Imperial College London

<<insert local Hospital Logo>>

PATIENT INFORMATION SHEET and INFORMED CONSENT FORM

Version and Date:	**Version 1.2, 16th September 2021**
Study Full Title:	**Treating Multiple Myeloma and Diffuse Large B Cell Lymphoma by Targeting the NF-κB Pathway with the First-in-Class GADD45β/MKK7 Inhibitor, DTP3**
Short Title:	**DTP3**
Protocol number:	**072021**
Study Sponsor:	**Imperial College London**
Funder:	**Medical Research Council**
Study Coordinating Centre:	**Imperial College London, Department of Immunology and Inflammation**

You are being invited to take part in a research study. Before you decide to do so, it is important for you 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. If there is anything that is not clear in this document, please let us know and we will answer your questions as best we can.
Thank you for taking the time to read this.

1. What is the purpose of the study?

The purpose of this study is to investigate a new drug called DTP3 in patients with multiple myeloma or diffuse large B cell lymphoma. This is a new drug and we wish to determine if it is effective in treating the disease and to decide on the safest dose level of the drug to use in the future.

2. Why have I been invited to participate?

You have been chosen because you have been diagnosed with multiple myeloma or diffuse large B cell lymphoma. Further, you have either not responded as well as your doctor would have hoped to your most recent therapy, or your disease has progressed since the last treatment. This means that your disease is now at a stage where there are fewer treatment options available to you and it may be appropriate to consider a clinical trial drug.

3. Do I have to take part?

Your decision on whether to take part is entirely voluntary, so it is up to you whether or not to take part. If you do decide to participate you will be given this information sheet to read and keep. You will be asked to sign a consent form (found on the last page of this document). If you decide to take part, you are still free to withdraw at any time and without giving a reason.

A decision to withdraw at any time or a decision not to take part, will not affect the standard of the care you receive.

4. Who is organising and funding the research?

This trial is being funded by the Medical Research Council (MRC), which is the country's largest publicly funded medical research organisation. The trial is being sponsored, that is being run by, Imperial College London.

Imperial College London will receive money from the MRC for undertaking this study. The sponsor of this study will pay the collaborating hospitals for their work involved in including you in this study. No members of the study team will receive a personal financial benefit from your involvement in this study other than their ordinary wages.

5. What is the drug or intervention that is being tested?

DTP3 is a new drug that has been developed for the treatment of multiple myeloma and diffuse large B cell lymphoma. DTP3 can cause the death of myeloma/lymphoma cells, but not the normal healthy cells in both laboratory and early human studies.

During a recent first-in-human trial in a small number of multiple myeloma patients, there were encouraging signs of clinical benefit from DTP3 and no significant side effects were experienced by participants This study will further expand on this investigation of the DTP3 drug.

6. What happens in this trial?

There are approximately 7 UK NHS centres, including your NHS centre, that will be involved in this clinical trial. Potentially eligible patients from these centres will be invited to take part. There are two parts to this trial.

The initial stage will involve the first patient being given the study drug (DTP3) at a particular starting dose. If this is well tolerated for one treatment cycle (4 weeks), the next patient will be dosed at the next higher dose. This will help the investigators determine what the optimal dose is most effective, whilst balancing potential side effects.

Once the optimal dose is known, the second part of the trial involves participants being given the study drug (DTP3) at this optimal dose.

Each participant would continue with ongoing treatment cycles of the study drug until either unacceptable side effects, progression of their myeloma or lymphoma, or until the study ends. We would also follow up survival status after your participation in the trial through your hospital/clinic, or otherwise your GP or nominated next of kin if you no longer attend the hospital.

At the end of this trial, we should know the optimal dose, potential side effects and how effective DTP3 is as a drug for treating cancer. This may lead on to further larger studies into DTP3 as a possible new treatment for multiple myeloma and/or diffuse large B cell lymphomas.

7. What does participation in this clinical trial involve?

If you agree to take part and sign the consent form, you will attend for a first visit, known as the Screening Visit.

At your Screening Visit, we will take a full medical history, information about previous and current medication, and perform a physical examination and an ECG (which is a recording of the heart's electrical activity). We will also carry out blood tests, urine test, a pregnancy test (where appropriate), and a bone marrow or tumour biopsy. We will also carry out standard imaging tests, such as a CT, MRI, or PET-CT scan, whichever is considered most appropriate by your doctor. These are all routine procedures used in the diagnosis and management of myeloma and lymphoma and you will have undergone most or all of them at some point in the past. These screening tests must be performed and the results available within 28 days of the start of study treatment.

After we have reviewed all the test results, we will confirm whether you are suitable for the study. If for some reason you are not able to take part, your doctor will explain the other treatment choices which are available to you. It is important for you to understand that undergoing the screening procedures does not guarantee you will be able to proceed in the clinical trial.

To then receive the drug, we will ask you to come into the hospital where you will receive DTP3 (the study drug) through a vein. The treatment will take one hour. If we find it difficult to find a suitable vein in your arm, we may need to insert a tube into one of the veins in your chest, which will then stay there for the duration of therapy. You may have had one of these tubes inserted earlier in your treatment course.

During the first two days of the first cycle of treatment, we would like to measure the level of DTP3 (the study drug) in your blood which will take place over the course of two days, periodically. Ideally this would involve an overnight stay in the hospital. If you can stay overnight after your first treatment, we will take a small amount of blood (equivalent to approximately 1 teaspoon of blood) on a number of occasions over the next two days. If you are unable to stay overnight, blood samples will still be taken from you on your first visit, but these would stop at the end of the first day, to allow you to return home. The first visit will therefore last either up to 32 hours if you stay overnight or up to 10 hours if you do not stay overnight. It is entirely your decision whether you wish to stay overnight. Whether you have blood samples taken overnight or not will make no difference to your participation in the study or how the drug works; the extra samples will give us more information as to how the drug is processed in the body.

You will then receive the drug at your hospital on 3 days in every 7, most likely a Monday, Wednesday and Friday, although we will provide you with more details of this. At each subsequent visit, you will undergo a blood test prior to receiving the study drug. Additionally, extra blood and urine tests, an ECG and blood pressure measurements will be made at specific scheduled visits. Some of these tests are taken to make sure the treatment is safe and others to better understand the effects of the drug in the body. We think that each visit you make to receive DTP3 treatment will last approximately 3 hours which will include time for observation after your treatment.

If you take part in the study, you will be asked to provide an additional bone marrow or tumour biopsy during the third week of your treatment, in which you would be asked to attend the day after your seventh dose, on a non-treatment day. Lymphoma participants may also be offered additional scans every couple of treatment cycles (every eight weeks) to evaluate response to treatment. Aside from these biopsies, which help us determine the effectiveness of your DTP3 treatment, you will only be asked to have another biopsy if we feel this is necessary as part of the normal clinical management of your disease.

Your treatment within the clinical trial will continue for as long as both you and we feel that you are still benefiting from the therapy. One treatment cycle is 4 weeks and you will continue to undergo treatment cycles as long as you do not experience unacceptable side-effects, worsening of your cancer, or until the study ends. We will subsequently follow-up your survival status after the trial through you medical records at the hospital, or otherwise your GP or nominated next of kin.

Additionally, as this is a new drug, we would provide you with a card (similar to a credit card) with details of the trial you would be taking part in which you can show to your other treating medical professionals. You should carry it at all times.

8. What will happen to any samples I give during the study?

By agreeing to take part in the study, we will be taking a little extra blood, bone marrow and/or biopsy tissue than we normally would if you were not participating in a clinical trial. However, you may decline to provide these samples and continue your participation in the study as normal. Some of these samples taken from you during the trial will be used to study proteins and genetic material present in your cells. This information will help us to find the best dose of DTP3 to use and perhaps to find tests that predicts how likely it is patients might respond to the drug. With your consent, your samples may also be stored securely for future research into multiple myeloma and lymphoma.

9. Coming off the trial before completion of treatment?

In some situations, you or your doctor may decide to stop the therapy. Some examples of reasons for this include:

- You may decide you no longer wish to take part in the study. If this occurs, we will perform a final assessment of the safety and effectiveness of DTP3 before you start any non-study treatment. Your doctor will then make arrangements for your care to continue.
- We may take you out of the study if you suffer from side effects on the drug. If this occurs, we will perform a final assessment of the safety and effectiveness of DTP3 before you start any non-study treatment.
- Persistent failure to attend your scheduled visits could result in removal from the study.
- If there is evidence of disease progression or symptomatic deterioration of your condition while you are on study treatment, you will be advised to come out of the trial.

If we are thinking of stopping your participation in the study, we will discuss the reasons for this with you and also talk to you about further treatment options. We may ask also you your permission to follow-up your survival status through your medical records at the hospital/clinic after you are withdrawn from study participation.

10. Will I be provided with any with any travel expenses for treatment visits?

As the treatment schedule requires frequent visits to your treatment centre, we will offer up to £20 per visit in reimbursement for your travel expenses. Please retain all your travel receipts and/or mileage records from each visit for reimbursement.

11. Are there any restrictions to follow during the trial?

You can continue your normal daily activities and take all your medication (except anti-cancer medicine or other experimental treatments) as normal.

However, there are a couple of potential lifestyle restrictions to consider if you decide to take part in this study:

- If you are sexually active and you could become pregnant, then you must use TWO types of contraception (eg. hormonal pill and condom or intrauterine device and condom) while you are on the trial and for 90 days after finishing treatment with DTP3.
- If you are a man and your partner could become pregnant then you must use a condom and spermicidal gel while you are on the trial and for 90 days after finishing treatment with DTP3.

This is to protect any child which may be conceived from any potential harmful effects of the study drug. If you do become pregnant during the study, we will withdraw you from the trial and discontinue DTP3. We would however need to follow you until you had your baby, in order to make sure that the pregnancy was normal.

We also request that you do not participate in any other drug studies during your time participating in this study.

12. What are the potential side effects of any assessment or treatment received when taking part?

The study drug DTP3 has been tested on 3 previous patients prior to this study and it was found that there were no significant side effects experienced. However, side effects may occur as we increase the dose as the investigators determine what the optimal dose is to be most effective at treating the cancer whilst balancing minimal side effects.

The drug has also been given to animals and was well tolerated.

To ensure the safety of all patients in the trial, an internal safety monitoring committee, consisting of all the doctors involved in the study and an independent expert will be regularly reviewing the patients throughout the study.

The routine procedures to take blood and tissue samples are invasive and carry additional risk. These can include bleeding, pain, infection and tissue injury at the local site. In very rare circumstances they can cause serious and life-threatening events, such as bleeding and injury to organs. You may decline to have these invasive tests and still continue with your study participation. Please speak to your study doctor is you have any concerns about these study procedures.

You may experience some soreness or bruising around the site where the drug is administered after each treatment course, similar to other treatments administered through the vein that you may have previously had. If at any point on the study, you become concerned that you are suffering from a side effect of the drug, please contact your study doctor (see contact details on later page) and/or report it next time you meet.

You should not experience any side effects from having the imaging tests, but you may feel some discomfort from having to stay still until the scan is complete. This may take up to 60 minutes. If you are having a PET scan, you may feel some discomfort from having a tracer injected into your vein. The tracer is a harmless solution which is injected into your vein and allows the doctors to see the cancer in your body. If you are having a biopsy, it may be guided by images such as ultrasound.

If you take part in this study you will have either a CT, MRI or PET-CT exams. If you are in the cohort with diffuse large B cell lymphoma you will also have follow up PET-CT scans. All of these are part of your routine care. If you take part in this study you will not undergo any additional x-ray or nuclear medicine exams. These procedures use ionising radiation to form images of your body and provide your doctor with other clinical information. Ionising radiation may cause cancer many years or decades after the exposure. The chances of this happening to you are the same whether you take part in this study or not.

13. What are the possible disadvantages and risks of taking part?

As this drug has not yet been extensively tested in large scale clinical trials, some side effects may be unknown.

To start with, we do not know what dose level will be the best to use. This could be a high dose or it could be a low dose, which is why the study is examining a wide range of doses. If you enter the study as part of the first group of patients, you could receive a low dose of study drug. Although it is possible that the drug will work, even at the lowest doses being studied, it is more likely that it will work better at higher doses. If you are allocated to a low dose of study drug, it is therefore possible that it might be less effective than if you had entered the study later and been given a higher dose, but we can't know this for sure. However, your study doctor also has the option to slowly increase the dose of DTP3 that you start off with, if he/she believes it would be appropriate to do this. Your study doctor will discuss this with you after you have completed the first 4 weeks of DTP3 treatment.

It is possible that if the treatment is given to a pregnant woman it could harm the unborn child. Therefore, pregnant women should not take part in this study; neither should women who plan to become pregnant during the study. Women who are at risk of pregnancy may be asked to have a pregnancy test before taking part to exclude the possibility of pregnancy. Woman who could become pregnant should use two types of contraception during the period of the study and for 90 days after ceasing treatment with DTP3. Any woman who finds that she has become pregnant while taking part in the trial should immediately tell the study doctor.

It is also possible that the treatment could damage the sperm. For this reason we ask that men in the study use barrier methods of contraception (a condom plus spermicidal gel) during the study and for 90 days after ceasing treatment with DTP3 if there is any possibility that their partner might become pregnant.

If you have any private medical or health insurance, please check with your provider if participation in this study will affect your cover.

14. What are the possible benefits of taking part?

We do not know if DTP3 will be effective in myeloma or lymphoma which is why we are doing this study. It is possible that the study drug will help your condition, but we cannot give you any assurance that it will do so. Information from the trial could also potentially help towards treating patients with myeloma, lymphoma, or other cancersn the future.

15. What are the alternatives for treatment?

Unfortunately, as you have not responded as well as your doctor would have hoped to your most recent therapy or your disease has progressed since the last treatment, your cancer is now at a stage where there are fewer treatment options available to you. A clinical trial may offer new advanced treatments and drugs that are otherwise not otherwise available yet. However, you may wish to discuss other treatment options with your doctor.

16. What if new information becomes available during the trial?

Sometimes during the course of a research project, new information becomes available about the treatment or drug that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw, your study doctor will make arrangements for your care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form.

17. What will happen to the results of the research study?

Once the study results are known, a written plain-English summary of the results of the study will be shared with the site teams for them to discuss with you. The results of this study will also be provided to the Medical Research Council who are funding this trial and to the health regulatory authorities in the UK as is required for all clinical trials. A summary of the results will also be published on clinical trials.gov.uk. It is anticipated that the results of this study will be published and/or presented at professional meetings. It is also expected that results may be presented at Medical Conferences and published in Medical Journals. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

18. What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial College, Research Governance and Integrity Team

19. What will happen to information about me?

By signing the Consent Form you consent to your study doctor and study staff at <<insert site>> collecting and using personal information about you for the study. Your study team will keep your personal details such as you name, NHS number and contact details confidential and will not pass this information to the Sponsor organisation. Your study team will use this information as needed, to contact you about the study, to make sure that relevant information about the study is recorded for your care and to oversee the quality of the study.

Your GP will be notified of your participation in the trial and we will ask for your consent to inform them. We may need to use information from your medical records and your GP for this research project. This information will include your NHS number, name, contact details. It is possible that tests performed as part of this study might identify an undiagnosed health condition (known as an 'Incidental finding'). If this occurs, your doctor will endeavour to inform you as soon as possible and discuss the options available. Your GP would be kept informed of your ongoing care on the trial, including any incidental findings unless you object to this and communicate your objection to your study doctor.

The Sponsor (Imperial College London) will only receive information without any identifying information. However, the sponsor has appointed a Monitor, who is responsible for ensuring that:

i) the rights and well-being of participants is protected,
ii) the trial data is accurate, complete and verifiable, and
iii) that the trial is conducted according to the protocol and applicable regulatory and quality standards (Good Clinical Practice).

In order to fulfil these responsibilities, the monitor will need to review your personal information which is collected as part of this trial. They will visit the research site to access original records when required, which will contain your full name and other identifying information, but your identifying information will not be taken away from the research site.

Scanned records may also be sent to the monitor via email, but these will be labelled with your study number, with personal information such as your name and address removed. The monitor is employed by the NHS and subject to the same duty of confidence as your doctor and other NHS staff. Information will be sent via NHS Mail, which is the secure email service used across the NHS for transferring patient information securely. The sponsor or your local research site might also audit the study to check it is being conducted properly, and it can be inspected by the Medicines and Healthcare Products Regulatory Agency (MHRA). Any monitors, auditors or inspectors who access personal information must adhere to all applicable UK Data Protection Regulations.

Your study information will be coded to a unique ID number, and entered electronically in a highly secure study database within the UK, by SQN Clinical. The research team who analyses the study data will not be able to identify you and will not be able to find out your name, address or date of birth. Your information will be used only for the purpose of this study and future ethically approved research studies. Your information would only be disclosed with your permission, except as required by law. Apart from your GP, study doctor and study team, only the Monitor or an authorised Auditor or Inspector would be able to link the code number to you personally.

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. Your study data, including your personal data stored at the site, will be kept for at least 10 years, after which it will be securely destroyed.

20. How will we use information about you?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from you, your medical records and your GP for this research project.

This information will include your initials, NHS number, Hospital number, name and contact details. 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.

Legal Basis

As a university, we use personally identifiable information to conduct research to improve health, care and services. As a publicly funded organisation, we have to ensure that it is in the public interest when we use personally identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study. Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the UK Policy Framework for Health and Social Care Research.

International Transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (**EC**) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that

incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing information with others

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain limited third parties. This includes other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

We will be working with other research collaborators and partners in this study, which include other NHS hospitals, Covance (laboratory) and a Data Management Company (SQN clinical). Your personal data such as name, contact details, NHS number will not be sent to our research partners. Instead, the data we collect about you for the clinical trial will be linked to your study ID. Our research partners will help us analyse the results of the clinical trial and will have access to relevant pseudonymised (linked to your study ID) data. Government agencies such as the MHRA, may wish to conduct an inspection of this study and would require access to patient personal data during an inspection or audit. This would only be to check the study has been taking place as it should be, in line with the relevant laws, guidelines and procedures.

What are your choices about how the information is being 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. If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital/clinic. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. In accordance with relevant data protection legislation, you have the right to request access to your information collected and stored by the study team. However you won't be able to change or delete the data we hold about you, but you have the right to request that any incorrect information be corrected.

If you agree to take part in this study, you may have the option to take part in future research using your data or samples saved from this study.

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/, or by asking your study doctor.

21. Data Complaints

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via

telephone on 020 7594 3502, or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial College) first before involving the regulator.

22. Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the UK NHS by London Bridge Research Ethics Committee.

23. Who to contact for further information?

If you want any further information concerning this study or if you have any medical problems which may be related to your involvement in the study (for example, any side effects), you can contact the following study contacts:

The Project Trial team from Imperial College London can be contacted on:

Name:	Dr Holger Auner	<<insert>>
Position:	Chief Investigator	Project Manager
Telephone:	<<Telephone>>	<<Telephone>>
Email:	<<Email>>	<<Email>>

Your local site research team, <<insert name>>, can be contacted on:

Name:	<<Site PI>>	<<Site Coordinator/RN>>
Position:	<<position>>	<<position>>
Telephone:	<<Telephone>>	<<Telephone>>
Email:	<<Email>>	<<Email>>

You can also contact the **emergency 24-hour contact number, <<xx>>,** with any urgent medical problems.

Thank you for taking the time to read this

Imperial College London

<<insert local Hospital Logo>>

INFORMED CONSENT FORM

Full Title of Project:	Treating Multiple Myeloma and Diffuse Large B Cell Lymphoma by Targeting the NF-κB Pathway with the First-in-Class GADD45β/MKK7 Inhibitor, DTP3
Study Protocol Number:	072021
EudraCT number:	2021-004028-13
Site Name:	<<insert>>
Centre Number:	<<insert>>
Principal Investigator:	<<insert>>

Participant Study ID: _____

Please initial each box (do not tick/cross)

1.	I confirm that I have read and understand the Participant Information Sheet dated..... version ..... for the above study and have had the opportunity to ask questions which have been answered fully.	☐
2.	I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason and without my medical care or legal rights being affected.	☐
3.	I understand the purposes, procedures and risks of the study described in the Participant Information Sheet.	☐
4.	I understand that sections of any of my medical notes may be looked at by responsible individuals from Imperial College London (eg. the Study Monitor), from the NHS Trust or from regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research.	☐
5.	I agree to my GP being informed of my participation in the study.	☐
6.	I consent to the intervention of new study drug, DTP3, as detailed in the Participant Information Sheet.	☐
7.	I consent to providing biological samples (blood, bone marrow and/or tumour) to be collected for this study and to be used for laboratory and genetic testing during the study.	☐
8.	I consent to being followed up for the purpose of survival status only after my participation in the trial, through my hospital record, or alternatively through my GP or nominated next of kin.	☐
9.	I understand that the information collected about me will be used to support other research in the future and may be shared as de-identified data, with other researchers.	☐
10.	I agree to take part in the above study.	☐

Continues on next page

***Optional*: you may opt out of the following and still take part in the study:**

11.	I am to happy to consider an overnight stay in hospital after my first dose of DTP3 treatment to provide additional blood samples which will provide more information as to how the drug is processed in my body. I am aware I may change my mind at any point and alternatively go home after the first infusion, without any impact on my participation in the trial (optional).	☐
12.	I consent to my biological samples (blood, bone marrow and/or tumour) collected for this study that remain after this study, to be stored and used in future research, including those outside of the EEA (optional).	☐
13.	I consent to being contacted for potentially taking part in other future research studies, including those outside of the EEA (optional).	☐

_____	_____	_____
Name of Participant	**Signature**	**Date**
_____	_____	_____
Name of Person taking consent	**Signature**	**Date**

(Original for Site File; 1 copy to be kept with hospital notes; 1 copy for participant)