Central Remedial Clinic­

**PARTICIPANT INFORMATION LEAFLET**

|  |  |
| --- | --- |
| **RESEARCH STUDY TITLE:** |  |
| **SITE:** |  |
| **Principal Investigator(s) and Co-Investigator(s)****(insert names, titles and contact details):** |  |
| **STUDY ORGANISER/ SPONSOR (if applicable):** |  |
| **Data Controller(s):** |  |
| **Data Protection Officer:** |  |

**Introduction**

Your child is invited to take part in a research study in the Central Remedial Clinic (CRC), involving <insert details here>.

Before you decide whether your child will take part, please read the information provided below carefully and if you wish, discuss it with your family. Take time to ask questions.

You should clearly understand the risks and benefits of taking part in this research study so that you can make a decision that is right for your child. This process is known as ‘Informed Consent’.

Your child does not have to take part in this study. If you decide not to take part, it will not affect your child’s future care at the CRC.

This leaflet has four main parts:

Part 1 – The Research Study

Part 2 – Data Protection

Part 3 – Costs, Funding and Approval

Part 4 – Further Information

PART 1 – THE RESEARCH STUDY

**Why is this research taking place?**

<insert details here>

**Why has my child been invited to take part?**

<insert details here>

**Does my child have to take part? Can I withdraw my child?**

* Your participation is **voluntary**;
* Any decision not to participate will not **affect your child’s health care in any way**.

**How will the research be carried out?**

<insert details here>

**What are the benefits and risks of taking part in this research?**

<insert details here>

Your child’s personal data will be tightly safeguarded, however there is always a risk of a data breach when processing personal data. Your child’s personal data will be processed and stored securely in accordance with GDPR guidelines (the General Data Protection Regulation).

PART 2 – DATA PROTECTION

**What will happen to my child’s data?**

If you do decide to take part, you will be asked to also consent to the processing of your child’s personal data and will be given a privacy notice that will explain how your child’s data will be collected and used. After you consent to the processing of your data, you are still free to withdraw your consent at any time by contacting the principal investigator. No further processing of your personal data will take place once you withdraw your consent.

Personal data accessed will be processed only as is necessary to achieve the objectives of the research study. No other information will be accessed or processed in a way that could cause damage or distress.

Data will be securely stored at the Central Remedial Clinic, Dublin.

**Will my child’s personal data be kept confidential?**

All persons with access to the personal data are bound by a professional code of confidentiality, that would mean disciplinary action for employees who disclosed or facilitated unauthorised access to the personal data) or some other arrangement that emphasises confidentiality (this may be applicable in the case of medical students).

GDPR training and awareness has been provided to those individuals involved in carrying out the research.

PART 3 – COST, FUNDING AND APPROVAL

**Has this study been approved by a research ethics committee?**

<insert details here>

**Who is organising and funding this research study?**

<insert details here>

**Is there any payment for taking part? Will it cost me anything if I agree to take part?**

<insert details here>

PART 4 – FURTHER INFORMATION

**Who should I contact for information or complaints?**

If you have any concerns or questions, you can contact:

<insert details here>

**Will I be contacted again?**

<insert details here>

If you would like to take part in this pilot study, you will be asked to sign a Consent Form. You will be given a copy of this information leaflet, a privacy notice and the signed consent form to keep.