PARTICIPANT INFORMATION SHEET

Olanzapine for young PEople with aNorexia nervosa: An open-label feasibility study to test recruitment, treatment acceptance, adherence, safety, and outcome measures assessment and patients' experience to prepare for a definitive randomised placebo-controlled trial (OPEN)

Short Study Title: OPEN

Co-Sponsors: King's College London and South London and Maudsley NHS Foundation Trust

King's Health Partners Clinical Trials Office, Floor 16, Tower Wing, Guy's Hospital, Great Maze Pond, London, SE1 9RT

Clinical Trial.Gov Identifier:

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Study Coordinators: *<site to add name, role, department, contact number>*

INVITATION:

We are inviting you to take part in our research study because you have been diagnosed with Anorexia Nervosa and your doctor recommends the medication olanzapine to help you with the problems related to Anorexia Nervosa such as anxiety, low mood, sleep problems, the so-called "anorexic voice" and the physical health consequences of Anorexia Nervosa. This has been a clinical recommendation. However, as this clinical decision has been made, we would like to do some research on the effects of olanzapine and how you experience the treatment. This project has been developed by experts and

people with lived experience of Anorexia Nervosa to cover as many important aspects of your whole treatment - which olanzapine is one part of - as possible.

Before you decide to take part, we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Please talk to family, friends, or others about the study if you wish.

Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear. Take time to decide whether or not you wish to take part.

PART 1:

1. WHAT IS THE PURPOSE OF THE STUDY?

Some patients diagnosed with Anorexia Nervosa do not recover under psychotherapy. Despite one or more months of outpatient or inpatient psychotherapeutic treatment, they may still experience anxieties, sleep disturbances, a strong anorexic voice, problems with concentration and memory, thoughts obsessed with body shape and calories, and they may not manage to gain enough weight to become physically stable. The persistence of these symptoms prevents them from recovery, from resuming school, university or work, and leads to a loss of quality of life. Previous small studies have indicated that Olanzapine, a medication that is already approved to treat psychotic and mood disorders, might also help with anorexia nervosa.

We are planning a large clinical trial to find out whether Olanzapine is effective in improving physical and psychological problems associated with Anorexia Nervosa and whether it helps people with anxieties, depressive mood, tiredness and problems in their families. To prepare for such a large trial, we are conducting a smaller study to learn whether olanzapine is accepted by patients with Anorexia Nervosa and how they experience the treatment. This smaller study will already include all aspects of a bigger trial. The only difference is that in this current small study every patient will get Olanzapine prescribed as normal and will know that they are receiving Olanzapine, whereas in the later bigger trial they will receive either olanzapine or a dummy pill called placebo.

The primary objective of this study is to look into acceptance of Olanzapine in people with Anorexia Nervosa and get an impression of whether people take their olanzapine on a regular basis, for how

long they take it, how they experience the treatment and to collect preliminary evidence on the effects of Olanzapine regarding anxiety, depressed mood, sleepiness, quality of life and physical and psychological consequences of Anorexia Nervosa.

Olanzapine has been used for two decades in the treatment of Anorexia Nervosa because of the favourable experience patients and clinicians had with this medication, and the decision to take olanzapine is a clinical decision by you and your doctor based on this experience. However, olanzapine has not been studied scientifically in large and long-term clinical trials for Anorexia Nervosa. Therefore, our research is necessary.

2. WHAT IS THE STUDY MEDICATION THAT IS BEING USED

In the UK, Olanzapine is a frequently used anti-psychotic medication, and is currently only approved to treat Schizophrenia and Bipolar Affective Disorder which is a disorder with phases of depressed or elevated mood. For the time being, Olanzapine is not approved to treat Anorexia Nervosa in the UK. However, previous small studies in adolescents and adults indicate that Olanzapine might be helpful and beneficial in the treatment of Anorexia Nervosa. The daily Olanzapine dose we will be using is between 1.25 and 10 milligrams. This dose is lower than the doses usually used in the treatment of Schizophrenia.

3. WHY HAVE I BEEN INVITED?

You have been invited to take part as you have been diagnosed with Anorexia Nervosa, and the results of the first weeks of your treatment have been deemed not sufficient to reach full recovery in the long-term.

4. DO I HAVE TO TAKE PART?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You may also be invited to take part in a qualitative interview about your experiences of the study. Your participation is voluntary, and you are free to withdraw at any time without giving a reason. This would not affect the standard of care you receive.

5. WHAT WILL HAPPEN TO ME IF I TAKE PART?

If you decide to take part, you will have 6 clinical appointments over a period of 12 months: A screening visit, a baseline visit and 4 further visits after 8 weeks, 16 weeks, 6 months and 12 months.

Screening Visit – Clinic or Online Visit: (approximately 2 hours)

Your clinical team will check how old you are, your gender, whether you have a diagnosis of Anorexia Nervosa, whether you have or have not responded to the normal treatment, whether you are suffering from problems which exclude you from the study (acute suicidal plans or serious medical conditions), whether you are pregnant or breast feeding and whether you are on any medication that cannot be combined with Olanzapine. This information will be forwarded to our study team which will then decide whether you are eligible for the study. If so, the screening visit will go ahead.

- During this visit the Informed Consent Form will be reviewed with you in detail and you will have the opportunity to decide if you wish to participate in the study or not. If you meet all the requirements and all your questions have been answered, you will be asked to sign the consent form.
- You will be asked questions about your medical and psychiatric history including family psychiatric history and prior treatments. You may choose not to answer any questions that you are uncomfortable with.
- In addition to the above procedures, you will also have a physical examination, which includes measuring your weight and blood pressure.
- To ensure safety of participation in the study, you will be asked to have routine clinical blood work, including a pregnancy test for female participants, and urine test for a drug screen. If you had this recently, we will use the already available blood results.
- An ECG (a tracing of the heart beats) will be performed, or the results of a recent ECG will be used for safety reasons

Qualitative interview

You may also be invited to take part in the qualitative interview even if you decline to take part in the main study. If you do not agree to take part in the study, you will be asked to take part in an interview to find out why you preferred not to take part. This would expand our knowledge on the barriers of participation associated with the study. You will receive an additional consent form to take part in this

interview. Your participation in this interview is, again, voluntary and you are free to withdraw from your decision to take part or not to take part without giving a reason. This would not affect the standard of care you receive.

Baseline Visit – Clinic or Online Visit (approximately 3 hours)

- At the baseline visit, a physical assessment will take place, vital signs and weight measurements will be obtained or clinical information will be obtained from your clinical team. This will include information about a potential medication you are currently on.
- Laboratory parameters will be obtained from your clinical records, or your team will be asked to control certain laboratory parameters related to your blood, your electrolytes, your liver and your kidneys.
- You will be asked to complete questionnaires about your Anorexia Nervosa symptoms, your mood and anxiety, obsessive or compulsive symptoms, and your quality of life. The questions are generally multiple-choice questions or rating scales. You will be given paper forms to answer those in the presence and support of a clinician. You can take breaks as you wish. Some of the questions may make you feel sensitive or uncomfortable. If this happens, or if you needed support or to talk to someone when answering these questions, there will always be a clinician available for you. You can also choose not to answer a question or a form.
- You will also be asked to complete a questionnaire on your use of alcohol, drugs and tobacco.
- You will be asked to have a conversation with a researcher and complete a questionnaire about the reasons why you joined the study, how you experienced the process of inclusion into the study and what you expect from the treatment with olanzapine.
- You will be prescribed olanzapine. You will be asked to bring the remaining unused medication to your next appointment; or, if you are an inpatient, staff will be asked to document whether you took your medication.

Week 8 – Clinic or Online Appointment: (approximately 3 hours)

This visit will be similar to your baseline visit.

- Like in the baseline visit, a physical assessment will take place, vital signs like pulse rate, blood pressure, body temperature and weight measurements will be obtained or clinical information will be obtained from your clinical team.

- Laboratory parameters will be obtained from your clinical records, or your team will be asked to control certain laboratory parameters related to your blood, your electrolytes, your liver and your kidneys.
- You will again be asked to complete questionnaires about your Anorexia Nervosa symptoms, your mood and anxiety, obsessive or compulsive symptoms, and your quality of life. These will be similar questionnaires to the baseline visit, and you will be asked to complete those in the presence and support of a clinician. You can take breaks when completing these forms and can choose not to answer certain questions. A clinician will always be available for you if you became uncomfortable, needed support, or wanted to discuss things.
- Your prescription olanzapine will continue. You will bring the remaining unused medication to your next appointment; or, if you are an inpatient, the documentation of medication intake will be recorded.
- The olanzapine level in your blood will be measured.
- In contrast to the baseline assessment, you will not be asked about information on alcohol, drug and tobacco use again.
- Another difference to your baseline assessment is that there will not be an interview with a researcher about the reasons why you joined the study or what you expect from the study.

Week 16 Clinic or Online Appointment: (approximately 3 hours)

This visit will be similar to your week 8 appointment.

- A physical assessment will take place or clinical information will be obtained from your clinical team.
- Laboratory parameters will be obtained from your clinical records, or your team will be asked to control certain laboratory parameters.
- You will be asked to complete questionnaires and you will be supported doing that.
- Your prescription of olanzapine will continue. You will bring the remaining unused medication to your next appointment; or, if you are an inpatient, the documentation of medication intake will be recorded.
- There will potentially be an interview with a researcher about your experiences in the first 16 weeks of olanzapine treatment and whether you adhered/did not adhere to the medication and the reasons why.
- The olanzapine level in your blood will not be measured unless there is a clinical reason to do so.

6 months Clinic or Online Appointment: (approximately 3 hours)

This visit will be similar to your week 16 appointment and will include:

- A physical assessment

- Laboratory parameters
- Completion of questionnaires
- Prescription of olanzapine
- In contrast to previous appointments, there will not be an additional interview or a measurement of olanzapine level unless clinically necessary

12 months Clinic or Online Appointment: (approximately 3 hours)

This visit will be similar to your week 16 appointment and will include:

- A physical assessment
- Laboratory parameters
- Completion of questionnaires
- Prescription of olanzapine
- In contrast to previous appointments, there will not be an additional interview and or a measurement of olanzapine level unless clinically necessary.
- You will decide with your clinical team or your psychiatrist whether olanzapine treatment should continue or whether it should be tapered down and stopped.

6. EXPENSES AND PAYMENTS

For your baseline visit and after the final 12 months assessment you will receive a £10 thank you voucher.

7. WHAT WILL I HAVE TO DO?

If you decide to participate, you will agree to co-operate fully with taking the medication as instructed and with the study visit schedule (as outlined in section 5), and will follow the study doctor's instructions. You will be asked to contact the study staff before starting any new medications. In addition, if you are a female participant, you will be asked to inform the study staff immediately if you become pregnant.

8. WHAT ARE THE ALTERNATIVES FOR DIAGNOSIS OF TREATMENT?

There may be alternative treatments for your illness other than this study, including other medications. You can discuss these options with your doctor before deciding whether or not to participate in this research project.

9. WHAT ARE THE POSSIBLE DISADVANTAGES AND RISKS OF TAKING PART?

Olanzapine is usually well tolerated. As with any medication, there is the possibility that you may experience some side effects. Here we list all side effects which we expect to appear in at least 1% of study participants.

Sleepiness/Sedation: There is a risk that you may feel sleepy when taking this medication, or a risk that you feel fatigue which is like tiredness. If you experience any of these side effects, please report these to your doctor. Olanzapine is usually prescribed as an evening or night medication in order to help improve sleep.

Low blood pressure: There is a risk of a drop in blood pressure when you stand from a seated or lying position.

Weight Gain and increased appetite: There is a risk that you may experience increased appetite and gain weight when taking the study medication. Some weight gain is, however, intended as part of the treatment of Anorexia Nervosa. The Olanzapine tablets themselves do not include calories. The weight gain is a consequence of increased food intake. If you have any concerns, or become worried about gaining weight, please speak to your doctor.

Blood count changes: Olanzapine can cause changes in your blood cells. For example, “eosinophilia” may appear which is a higher-than-normal level of the so-called eosinophils. Eosinophils are a type of disease-fighting white blood cell. Other potential blood count changes include leukopenia and neutropenia which means lower-than-normal levels of white blood cells or the so-called neutrophils which is another subgroup of disease-fighting white blood cells. For this reason, we will obtain laboratory parameters for the study assessments.

Other changes in laboratory parameters: Other potential changes of your laboratory parameters include transient elevated liver function tests (high aminotransferases or high gamma glutamyltransferase), increases in cholesterol, blood sugar or triglycerides in your blood, or increases

in alkaline phosphatase, uric acid or creatine phosphatase. These laboratory parameters will be checked during study visits.

Movement problems: There is a very low risk that you may develop Parkinsonism. The signs of this are tremor, muscle stiffness, slow movement, and abnormal balance. Other potential movement problem is the feeling of inner restlessness or an inability to sit still (akathisia) or the feeling of physical weakness (asthenia). If you start to experience any of these symptoms, please alert your doctor.

Because the effects of Olanzapine on an unborn child are not fully known, you should not become pregnant while on this study. Effective methods of contraception (barrier methods such as male condom, female condom, cervical cap, diaphragm, contraceptive sponge) should be used to avoid pregnancy from the day you sign consent up to the last dose of study drug, and for 7 days after dosing stops. Use of these methods of contraception may cause discomfort or side effects. It is not known whether Olanzapine or its metabolites are excreted in human milk therefore you should not breastfeed while taking this medication. If you become pregnant during the study, you will be withdrawn from the study, and we would like to follow-up on your pregnancy.

Whereas many participants find answering the questionnaires for this study interesting or challenging, some individuals may experience minor anxiety. It is possible that interview questions or questionnaires relating to your psychiatric history may also elicit minor distress. To minimise this, we are providing information about the content and type of the questions you will be asked in the information sheets. There will always be a clinician available to you during the interview and completion of the questionnaires if you need support or to talk to them. You can choose not to answer questions or stop at any time if you wish. Members of the research team will remain sensitive to signs of distress and will check your mental state and safety upon completion of the processes at each encounter. If there are ongoing concerns due to distress, the research team will liaise with your clinical team to ensure there is ongoing clinical support available and if necessary, to discuss whether it is appropriate for you to remain in the study.

10. WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

There may or may not be direct benefits to you from taking part in this study. However, we have reviewed the literature, and Olanzapine is the medication with the highest chance to help with Anorexia Nervosa.

We hope that the information learned from this study will increase general knowledge about Anorexia Nervosa and its treatment with Olanzapine and assist others with the condition, as well as help in determining better treatment options for patients with Anorexia Nervosa.

11. WHAT HAPPENS WHEN THE RESEARCH STUDY STOPS?

Once the study has stopped you will return to your usual care and treatment. You may not be able to receive the study treatment after your participation in the study is completed. There are several possible reasons for this, some of which include:

- The treatment may not turn out to be effective or safe.
- The treatment may not be approved for use in people with Anorexia Nervosa in the UK.
- Your caregivers may not feel it is the best option for you.

If you have further questions about continuing with the study drug once the research study ends, please discuss this with your study doctor.

12. WHAT IF THERE IS A PROBLEM?

Any complaint about the way you have been dealt with during the clinical trial or any possible harm you might suffer will be addressed. The detailed information concerning this is given in Part 2 of this information sheet. If you have any concerns or complaints, you should contact your study doctor in the first instance.

13. WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

14. CONTACT DETAILS

Your Doctor

Name: *<site to add name>* Tel. Number: *<site to add Tel. number>*

Your Research/Specialist Nurse/Research Fellow/Research Coordinator <*delete as appropriate>*

Name: *<site to add name>* Tel. Number: *<site to add Tel. number>*

This completes Part 1 of the Information Sheet.
If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2:

15. WHAT IF RELEVANT NEW INFORMATION BECOMES AVAILABLE?

Sometimes we get new information about the treatment being studied. If this happens, we will tell you about it and discuss whether you want to or should continue in the study. If you decide not to carry on, we will make arrangements for your care to continue. If you decide to continue in the study, we will ask you to sign an updated consent form. **OR** On receiving new information, we might consider it to be in your best interests to withdraw you from the study. If so, we will explain the reasons and arrange for your care to continue. If the study is stopped for any other reason, we will tell you why and arrange your continuing care.

16. CAN I BE ASKED TO LEAVE THE STUDY?

If you are not able to follow the requirements of the study, or if your mental state worsens, your study doctor will assess you to determine whether it would be in your best interest to continue or be withdrawn from the study. If you are withdrawn, arrangements will be made for your care to continue.

17. WHAT WILL HAPPEN IF I DO NOT WANT TO CARRY ON WITH THE STUDY?

You may withdraw from the study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected. You will be asked to consent for this.

If your participation in this study includes enrolling in any optional studies or long-term follow-up, you will be asked whether you wish to withdraw from these as well. You will also be asked to consent to this.

18. WHAT IF THERE IS A PROBLEM?

You have the right to ask questions at any time. Please call the contact number detailed on page 1 of this information sheet if you:

- have any questions about this study
- experience a side effect, study-related injury, or have a problem
- have a medical emergency; or please report to the Accident and Emergency (A&E) department if this a medical emergency

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:

[insert Principal Investigator name, telephone number and e-mail address].

If you remain unhappy and wish to complain formally, you can do this through the local Patient Advice and Liaison Service (PALS):

The Patient Advice and Liaison Service (PALS)
Phone: 0800 731 2864 (Option 2)
Email: pals@slam.nhs.uk

If you would still like to complain you can do so by contacting Dr Gill Dale, Director of Research Quality via the R&D office slam-ioppn.research@kcl.ac.uk.

If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you.

19. COMPENSATION FOR INJURY

In the event that something does go wrong and you are harmed during the research, you may have grounds for legal action for compensation against King's College London and/or SLaM NHS Foundation Trust, but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

By signing and dating this form, you have not waived any of the legal rights, which you would have otherwise, if you were not a participant in a medication research study.

20. WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. Your GP and clinical team will be informed that you are involved with the study. This is to ensure that your GP and clinical team are aware of you being treated with olanzapine as well as the monitoring and care processes are in place for you during and after the study. The NHS site where the research is being conducted may also review your records to ensure the research is being conducted correctly. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law. During the study, if it appears that you are or someone else is at risk of serious harm or abuse, or you need urgent care, relevant information might be shared with others, as appropriate, to ensure health and safety of you and/or others`.

You will be assigned a unique study number and /or code letters (not real initials) as a participant in this study. This number (and/or code letters) will not include any personal information that could identify you (e.g., it will not include your NHS Number, Hospital Number, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released from the hospital without your consent unless required by law. Your research data and your study number will be stored in the online Clinical Report Form (CRF), which is managed by Kings College London and South

London and Maudsley NHS Foundation Trust (SLaM). Your data will be held securely at Kings College London at the Institute of Psychiatry, Psychiatry and Neuroscience.

The study is also running in conjunction with the University of Sydney, so researchers from the UK will interpret and evaluate the anonymized data in order to publish the results as one research study in collaboration with the researchers from Australia. Your data will not be identifiable from the results shared with University of Sydney.

Your rights to privacy are legally protected by the General Data Protection Regulation (GDPR) to ensure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

21. GENERAL DATA PROTECTION REGULATION (GDPR) COMPLIANCE

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained, and we will keep samples up until this point if you have consented, or if they are no longer identifiable. To safeguard your rights, we will use the minimum personally-identifiable information possible.

[enter name of investigation site here] will collect information from you and/or your medical records for this research study in accordance with our instructions. [enter name of investigation site here] will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. [enter name of investigation site here] will keep identifiable information about you (for example, the consent form) from this study for 25 years after the study has finished.

22. HOW WILL WE USE INFORMATION ABOUT YOU?

We will need to use information from you for this research project.

This information will include your initials and your date of birth. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

23. WHAT ARE YOUR CHOICES ABOUT HOW YOUR INFORMATION IS USED?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

24. WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by contacting King's College London's Data Protection Officer, Mr Albert Chan at info-compliance@kcl.ac.uk (or if SLaM is storing the research data, dataprotectionoffice@slam.nhs.uk)

25. WILL MY GP BE INFORMED OF MY INVOVLEMENT?

With your permission, your GP, and other doctors who may be treating you, will be notified that you are taking part in this study. A letter will be provided to your GP outlining that you have been enrolled to the study and are receiving Olanzapine. Your outpatient specialist service or your GP will be asked to prescribe Olanzapine during the duration of the study. This will help to provide any medical care during and after the study.

26. WHAT WILL HAPPEN TO ANY SAMPLES I GIVE?

During the study, laboratory samples are collected. However, any samples taken and tested will be measured for routine care reasons in the local laboratory collaborating with your specialist eating disorders service or with your GP. The researchers will only need access to the results of these routine tests. No samples will be taken or kept for the research project.

27. WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

The results of the study will be available after it finishes and will usually be published in a medical journal or be presented at a scientific conference. The data will be anonymous and none of the patients involved in the trial will be identified in any report or publication. The study is also running in conjunction with the University of Sydney, so researchers from the UK and Sydney will interpret and evaluate the anonymized data in order to publish the results as one research study. The results of the study will be available on the website clinicaltrials.gov, this may be a number of years after the study finishes to allow for the results to be analysed by the study doctors.

We will also hold an event for all patients involved in the study who are interested in the outcome of this study. You will be invited to this event.

28. WHO IS ORGANISING AND FUNDING THE RESEARCH?

This trial is supported by a grant from the Health Technology Assessment (HTA) Programme. This programme funds research about the clinical and cost-effectiveness, and broader impact of healthcare treatments and tests, for those who plan, provide or receive care from NHS, and social care services. This programme is funded by the National Institute for Health Research (NIHR). King's College London and South London and Maudsley NHS Foundation Trust will be the co-sponsors for the study.

29. WHO HAS REVIEWED THIS STUDY?

In 2020, the NIHR HTA advertised the funding opportunity "Antipsychotics for young people with anorexia nervosa". We submitted an Expression of Interest which was reviewed by two independent reviewers and the HTA Funding Board, and we were invited to submit a full proposal. This was again reviewed by six independent reviewers and the HTA Funding Board.

In addition, all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion.

30. FURTHER INFORMATION AND CONTACT DETAILS

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug and study assessments involved. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Your Doctor

Name: *<site to add name>* Tel. Number: *<site to add Tel. number>*

Research/Specialist Nurse/Research Fellow <*delete as appropriate>*

Name: *<site to add name>* Tel. Number: *<site to add Tel. number>*

In an emergency please contact:

Department of Psychological Medicine, Section of Eating Disorders: *<site to add name>*
Tel. Number: *<site to add Tel. number>*