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Centre Number:

Study Number:

Patient Identification Number for this trial:

**BLOOD AND URINE SAMPLE COLLECTION CONSENT FORM**

Title of Project: **Rare and Undiagnosed Diseases Study (RUDY)**

Consent options can be reviewed within the secure page on the Rudy website.

Name of Researcher: Dr M K Javaid

RUDY Study, Botnar Research Centre, Old Road, Oxford, OX3 7LD

 ***If you agree, please insert the version number and date of the information sheet you have reviewed and please initial each box***

|  |  |
| --- | --- |
| 1. I confirm that I have read and understand the blood and urine sample collection sub-study information sheet. (Version ….;date ………………………). I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
 |  |
| 1. 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.
 |  |
| 1. I understand that data and medical records collected during the study may be looked at by individuals from University of Oxford, from regulatory authorities and NHS Trusts, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.
 |  |
| 1. I agree to have blood and urine samples taken for use in this research, including studying the response to vaccines. I consider these samples a gift and I understand I will not gain any direct personal or commercial benefit from this.
 |  |
| 1. I agree that my donated samples can be used in genetic research aimed at understanding the genetic basis for rare diseases and that any results that are clinically important as judged by the Rudy Data Oversight Governance Committee will be sent to the clinical team caring for me.
 |  |
| 1. I agree for the RUDY research team to contact me to arrange appointments to visit my nearest research facility up to 3 monthly until the study is completed.
 |  |
| 1. I agree to have an extra blood sample taken at least 3 weeks after receiving a vaccine dose.
 |  |
| 1. I agree to take part in this sub- study
 |  |

|  |  |  |
| --- | --- | --- |
| Addition:PLEASE INITIAL IN THE BOX UNDER EITHER YES OR NO | YES | NO |
| 8. I agree for my anonymised samples to be used in future research, here or abroad, which has ethics approval. I understand this research may involve commercial organisations. |  |  |

Name of Participant Date Signature

 *For completion by person taking consent:*

Name of Person Date Signature

Taking consent.

*1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in medical notes* (if participant is a patient).”