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Royal Papworth Hospital NHS Foundation Trust

Papworth Road

Cambridge Biomedical Campus

Cambridge

CB2 0AY

Tel: 01223 638000

**PATIENT INFORMATION SHEET**

**<ENTER TITLE TO MATCH PROTOCOL>**

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it will involve. ***One of our team will go through the information sheet with you and answer any questions you have.*** Feel free to discuss it with others if you wish. Ask us if there is anything that is not clear or if you want more information. Please take your time to read the following information carefully and decide if you wish to participate.

**1. What is the purpose of the study?**

*[Explain why you are doing the study. Purpose is an important consideration for subjects, and we*

*recommend that you describe the purpose of your study, clearly and succinctly, in the brief context of other work in your field. It is entirely reasonable for projects to be primarily educational. This purpose should be made clear. Remember the aim of a patient information sheet is to provide sufficient information, in an understandable format to support potential participants in making the right decision about agreeing or declining to participate in your study. Potential participants should be given very brief information about your Study: just enough to decide if they wish to read further.]*

**2. Why have I been invited?**

You have been invited to take part in our study because ……

*[You should explain briefly why and how (particularly if the approach is not by the health care worker) the participant was chosen or recruited and how many others will be in the study.]*

**3. Do I have to take part?**

No. Your participation in this study is entirely voluntary and you are under no pressure to take part.

If you do decide to take part we will be ask you to sign a consent form. If you later change your mind, you are free to withdraw from the study at any time without having to explain why.

If you do not wish to take part in this study, the standard of care that you receive will not be

affected.

**4. What will happen to me if I take part?**

*[Describe everything from being given this information sheet to final follow up visit – try to put*

*yourself in the patient’s shoes. It should be clear which procedures are over and above those*

*involved in standard diagnosis, treatment or management. It is also essential to explain whether*

*any normal treatment will be withheld for all or part of the study.*

*This section should include:*

 *how long the participant will be involved in the research;*

 *how long the research will last (if this is different);*

 *if and how often they will need to meet a researcher, visit a clinic or their GP;*

 *how long these visits will be;*

 *what exactly will happen e.g. access to personal information/samples questionnaire, interview,*

*discussion group, measurement, sample collection, blood tests, x-rays, etc;*

 *You should set out simply the research methods you intend to use (e.g. randomised controlled*

*trial, cross-over design, blinding etc).*

*Use the most appropriate format (tables, diagrams, photos etc). The detail required will depend on the complexity of the study. It may help if the information is displayed in a simple flowchart or grid indicating what will happen at each visit rather than lengthy lists in the text. Long-term monitoring/follow-up should be mentioned.*

*You should inform the participant if your study will involve video/audio-taping or photography.*

*Specific consent will be needed if published material identifies the subject.]*

**5. Expenses and payments**

*[You should explain if expenses (e.g. travel, meals, child-care, compensation for loss of earnings,*

*etc.) are available.]*

**6. What will I have to do?**

*[Set down briefly and clearly what you will expect of your research subjects. For medical studies*

*you should include a short description of the drug, device or procedure and give the stage of*

*development. Explain (if appropriate) that the participants should take the study medication*

*regularly as directed and whether they can continue to take their regular medication or other*

*prescribed or over-the-counter drugs. It should also be explained that they will need to consider*

*whether they should participate if they are in other drug studies, or have been in the recent past*

*(specify how long). Explain other essential study requirements, e.g. attendance at all scheduled*

*visits, keeping diaries, filling questionnaires, etc. Any lifestyle, medical health product or dietary*

*restrictions, impacts on possible pregnancy and breast feeding and specific contraception requirements should be stated.]*

**7. What are the alternatives for diagnosis and treatment?**

*[You should explain other possible treatments in routine clinical practice and, if available, in therapeutic research, with the important comparative risks and benefits (check on local variations in alternative treatments, which may need to be reflected in the information given to the REC for approval).]*

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

*[Risk of the disease/condition/illness and the risk of research should be carefully separated. Below we consider the risk of participation itself.*

*Any risks, discomfort or inconvenience should be outlined. However, explanation of risk is difficult*

*and researchers should consider carefully how to explain any risk in their study. The published*

*literature should be consulted and material presented to likely participant groups to assess its*

*value. Try to describe the likelihood of adverse things happening, as well as severity in language all potential participants are likely to understand.*

*Consider insurance issues e.g. health, life and vehicle insurance and whether patients should be informed that their participation may affect insurance cover. It might be prudent to advise participants to check with their insurance providers for advice.*

*Impact on possible pregnancy and breast feeding, including young people and pregnancy should be stated.*

 *If possible, the potential participant should be told what would happen if other conditions were discovered of which he or she was unaware.*

*Include risks regarding ionising radiation*

*The risks associated with genetic studies are very variable. Research design, information and*

*information sheets therefore need to recognise public concern yet be commensurate. Expert*

*advice should be sought. For gene therapy follow guidance from the Gene Therapy Advisory*

*Committee (http://www.advisorybodies.doh.gov.uk/genetics/gtac). For a genetic sub-study to a*

*main study, the participant should be able to refuse participation in the genetic sub-study but still*

*take part in the main study.*

*For any drug or procedure you should explain the possible side effects. For any new drug it should be explained that there might be unknown side effects. Side effects should be listed in terms the participant will clearly understand (e.g. “damage to the heart” rather than “cardiotoxicity”;“abnormalities of liver tests” rather than “raised liver enzymes”).*

*The information should be prioritised in terms of seriousness, severity and frequency, with a*

*simple example of frequency, which a participant would understand. It should reflect what a*

*reasonable person would expect to be mentioned (i.e. rare side effects are relevant if they may be serious or permanent). The level of detail should also be influenced by the expected benefit from the treatment and the underlying prognosis of the condition. For a very new or very potent*

*investigational drug, a fuller list of suspected side-effects may be appropriate.*

***If participants suffer these or any other symptoms they should be given clear guidance on***

***when, how and to whom to report them. Contact numbers should be given clearly and***

***boldly.****]*

**9. What are the possible benefits of taking part?**

*[Explain these, but where there is no intended clinical benefit, this should be stated clearly.* ***It is***

***important not to exaggerate the possible benefits.*** *It is likely that you cannot guarantee any specific treatment benefits, and this should be made clear to potential participants. However, research does deliver wider benefits to society / others with a similar condition and some indirect benefits might be foreseeable for participants themselves]*

E.g.: We cannot promise the study will help you but the information we get from this study will help improve the treatment of people with [name of condition].

*[Separation of risks, benefits and purpose of the study may sometimes lead to a loss of clarity*

*about the balance of risk and benefit. In such cases risks and benefits should be sensibly linked.]*

**10. What happens when the research study stops?**

*[The arrangements after a therapeutic trial must be given, particularly if this differs from that*

*normally expected for their medical condition. It must be clear whether the participant will have*

*continued access to any benefits or intervention they may have obtained during the research. If*

*the treatment will not be available after the research finishes, this should be explained to the*

*participant with information on what treatment will be available instead. You should consider*

*whether and when it may be possible to tell participants which arm of the study they were in.]*

**11. What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied. If this happens, your

research doctor will tell you and discuss whether you should continue in the study. If you decide

not to carry on, your research doctor will make arrangements for your care to continue. If you

decide to continue in the study he may ask you to sign an agreement outlining the discussion

(delete if not appropriate). If the study is stopped for any other reason, we will tell you and arrange your continuing care.

**12. What will happen if I don’t want to carry on with the study?**

You can withdraw from the study at any time. *[Add study specific details explaining what will*

*happen to samples or data that have been collected.]*

**13. What if there is a problem?**

If you are concerned about any aspect of this study you should ask to speak to one of the researchers (contact details below) who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS) (contact details below*).*

If something goes wrong and you are harmed during the study due to someone’s negligence then you may have grounds for a legal action for compensation against the hospital involved, but you may have to pay your legal costs. The normal NHS complaints mechanisms will still be available to you.

NHS hospitals are unable to agree in advance to pay compensation for non-negligent harm

(situations where no one can be blamed for what happened). However, NHS Trusts are able to

consider offering an ex-gratia payment in the case of a claim.

**14. How will we use information about you?**

We will need to use information from *[you] [from your medical records] [your GP] [OTHER]* for this research project.

This information will include your *[initials/ NHS number/ name/ contact details/* ***provide a bullet list of identifiers held by site and/or sponsor for the research****].* People will use this information to do the research or to check your records to make sure that the research is being done properly.

***OPTION where applicable:*** 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.

***OPTION if not already stated:*** *[insert name of sponsor*] is the sponsor of this research and is responsible for looking after your information. We will keep all information about you safe and secure by:

* Limiting access to your personal data to those staff that need it to be able to perform their job or undertake this research study.
* Making sure that your data is stored in a location which is either physically and/or electronically secure e.g. in a locked filing cabinet in a location with controlled access or in an encrypted database that is password protected.

**International transfers**

***[IF NO TRANSFERS OUT OF UK WILL OCCUR***] Your data will not be shared outside the UK.

**OR**

[*IF TRANSFERS OUT OF UK WILL OCCUR, WHICH IF IT REMAINS A POSSIBILITY E.G. IN THE FUTURE – INCLUDING SHARING IN DE-IDENTIFIED FORM WITH OTHER RESEARCHERS - SHOULD BE INCLUDED AND ABOVE DELETED*]

We may share data about you outside the UK for research related purposes to:

***In bullet points, concisely list the reasons why you will send data out of the UK***

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:

* [*insert list e.g. our partners who analyse your data, companies to pay your expenses, organisations who store your data*]

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 [*DELETE AS APPLICABLE*]:

* (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](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/)
* 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](https://ico.org.uk/for-organisations/report-a-breach)
* [*OTHER*]

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.

***DELETE one option in square brackets:*** We will keep your study data for the minimum period of time required by [*state the conditions that will be used to determine this time period*] **OR** [we will keep your study data for a maximum of **XX** years]. The study data will then be fully anonymized and securely archived or destroyed.

**15. 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.
* ***OPTION if follow up data will be collected after withdrawal:*** If you choose to stop taking part in the study, we would like to continue collecting information about your health from *[central NHS records/ your hospital/ your GP].* If you do not want this to happen, tell us and we will stop.
* 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.
* ***OPTION if data will be used for future research:*** 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. *[Insert details of any specific bank/ repository].*

**16. Where can you find out more about how your information is used?**

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.

* our leaflet [X]
* by asking one of the research team
* by sending an email to [email], or
* by ringing us on 01223 638000 and ask for the Information Governance Manager
* **OPTION if the sponsor has appointed a UK representative:** By contacting our UK representative at [**provide name and contact details of the UK representative**]

For [X] sponsors can either provide the HRA link: [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch) or if this is available on sponsor website, the sponsor may choose to include their own website link.

**17. Will my taking part in this study be kept confidential?**

***Please delete any section marked with an asterisk if not applicable.***

**Royal Papworth Hospital NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from [you and/or your medical records] in order to undertake 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. Royal Papworth Hospital NHS Foundation Trust will keep identifiable information about you [for x years after the study has finished/ until x].**

**Your rights to access, change or move your information is 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. To safeguard your rights, we will use the minimum personally-identifiable information as possible.**

**You can find out more about how we use your information [at URL and/or by contacting XXX].**

**\* <<*Where participants are providing personal data directly ie personal data is obtained for the primary purpose of research either verbally or in writing from participants eg questionnaires or interviews, or documented by care staff eg diagnosis, or obtained from care interventions eg lab results, please include the below sentence and either point 1 or point 2 (delete as applicable)>>:***

*\*[NHS/other site] will collect information from [you and/or your medical records] for this research study in accordance with our instructions.*

*EITHER:*

*\*1 [If a code system is used and the key is kept confidential and not disclosed to the sponsor, except where the sponsor is also the site]*

*[NHS/other site] will keep your name, [NHS number] and contact details [add other identifiers] confidential and will not pass this information to [sponsor organisation]. [NHS/other site] will use this information as needed, 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. Certain individuals from [sponsor organisation] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [Sponsor organisation] will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, [NHS number] or contact details.*

*[NHS/ other site] will keep identifiable information about you from this study [for x years after the study has finished/ until x].*

*OR*

*\*2 [If the sponsor will receive personal data, or where the sponsor is also the site]*

*[NHS/other site] will use your name, [NHS number] and contact details [add other identifiers] 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. Individuals from [sponsor organisation] and regulatory organisations may look at your medical and research records to check the accuracy of the research study. [NHS site] will pass these details to [Sponsor organisation] along with the information collected from [you and/or your medical records]. The only people in [sponsor organisation] who will have access to information that identifies you will be people who need to contact you to [insert reason] or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, [NHS number] or contact details.*

*[NHS/ other site] will keep identifiable information about you from this study [for x years after the study has finished/ until x].*

***\*<<Where participants are providing information indirectly eg being obtained from previously collected medical records or database, please include either point 3 or point 4 below (delete both if not applicable)>>:***

*EITHER*

*\*3 [If a code system is used and the key is kept confidential and not disclosed to the sponsor]*

*[Sponsor organisation] will collect information about you for [research/ this research study] from [source]. [Source] will not provide any identifying information about you to [sponsor organisation]. We will use this information to [purpose].*

*OR*

*\*4 [If the sponsor will receive personal data]*

 *[Sponsor organisation] will collect information about you for [research/ this research study] from [source]. This information will include [your name/ NHS number/ contact details/ add other identifiers] and health information, which is regarded as a special category of information. We will use this information to [purpose].*

***\*<<Where data is intended to or likely to be used for future research, please include the below statement and either point 5 OR point 6 (delete both if not applicable)>>:***

*\*When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.*

*EITHER:*

*\*5 This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.*

*OR:*

*\*6 Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government.*

*Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.*

*Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.*

**18. Involvement of the General Practitioner**

*[You should explain if the patient’s GP (or other health care practitioner) will be notified of their participation and seek consent. Explain what information will be exchanged.]*

**19. What will happen to any samples I give (where applicable)**

 *[The same type of information, as for data, is needed. This should include:*

 *the secure procedures for collecting, using and storing samples;*

 *any possible intended use in the future for research that cannot yet be specified. A separated or*

*two part consent form is recommended if future use is intended, and it should be clear if further*

*REC approval will be sought;*

 *who will have access;*

 *the level of identifiability (for this study and for storage for future studies);*

 *provision for destruction;*

 *procedures for possible feedback of individually significant information from their use;*

 *Whether samples will be transferred outside the UK.*

***If there is any possibility that samples may be used in future research, we strongly advise***

***prospective consent is obtained.]***

***OPTION if future use of samples will be included as an optional consent point:*** Biological samples given as a donation for future use will not use your name and you cannot be identified (anonymised). With your permission, we will continue to securely store any remaining samples and your anonymised clinical data at *[add repository name]* for use in approved related research studies. Samples may be shared with other external researchers including commercial researchers and researchers based outside the UK.

***OPTION if future use of samples will include any genetic analysis:*** Some research studies may also obtain information from your donated biological samples by reading (sequencing) your DNA or RNA – your genetic code. Your genetic information defines you and genetic differences in people can help researchers to diagnose or treat diseases in the future. This may include studies which will ‘sequence’ part or whole of the genome (your entire genetic information). Only fully anonymised samples with relevant anonymised clinical data will be released to researchers and their findings cannot be linked back to you or your clinician.

**20. What will happen to the results of the research study?**

*[The results could be separated into “broad scientific results of a trial” and “results with relevance to the individual”. Consider both as appropriate but they may need different management.*

*You should tell the patients what will happen to the results of the research, whether it is intended to publish the results and how the results will be made available to participants. You should add that they will not be identified in any report/publication unless they have given their consent.]*

**21. Who is organising and funding the research?**

*Add details*

Another section to explain if patients and the public have been involved in design of study?

**22. Who has reviewed the study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics

Committee, to protect your interests. The study was reviewed by the XXXX Research Ethics

Committee and the Research and Development Department at Royal Papworth Hospital NHS

Foundation Trust.

**23. Further information and contact details**

For further information, you can speak to one of the study team:

*[Include details of CI/PI, research nurse/Clinical Trial Coordinator. For some studies an emergency contact number which will be manned out of hours should be provided. In a multi-site trial, the numbers must be appropriate for each site.]*

Alternatively, you can speak to an independent contact:

Patient Advice and Liaison Service (PALS)

Royal Papworth Hospital NHS Foundation Trust

Papworth Road

Cambridge Biomedical Campus

Cambridge

CB2 0AY

Phone: 01223 638896

Email papworth.PALS@nhs.net

***Thank you for considering taking part in this study.***

***If you decide to participate you will be asked to sign a consent form and will be given a***

***copy of this information sheet and the consent form to keep.***



Royal Papworth Hospital NHS Foundation Trust

Papworth Road

Cambridge Biomedical Campus

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CB2 0AY

Tel: 01223 638000

Centre Number: *If applicable*

Study Number: P0XXXX

Patient Identification Number:

**CONSENT FORM**

Version XX, dated XX

**Study title: ADD to match protocol and patient information sheet**

Study IRAS ID:

**Local Investigator:** *XXXXX*

 **Please initial box**

1. I confirm that I have read and understood the information sheet dated XX

(version XX) for the above study. I have had the opportunity to consider the information,

ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time

without giving any reason, without my medical care or legal rights being affected.

3. I understand that relevant sections of my medical notes and data collected during

the study may be looked at by individuals from [*company name*], from regulatory

authorities or from the NHS Trust, where it is relevant to my taking part in this research.

I give permission for these individuals to have access to my records.

4. I agree to my GP being informed of my participation in the study. [*If applicable*]

5. I agree to take part in the above study.

**OPTIONAL: *[Include optional consents below as appropriate to the study]***

6. I consent for my data to be used for further research in accordance with the UK Policy Framework for Health and Social Care Research.

**Please INITIAL one box**

NO

YES

7. I give consent for my samples and the associated anonymised data to be used in future research studies. I understand samples may be shared with commercial or overseas researchers and that I will not benefit financially if this research leads to new medical tests, treatments or inventions.

**Please INITIAL one box**

NO

YES

8. I give permission for DNA/RNA to be extracted from my donated material for use in genetic/genome research and for the anonymised results of this research to be published.

**Please INITIAL one box**

NO

YES

Name of Patient (PRINT) Date Signature

Name of person taking consent (PRINT) Date Signature

When completed: 1 for participant; 1 (original) for researcher Site File; 1 to be kept in medical notes.