for people that you may wish to speak to are provided at the end of this form.

WHAT ARE MY RIGHTS?

Your participation in this study is entirely voluntary. You do not have to participate, and you may withdraw from this study at any time and without any disadvantage of any kind. We will inform you of any new information collected in this study, such as any effects of SSRIs on improvements in mental health etc.

To ensure confidentiality, any data collected in this study will have your name removed prior to analysis. This will ensure no one would be able to identify who the data belonged to. We may also use your data for research beyond this study, but will only ever use this data with your personal details removed.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind, you can withdraw from this study at any time. You do not have to provide a reason for your withdrawal, but if you would like to tell us then we would welcome any feedback.

All data collected will be securely stored in such a way that only those involved in the research program will be able to gain access to it. As required by the University's research policy, any raw data on which the results of the project depend will be retained in secure storage for at least ten years.

If you wish, we can send you the information that we will learn from the study in the form of publications, or any media releases, blogs etc. Publications would be expected after approximately 12 months once the whole study is finished.

WHAT WILL HAPPEN TO MY INFORMATION?

During this study the researchers, study nurse and study doctors will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

IDENTIFIABLE INFORMATION

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Researchers who are part of the study team will have access to your identifiable information, and the following groups may have access to your identifiable information if required:

- The sponsor, ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.

DE-IDENTIFIED (CODED) INFORMATION

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study team or any study information sent to the sponsor. Instead, you will be identified by a code. The researcher will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

FUTURE RESEARCH USING YOUR INFORMATION

Your coded (de-identified) information may be used for future research related to anxiety, and may also be used for other medical and/or scientific research that is unrelated to the current study. This future research may be conducted overseas. You will not be told when future research is undertaken using your information, and you will not receive reports about any research that is done using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

Your de-identified information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

SECURITY AND STORAGE OF YOUR INFORMATION

Your identifiable information is held at the University of Otago during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. Your coded (de-identified) information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

RISKS

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

RIGHTS TO ACCESS YOUR INFORMATION AND RESULTS

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

You can request a letter telling you about the study results. The letter will be sent to you once the final study report is available (this can take 1 – 2 years). A description of this trial will also be available on the Australia and New Zealand Clinical Trials Registry (https://www.anzctr.org.au). This website will not include information that can identify you. At most, it will include a summary of study results.

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.

Please ask if you would like to access the results of your screening and safety tests during the study. If you have any questions about the collection and use of information about you, you should ask a member of the study research team.

RIGHTS TO WITHDRAW INFORMATION

You may withdraw your consent for the collection and use of your information at any time, by informing a member of the study team. If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

OWNERSHIP RIGHTS

Information from this study may lead to discoveries and inventions or the development of a commercial product. The rights to these will belong to Dr Olivia Harrison. You and your family will not receive any financial benefits or compensation, nor have any rights in any developments, inventions, or other discoveries that might come from this information.

DATABANK/REGISTRY

As part of this study, we may submit your de-identified information into a databank in the future. Consent for submitting your information into the databank is mandatory to participate in this study.

The purpose of putting the data from the study into a databank is to promote open access to important scientific resources, such as the measures we collect in this study. Sharing data and resources encourages collaboration to help improve the scientific process. Therefore, the data may be used for many types of research by those who agree to the terms and conditions of the databank. You will not receive any results from this research.

The databank has strict standards for inclusion of only de-identified data, which will ensure that your privacy will be protected. Your information stored in the databank will be stored indefinitely.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Olivia Harrison, Department of Psychology
Phone: 03 479 8818
Email: olivia.harrison@otago.ac.nz

Professor Bruce Russell, School of Pharmacy
Phone: 03 479 7272
Email: bruce.russell@otago.ac.nz

If you would like to speak to someone involved in the study about your mental health, you can contact either our Clinical Consultant or the Psychiatrist in our study team (or ask another member of the study team to do this for you). Details are as follows:

Clinical Consultant:
Ms Faye Gorman (RPN MNZAP, Registered Psychotherapist, Ngāpuhi, Ngati Kahu)
Phone: 027 2788630
Email: fayegorman@gmail.com

Psychiatrist:
Professor Paul Glue, Department of Psychological Medicine
Phone: 03 470 9430
Email: paul.glue@otago.ac.nz

If you would like to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

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

For Māori support please contact:

Ms Faye Gorman (Ngāpuhi, Ngati Kahu)
Phone: 027 2788630
Email: fayegorman@gmail.com
Note: Ms Gorman may act in consultation with Mana Whenua or community members to assist with tikanga and/or specific participant requirements (with your consent).

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone:	0800 4 ETHICS
Email:	hdecs@moh.govt.nz

Consent Form

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	
I have been given sufficient time to consider whether or not to participate in this study.	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	
I consent to the research staff collecting and processing my information, including information about my health.	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	
Women only: I understand that there may be risks associated with the study in the event of becoming pregnant. I take responsibility for the prevention of pregnancy during the study.	
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic 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 that could identify me personally will be used in any reports on this study.	

I understand that my data can be shared and used for research beyond this study, in de-identified form only.	
I understand that if I withdraw from the study, my data will be de-identified and included in data analysis and publication.	
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.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____