Parent/Guardian Information sheet

Title of the project:

Name of PI:

**Introduction.**

You and your child are being invited to take part in the following research study (***insert name here***) because: (***insert reason here***)

The research is supported by (***insert funder here***) and is taking place (***insert single NHS site or nationally or internationally***)

Before you decide whether to take part, it is important that you 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.

**What are we researching and why are we doing this?**

Give a lay summary of your research here.

* What are you proposing
* Why are you doing this research
* what is already known

**Why have I and my child been asked to take part?**

***Explanation why the person approached meets the inclusion/exclusion criteria:*** Your child has been asked to take part because they have or don’t have the following conditions and meet the following criteria.

**What would taking part involve? /**

Synopsis of the research protocol as it applies to the participant, procedures involved in participation/including data and sample collection, how many and how much samples, what will happen to them.

*Who owns the samples my child gives?*

If you and your child give consent to be part of this study and samples are taken. The samples are considered a donation or a gift from you to research, and (***insert here – the research group***) is responsible for the safekeeping, and appropriate use of the samples. The research sponsor will own all the results from this project and will control who has access to it.

**Voluntariness of research and potential to withdraw**

It is up to you if you and your child takes part in this study. If you agree to take part, we will then ask you to sign a consent form. If your child is able to understand the research and is happy to take part and can write their name, they will be asked to sign an assent form with you, if they want to. If you decide not to take part in this study or to withdraw at a later date it will not affect your child’s present or future treatment in any way, and you do not have to say why. You are free to withdraw at any time, without giving a reason and without affecting your child’s medical care. As the data and samples generated during the study analysis are anonymous, we would not be able to remove any data or results of analyses that we had already processed prior to the time of your child’s withdrawal. However no further samples would be taken, and you can request that any unused samples be destroyed.

**Benefits of taking part**

There may be no immediate benefit to your child from taking part in this study, but our research will help us and doctors to understand more about the condition (***insert here***) which will help the development of new treatments and help more children with this condition in the future.

***If you are potentially giving back data***: Also, there is a small possibility that we might find out more information related to your child’s specific condition. You will have the option whether any potential results are given to you. This may be of benefit to your child’s medical care. As this is a research study rather than an approved clinical “diagnostic” test, we would first check our findings on extra samples, and then repeat these studies in a clinical laboratory. The importance or implications of our research findings may not be known for some time, or clinical tests may not be readily available. It is very important to realize that our results are research findings and are not a clinical test.

**Potential disadvantages and risks of taking part**

This project has been given favourable opinion by an independent Research Ethics Committee who believes that it is of minimal risk to you and your child. No significant physical risk can be foreseen. Any samples will be taken at the same time as routine clinical tests. The discomfort of having a blood (***or insert other test***) sample taken will be no more than that incurred by having tests for medical care.

Informational risks: Some people are worried about being identified as being part of research. The chance is small and we will do everything we can to prevent this happening.

**Who will have access to my samples and data?**

Only the researchers working on this study will have access to the data collected during the study. If you agree appropriate sections of your child’s medical notes may be looked at by the research team who are supervised by (***Insert PI name here***) where it is relevant to this research.

All information that is collected about your child during the course of the research will be kept strictly confidential and in compliance with the General Data Protection Regulation 2018. All data and samples will be anonymised, this means they will be labelled with a code, not your child’s name or other identifier. All of the research – paper and electronic – records will be stored securely, according to national standards. Data will be kept for the duration of the study and for future ethically approved studies if agreed to. ***Further explanation to be tailored here to how the data is transferred, where it is stored, and how it will be destroyed.***

**Will data be shared with other researchers and from where?**

A lot of research can happen faster when scientists and doctors from around the world work together. Your child’s data may be shared with other approved researchers from other universities and hospitals based in the UK, Europe and Internationally for scientific and healthcare purposes if agreed to. All data will be shared in a way that means your child is not able to be identified. They will have to request access to the data first, and this will be assessed for appropriateness. Only those who are approved will have access to the data which answers their specific questions.

**Will genetic testing be done?**

***If yes:***

Yes, researchers will be examining genetic aspects of (***this disease***) so DNA will be stored and analysed.

***Insert information here about the genetic testing happening in this study. Do you know which genes will be tested, are you doing whole genome sequencing, gene panels etc.***

**Will information from the genetic testing be returned to us?**

*Please note: Unless there is the resources and access to genetic counselling as part of the research, results from genetic testing including incidental and secondary findings are not recommended to be returned to the participants and their families.*

*Additionally a lot of this section will need to be tailored to the study and the details of it.*

Yes, by participating in the study, your child and the rest of your family may be informed about the genetic abnormalities that may have caused this disease. If you would prefer not to know the results of any of our investigations then that is your choice.As this is a research study rather than an approved clinical “diagnostic” test, we would first check our findings on extra samples, and then repeat these studies in a clinical laboratory that undertakes genetic tests, if this is possible. The importance or implications of our research findings may not be known for some time, or clinical tests may not be readily available. It is very important to realize that our results are research findings and are not a clinical test.

Your child’s clinician, and the research team, will update you regarding the results of the genetic testing. This will be done by ***(insert method of disclosing results here – letter, face to face, with or without genetic counselling***). It is also possible that no results may be found. However we will continue to look as new information is discovered so you may receive results in the future.

The genetic results (***will aid your child’s medical team to provide the best available treatment now and in the case your child’s disease returns after treatment. Additionally, because these genetic abnormalities can run in families, your immediate family members will also have the opportunity to be tested, if your doctors think that the problem might be inherited – insert as is applicable to your research).***

We will not be looking for other findings, only those that may be connected to your child’s disease. We will not be able to give you information about risk of other diseases.

**Your child’s data may be stored in an open access database.**

***This section only needs to be inserted if applicable, for example using the European Phenome-Genome archive.***

Samples may be sent to external laboratories for analysis. Only approved laboratories and researchers will analyse your samples. Samples may be kept as there may be new ways to of doing testing in the future and the results will be held in a secure database.

When this testing occurs coded data may be placed in international archives (***expand on this if it is occurring***). This data will be completely unconnected to your child’s name or other identifiable data and stored for an indefinite period of time. Access to this anonymised information will only be given to bona fide researchers around the world who will use the information for good scientific reasons and if you agree. Access to the anonymised information stored in this archive will only be accepted via applications from appropriately qualified researchers who sign a legally-binding Data Access Agreement in which they commit to:

a) Use the data only for research purposes;

b) Protect the data confidentiality;

c) Provide appropriate data security;

d) Not attempt to identify individual participants from whom data were obtained;

e) Not redistribute the data or any subset or derivative that could be used to identify the research participant.

For the anonymous genetic information data to be useful to the research community, some information about your child and their medical problem/treatment such as age, sex, medical condition will be linked to this. There is a remote possibility that your child could be identified by looking at genetic information, but only if this information is matched to other genetic data held in databases which also store personal, identifiable data. We regard this event as extremely unlikely, but it is important that you are aware of this risk.

**Will my child’s data be shared with commercial industry?**

The samples and data collected as part of this research may be shared with approved commercial (for profit) organisations if you agree. The research shared will be de identified, so no one will be able to tell the data is from your child and your personal information will remain safe and confidential with the research team.

You or your child will not benefit financially if a product or test as a result of this research is does lead to the successful development of a new medical treatment or test.

**What will be done with the results of this study?**

Results from this study may be published in peer reviewed scientific and medical journals and/or presented at conferences to the scientific community. This will be reported in a way that will not identify you or your child and is important to share the results to help research advance as quickly as possible.

(***Will results be shared with participants through PPIE networks etc if applicable to your research***)

**What will happen when the study finishes?**

The (***data/information***) obtained from this research study will be stored indefinitely in an electronic data archive (***where***?) and may be shared with other bona fide researchers around the world, but your child’s identity will not be shared.

Samples that were not used during this project will be sent to the (***Insert name here***) biobank (***or other place of storage***) where they can be stored for future research. If you do not consent to this remaining samples will be destroyed.

**Are there any arrangements for compensation?**

***If yes – What compensation will you provide? Travel costs refunded etc.***

***If No -*** No special compensation arrangements have been made for this project.

***Either yes or no add in the following***: In the unlikely event that any harm should occur as a result of taking part in this study you have the right to claim damages in a court of law. This would require that you prove fault on the Hospital/Institute and/or any manufacturer involved.

**Will we be contacted again?**

If you agree to take part on behalf of your child, when they are old enough and able to give consent themselves we will be asking them to agree on their own behalf to stay in the project. At that time they will make their own decision.

In the future we may contact you or your child to take part in future research. It is up to you and child if wish to take part in these studies. We may also contact you to update you on the results of this research.

**What if we have questions or worries?**

If you or your child have a concern about any aspect of this study please discuss them in the first instance with the principal researcher (***Insert name and contact details here***) who will do their best to answer your questions.

If the problems are not resolved, or you wish to comment in any other way, please contact the ***Patient Advice and Liaison Service (PALS) at Great Ormond Street Hospital are available on telephone number 020 7829 7862***. If you wish to complain formally regarding how this study is run, please contact the hospital complaints department on ***020 7405 9200.***

**Thank you for taking the time to read this information sheet and considering taking part in research. If you and your child decide to take part in this study, you will be given this information sheet and signed consent and assent forms to keep.**