



Insert local contact details e.g. TRUST LOGO (for multi-centre studies can be done once approval is in place)

*Add contact details of the
local research team and
either the Chief or Local Investigator*

RAPID-driven Treatment of Pleural Infection (feasibility study) RAPTOR- f

We'd like to invite you to take part in a research study called RAPTOR-f. Before you decide to take part in this study, it's important to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please feel free to ask us if there is anything that is not clear or if you would like more information.

Summary or key facts

You have been asked to participate in this study because you have a condition called pleural infection due to a collection of infected fluid between the lung and the chest wall (also called the pleural space). Treatment of this condition requires you to be admitted to the hospital to receive antibiotics and to put a tube in your chest to help remove the infected fluid. When people do not respond to this treatment, they are usually treated with either surgery or medications through the chest tube (called Intrapleural Enzyme Therapy or IET) to help clear out the infected material.

Currently, all treatments for pleural infection, including antibiotics, chest tube, surgery, and medications through the chest tube, are given in a stepwise way. This means that there can be a delay in providing the most suitable treatment, which can affect patient care and recovery.

We have developed this study (called RAPTOR-f) to see if we can use a scoring system to tell us early on which patients will have more severe disease. This call the RAPID score, which uses clinical information and tests taken from patients when they are in hospital and collected as part of normal care. The score might help us guide the best initial treatment for each patient, as people with higher severity will receive stronger treatment, and those with lower severity might be able to get out of hospital sooner.

If you agree to participate , a computer system will randomly assign you to one of two groups:

1. **Standard care:** You will be admitted to hospital to receive antibiotics, and a chest tube will be placed into your chest to drain the infected fluid. If there is no improvement after 72hours, your doctor will consider surgery or IET.

2. **RAPID driven treatment:** Your treatment will be decided on according to the RAPID score. There are two main treatment plans:

- I. **Low RAPID score:** You will be admitted to hospital and treated with antibiotics and a brief period of drainage of the infected pleural fluid using a chest tube for 24 to 48 hours or shorter with early discharge from hospital if improving, and close monitoring as outpatient.
- II. **Medium / high score:** You will be admitted to hospital and treated with antibiotics and a chest tube to drain the infected pleural fluid with an early IET or surgery and follow up in the outpatient clinic following hospital discharge.

After the above, we will see everyone in clinic at 2 weeks and 4 weeks after discharge. We will make a telephone call to you at 12 weeks (3 months) after discharge.

Once you have recovered from your acute illness, a member of the research team may contact you to discuss your views on the treatment you received and your participation in the study through a series of standardised questions.

Participation in the study is completely voluntary, and you may choose to withdraw at any stage without any effect on your medical and nursing care. We will ask for your permission to take some samples (of blood and pleural fluid) which will be stored for research now and in the future.

You always have the right to leave the study without giving us any reason. If you do so, you can allow us to still use your data and contact information.

PARTICIPANT INFORMATION SHEET

What is the purpose of the study?

The RAPTOR-f study will assess if patients suffering from pleural infection can be treated according to the severity of the disease, using a scoring system called RAPID (all detailed below). It is a small-scale study to understand if this approach to treatment is possible and safe before undertaking a largest study.

Pleural infection is when there is a collection of infected fluid between the lung and chest wall. This condition is commonly treated with admission to hospital; antibiotics and a tube put into the chest to drain the infected fluid. These treatments together are called “standard treatment”. If patients do not respond to initial treatment, we refer them for surgery to drain the infected fluid collection. Alternatively, they can be treated with medications through the chest tube called Intrapleural Enzyme Therapy or IET to improve drainage. Details of surgery, IET treatment and the RAPID score are given below.

Details of study-related procedures:

RAPID score:

The RAPID score is a clinical score that has been developed to understand the severity of pleural infection. The score is calculated using the results of blood tests (function of your kidneys and level of certain protein in your blood called albumin, which reflect your nutritional status) and pleural fluid as well as and clinical information. According to these parameters you will score from 0 to 7. If the score is 0 – 2, you fall into the low risk group and if you score from 3 to 7, you fall into the moderate or high risk group.

This score helps to predict who will stay longer in hospital and will have worse outcomes from pleural infection. This provides extremely important information to the treating doctor to help them give the best treatment to the right patient at the right time. This can lead to less intense treatment and early home discharge for patients at low risk and more focused treatment for patients who are at risk of a bad outcome. This calculation and use of this score is recommended in the national treatment guidelines for pleural infection to help the clinical team in making better treatment decisions.

Treatment arms:

If you agree to participate in the study, we will randomly allocate you (using a computer system) to one of the two following treatment arms. These are either **standard care** or **RAPID driven treatment** as follow:

1. **Standard care:** You will be admitted to hospital to receive antibiotics, and a chest tube will be placed into your chest to drain the infected fluid. Your doctor will monitor your progress by monitoring certain parameters, including clinical assessment, blood test and images of your lung, if you do not respond to this treatment within 72 hours, you will be offered surgery or Intrapleural Enzyme Therapy (IET). This treatment is exactly the same as you would receive if you were treated for the infection outside the study.

2. **RAPID driven treatment:** In this group, treatment will be decided on according to the RAPID score. There are two main treatment plans:

- I. **Low RAPID score:** If the score is low, you will be admitted to hospital and treated with antibiotics and a brief period of drainage of the infected pleural fluid using a chest tube for 24 to 48 hours or shorter. Your doctor will assess your progress by monitoring certain parameters, including clinical assessment, blood test and images of your lung. If you are improving, the chest tube will be removed, and you will be discharged from hospital. When you go home, you will be given a mobile number to call if you have any concerns, (such as feeling more breathlessness, having pain at your chest, persistent temperature or feeling unwell). You can then talk to a doctor (the clinical fellow), receive advice and if necessary be seen. This mobile number will be active 24 hours a day. After going home, we will see you in clinic around 3 days after discharge to assess progress and symptoms.

- II. **Medium / high score:** If your score is higher, you will be admitted to hospital and treated with antibiotics and a chest tube to drain the infected pleural fluid. You will be given IET following the tube insertion (if safe to do so) and your doctor will refer you to the surgeons at the same time to assess your fitness for an operation to drain the infected fluid. Your doctor will assess your progress in 72 hours by monitoring certain parameters, including clinical assessment, blood test and images of your lung. If you are improving, you will continue on this treatment until you are discharged from hospital. However, if you do not respond to treatment, your doctor will ask the surgeons to consider surgery. Once you go home, you will be seen in clinic around 2 weeks after discharge. When you go home, you will be given a mobile number to call if you have any concerns, (such as feeling more breathlessness, having pain at your chest, persistent temperature or feeling unwell). You can then talk to a doctor (the clinical fellow), receive advice and if necessary be seen. This mobile number will be active 24 hours a day.

Intrapleural Enzyme Therapy or IET (Combined DNase and Alteplase):

Intrapleural Enzyme Therapy involves two drugs (DNase and Alteplase) that are given twice a day for 3 days through the chest tube to help improve the drainage of infected pleural fluid. These medications have been routinely and safely used in the treatment of pleural infection for more than a decade though they are not yet licenced. Possible side effects of IET include chest discomfort (20%), allergic reactions (3.8%) and bleeding (1.8%) but they are usually mild and well tolerated.

The IET drugs have been used separately in the treatment of multiple other conditions for decades. DNase is routinely used in patients with cystic fibrosis (where it is inhaled into the bronchial tubes). There has been extensive research to establish the safety of this medication, and it is now used as a standard for millions of patients in the world.

Alteplase is routinely given as an injection in veins for the treatment of patients with stroke, or lung clots and occasionally in those who have suffered a heart attack. It is also known as a 'clot-busting' treatment with a strong safety profile.

Samples (Bloods and Pleural fluid)

Routine blood tests which are part of the NHS usual care will be taken throughout the course of your treatment to monitor progress. These will be carried out by fully trained healthcare professionals including doctors, nurses and clinical support workers trained in phlebotomy. Possible side effects include bruising and/or fainting. There is a very small risk of infection, but blood sampling will be carried out using strict infection control procedures.

In addition, specific research samples will be requested at the same time as routine samples and that there would be no additional venesection, as follows:

1. All participants recruited from Oxford will be asked (optional) for consent for the collection of samples of blood (10 millilitres, about two teaspoonfuls) and pleural fluid (100 millilitres, about 20 teaspoonfuls) on a few days when you are in hospital. They will not be collected if it is not convenient to collect them, for example if you

have been discharged home. We will use these samples to test certain markers in the blood which are related to the infection.

2. Participants from centres outside Oxford will have pleural fluid samples and blood collected (optional) at enrolment to the study when the chest tube is put in, and we will send the samples to the laboratory in Oxford for later analysis.

Patients will have the option to consent for sample donation, and this aspect of obtaining research samples is **optional** (i.e. lack of consent for this aspect will not affect your participation in the clinical study), **and the samples will be kept after analysis and dissemination of the results (Optional).**

Qualitative Interviews

You may be invited to participate in qualitative interviews along with some patients who chose not to participate in RAPTOR f study and healthcare professionals. You will be provided with a separate interview information sheet which explains the details of the qualitative sub-study. The aim of the study is to try to understand your views and experiences during the course of treatment. Your responses will be audio-recorded, and a member of the trial team will transcribe the data (which means we will write down your responses). We will keep the transcripts for later analysis, but no information identifying who you are will be kept.

Why have I been invited?

You have been invited to take part in this study because you have been diagnosed with pleural infection based on the following criteria; subjective and objective measures of infection, images(Chest x ray or computed tomography of the chest or thoracic ultrasound) showing fluid collection or isolation of the bacteria from the pleural fluid or presence of pus coming out through the chest tube or if the test of the pleural fluid prove its acidic or low glucose. This study is being conducted in hospitals within the UK, and we will aim to recruit 30 patients from different centres.

Do I have to take part?

No – the study is entirely voluntary. If you do take part, you will be given this information sheet to read. Then you will be asked to sign a consent form. Even after you sign this, you are still free to withdraw at any time without giving a reason. A decision to withdraw at any time or a decision not to take part will not affect your future clinical care outside the study.

If you decide not to take part, we may also ask for your consent (optional) for one of our study, to allow doctors to contact you to ask the reasons why you did not want to take part, as your views are very important to us and will be very valuable in adding to our understanding for the purposes of this study.

What will happen to me if I decide to take part?

If you decide to take part in the study, you will be asked to sign a written consent form. After that, a computer system will be used to randomly allocate you to one of the treatment arms of the study. The computer system is designed to ensure you will have an equal chance of being allocated to either arm. Furthermore, you should not enter the study unless you are happy to be allocated to either arm.

If you have been allocated to the standard care arm, you will be admitted to the hospital and treated with antibiotics and drainage of the pleural fluid via the chest tube. Your doctor will monitor your progress to assess if there are any features of treatment failure or no clinical improvement. If this is the case, the treatment will be escalated to IET or surgery in 48 to 72 hours. This is exactly the same sort of treatment you would receive if you were not part of this study and is standard in the current NHS.

If you are allocated to the RAPID-driven treatment arm, the RAPID score will be calculated. If you fall into the low-risk group, you will be admitted to the hospital and treated with antibiotics and a brief period of drainage of the pleural fluid. Your progress will be assessed by your doctor in 24 to 48 hours and if you are improving, you will be discharged from the hospital followed by an early clinic review in around 3 days after discharge. When you go home, you will be given a phone number which is available 24 hours a day to contact a doctor if there are any concerns about your recovery.

If you fall into the intermediate to high-risk group, you will be admitted to the hospital and treated with antibiotics and drainage of the pleural fluid via the chest tube. You will also be given IET via the chest tube (if safe to do so) and your doctor will refer you to the surgical team at the same time. Your progress will be assessed by your doctor in 48 hours and if you are improving, you will continue on the allocated treatment. Once you are clinically improved, you will be discharged from the hospital followed by a routine clinic review in around 2 weeks with a set of blood and lung imaging similar to what you had in the hospital. When you go home, you will be given a phone number which is available 24 hours a day to contact a doctor if there are any concerns about your recovery.

As part of the usual care of this condition in the NHS, everyone will undergo routine blood tests during the first week of treatment. Your doctor will look at these blood tests to help assess your clinical progress. You will also have chest X-rays and chest ultrasound scans and may need a Computed Tomography scan of the chest as well. All of these scans are part of normal care, and you will not be exposed to any more radiation than what would have been needed as part of routine clinical care.

During your stay in the hospital, a research team member may ask you to go through some questionnaires if you are well enough. These questionnaires will be about your health, mobility, activities and pain.

All People in the study will be followed up in a routine clinic at around 2 weeks and four weeks after discharge. During this appointment, your doctor will assess your clinical progress by conducting a clinical assessment and a set of blood tests and scans (chest ultrasound plus chest X-ray). If there are any concerns that your treatment is not going well, you may need to be admitted to the hospital for further treatment.

Chest imaging (using either Computed Tomography and/or plain film x-ray) is part of your routine care. If you take part in this study, you will not undergo any additional imaging. These procedures use ionising radiation to form images of your body and/or provide treatment and/or provide your doctor with other clinical information. Ionising radiation can cause cell damage that may, after many years or decades, turn cancerous. The chances of this happening to you are the same whether you take part in this study or not.

A further telephone follow-up will be undertaken at 12 weeks (3 months) after discharge.

During your clinic visits a member of the research team will go through the same set of questionnaires you may have completed whilst in hospital. They might also approach you to participate in an online interview to discuss your experience of participating in the study. This interview will be undertaken 4 to 6 weeks after you recover from the illness at a time of your convenience using an online platform e.g Microsoft Teams or Telephone, whatever works for you or if you have any difficulty with an online interview e.g., if you have no access to telephone or internet then we can arrange face to face interview.

What should I consider?

You might not be able to take part in the study if you are pregnant or you have a serious illness not related to the pleural infection that is likely to significantly affect your health in short term e.g., spreading cancer or if the infection occurs at the site of the previously removed lung or if the fluid around the lung is small and not amenable to chest tube drainage, if you previous received Intrapleural enzyme therapy or you are allergic to one of the intrapleural drugs.

Are there any possible disadvantages or risks from taking part?

Every effort will be made to combine follow up study visits for the study with routine clinical dates, to minimise extra trips to the hospital and inconvenience to you. However, this may not be possible. Overall, there are no obvious disadvantages of taking part in the study as all treatment being offered is part of the routine NHS care. During your visits, your doctor will conduct a bedside examination, routine blood tests and images of your lung, all of these as part of your routine NHS care, and you will be asked to complete questionnaires to assess your quality of life and recovery.

What are the possible benefits of taking part?

There are no direct benefits of taking part in the study. However, you will be helping to inform medical professionals whether a larger study to use the RAPID score would be possible in the future. This will provide a huge benefit to future patients being treated for pleural infection.

Will my General Practitioner (GP) be informed of my participation?

Your GP will not routinely be informed of your participation. Your participation in this study will not affect any other aspect of your clinical care. Your treatment and follow-up will be provided in full by your clinicians in the hospital or remotely by the study team. Any incidental findings or unexpected events will be handled directly by your treating doctors and the study team. If any action is required outside the scope of the study or managing your condition, your GP will be informed.

Will my taking part in the study be kept confidential?

Yes. All study records and samples will be identified only by a code. The University of Oxford will only use email addresses to enable the research team to send the relative questionnaires which are part of the study to assess your recovery and quality of life.

Confidentiality will be maintained as far as it is possible, unless you tell us something which implies that you or someone you mention might be in significant danger of harm. In this case, we would have to inform the relevant agencies, but we would discuss it with you first.

Responsible members of the University of Oxford, regulatory authorities, and the relevant NHS Trust(s) may be given access to the full data set for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

There will be no planned additional visits and therefore no reimbursement for travel costs or mileage.

What will happen to the samples I give?

If you agree and with your consent, samples that you provide will be used to do assess in a laboratory to determine whether certain proteins measures in the pleural fluid are associated with the treatment you received and whether you responded to treatment. The researcher will use a unique code to identify your samples; this protects your confidentiality but also means we will not be able to give you your individual results.

Moreover, these samples will be used in the future for ethically approved research(**Optional**). The infected chest fluid, blood samples and other information collected as part of this study may also be used in other research (some of which may be funded by commercial companies) with a view to developing medical diagnostic tools and new treatments for doctors to use to help other future patients like you. Your samples will not be used in the creation of immortal cell lines, animal studies or in the Human Genome Project.

If you agree to your samples being used in future research, your consent form will be held until the samples have been depleted or destroyed.

What will happen to my data?

Data protection legislation requires that we, the University of Oxford (whose legal name is The Chancellor Masters and Scholars of the University of Oxford), state the legal basis for processing information about you. In the case of research, this is a 'task in the public interest'. The University of Oxford is the sponsor for this study and is responsible for looking after your information and using it properly.

We will need to use information from your hospital records for this research project. We will share your information related to this research project with the following types of organisations: NHS Foundation Trusts and professional transcription service.

This information will include your initials and contact details (email address and phone number) 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 by keeping your data on secure university servers, limiting access to the personal data only to those who need it to do the research or for auditing/monitoring purposes and using a contract to safeguard the use of data transferred to third-party service providers (a professional transcription company).

International Transfers

We may share data about you outside the UK for research-related purposes to develop a multicentre study.

If this happens, we will only share the data that is needed. We will also make sure you can't be identified from the data that is shared where possible. This may not be possible under certain circumstances – for instance, if you have a rare illness, it may still be possible to identify you. If your data is shared outside the UK, it will be with the following sorts of organisations: Hospitals and Universities.

We will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following:

- (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
- we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner's Office \(ICO\) website](#)
- we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
- we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
- we have procedures in place to deal with any suspected personal data breach. We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the Information Commissioner's Office \(ICO\) website](#).

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.

We will keep your study data for the minimum period of time required by the University Policy on Management of Data.

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. You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital records. If you do not want this to happen, tell us and we will stop.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. Data and samples will be adopted into the Oxford Radcliff biobank.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK.

You can find out more about how we use your information, including the specific mechanism used by us when transferring your personal data out of the UK by:

- asking one of the research team Alguili.elsheikh@ouh.nhs.uk
- sending an email to respiratorytrialsunit@ouh.nhs.uk
- calling us on 01865 225230
- contacting the University's Data Protection Officer data.protection@admin.ox.ac.uk
- looking at the University's privacy notice available at: [How we use your personal data for research purposes | Compliance](#)

If you would like to find out more about the use of confidential data in research, the HRA has developed a general information leaflet which is available at: [Patient data and research leaflet - Health Research Authority](#).

We may use third party service providers or subcontractors to help with some of the research activities we carry out (e.g. IT provision, survey provision, transcription services etc.). We may therefore share your personal data with these providers when it is necessary to do so to allow them to carry out the services, we require them to provide. However, we require all our third-party providers to have appropriate security measures in place to protect your data, and we only allow them to process your data for the specific purposes we have stated in our instructions.

What will happen if I don't want to carry on with the study or lost capacity?

Participation in the study is completely voluntary, and you may change your mind at any stage. You can be completely reassured that your withdrawal from the study will not affect any care you receive from the medical and nursing team looking after you. Standard treatment of your condition will continue in keeping with current guidelines and you will be followed up after discharge in the usual way.

If you withdraw from the study, we will destroy all your identifiable samples but will use the data collected up to your withdrawal.

If you withdraw from the study, unless you state otherwise, any blood or fluid samples which have been collected whilst you have been in the study will be used for research as detailed in this participant information sheet. You are free to request that your blood or tissue samples be destroyed at any time during or after the study.

If you lose capacity, you will be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

What will happen to the results of this study?

At the end of the study, these results will be made available to all doctors, through publication of a medical “paper”, and presentation at medical conferences, or at the Oxford Respiratory Trials Unit website: <https://www.expmedndm.ox.ac.uk/ortu>. A copy of the lay summary of the study will be offered to share with the participant if they wish to have this.

Some of the research being undertaken will also contribute to the fulfilment of an educational requirement (e.g. a doctoral thesis) of Dr. Elsheikh.

What if we find something unexpected ?

As already discussed, this study is looking to assess the possibility of using RAPID score to guide treatment for pleural infection instead of treating all people in a stepwise manner and there is no new or experimental treatment being used.

The committee monitoring this study will continue to review all new research data. If any new information that influences the study becomes available, alterations will be made accordingly to the study (including patient randomisation, patient information etc. wherever appropriate). Patients will be contacted about new data via their hospital doctors at their recruiting centre.

What if there is a problem?

The investigators recognise the important contribution that volunteers make to medical research and will make every effort to ensure your safety and wellbeing. The University of Oxford, as the research sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your taking part in this study. If something does go wrong, you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation. While the Sponsor will cooperate with any claim, you may wish to seek independent legal advice to ensure that you are properly represented in pursuing any complaint. The study doctor can advise you of further clinical action and refer you to a doctor within the NHS for treatment, if necessary. NHS indemnity operates in respect of the clinical treatment which is provided.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact the chief investigator Professor Najib Rahman via email

najib.rahman@ndm.ox.ac.uk or sub-investigator Dr Alguili Elsheikh. Email Alguili.elsheikh@ouh.nhs.uk or telephone 01865 225230. Alternatively, you may contact the University of Oxford, Research Governance, Ethics and Assurance Team (RGEA office, at rgea.complaints@admin.ox.ac.uk

The Patient Advisory Liaison Service (PALS) is a confidential NHS service that can provide you with support for any complaints or queries you may have regarding the care you receive as an NHS patient. PALS is unable to provide information about this research study.

If you wish to contact the PALS team, please contact XXXXXXXXXXXX or alternatively you can email xxxxxxx (OTHER SITES TO ADD THEIR PALS EMAIL ADDRESS)

How have patients and the public been involved in this study?

Patients treated in the Oxford Pleural Unit helped develop the research topic and what research questions should be asked. A focus group of patients and carers were consulted about the design of the study and reviewed this participant information sheet. We have considered patient opinions on the frequency of hospital visits and the tests that we will carry out. Potential participants were involved in describing the inclusion and exclusion criteria for people taking part in this study.

If this is something that appeals to you, the following links provide general information about taking part in research:

- www.crn.nihr.ac.uk/can-help/patients-carers-public/how-to-take-part-in-a-study/
- www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx

Who is organising and funding the study?

The study is being sponsored by the University of Oxford and funded in full by a grant from the National Institute of Health Research as part of their Research for Patient Benefit Programme (NIHR RfBP grant). The chief investigator, Professor Najib Rahman, the sub-investigator Dr Alguili Elsheikh and other team members will regularly monitor the progress of the study in terms of both safety and benefits from the study treatment.

Who has reviewed the study?

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

Participation in future research:

Provided that you agree for us to do so, your personal details will be kept so that we may contact you regarding similar studies in the future. Agreeing to be contacted does not oblige you in any way to take part in future research.

Thank you very much for reading this information and for considering taking part in the RAPTOR f study.

Further information and contact details:

(Local Principal Investigator):

(Research Nurse):