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To adapt for: The whole ERN; National level; Site level;

**Delete this square afterwards**

**Please insert the ERN/ERN Registry Logo**

## PATIENT INFORMED CONSENT FORM

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| Dear parent(s)/legal representative,  We invite your child/the patient[[1]](#footnote-2) to take part in a patient registry for <please precise disease/group of diseases etc.>. Participation is voluntary and requires your written consent as a legal basis to use the data of your child/the patient. Please read this information carefully and ask the medical doctor of your child/the patient for explanation if you have any question. |

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| EUROPEAN REFERENCE NETWORK REGISTRIES   * Please include a brief description of the disease/group of diseases and the current burden encountered for their management (*e.g., causing chronic health problems, are life-threatening; requiring numerous resources and multidisciplinary teams for their correct diagnosis, management and treatment; representing a public health challenge; few curative treatments are available; the challenge to bring together sufficient data regarding patients to launch research and clinical trials to improve their management*.)> * European Reference Networks (ERNs) are networks of healthcare professionals for rare diseases across Europe working together to support patients with rare and complex diseases. * <Please include (1) an introduction of the ERN, (2) the name of the registry, and (3) the link to the patient page of the ERN-registry website> * To understand the course of a disease and investigate new diagnostic procedures and treatments in order to improve patient care, ERNs need databases (also known as “registries”) for research and knowledge development. * To build such registries, data from many patients must be combined. We ask for your consent to include the data of your child/the patient in the <name of ERN registry> to perform research, as described below, in accordance with national and European data protection laws and ethics guidelines[[2]](#footnote-3). * Only the data required for such research will be recorded and may be shared with users as outlined below. Such data may include age, sex, the signs and symptoms of the disease, results of diagnostic procedures (e.g., laboratory test results, genetic information, imaging studies), as well as therapeutic interventions and their long-term outcomes.   + Your child/the patient’s data privacy will be secured as described below in this form. Only the medical doctor of your child/the patient will be able to link your child/the patient to your child/the patient. Therefore, the risk of re-identification by unauthorized persons is minimal. |

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| **VALUE & BENEFITS** |

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| **HOW WILL THE DATA BE USED?**  The data collected in this registry is used to improve the delivery of healthcare, including the diagnosis, treatment and prognosis of patients with <please precise disease/group of diseases as above>.  <The following sentence on “research on genetic data, population origins or ancestry research” is optional, at ERN discretion> Research on genetic data, population origins or ancestry research may be carried out as well. <Please provide details (i.e., type of data, additional and appropriate safeguard measures, other information, if no such research is foreseen, please delete this part>.  Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered.  Only users authorised by the **Registry Data Access Committee** can use the data. This Committee is composed of qualified health professionals, patients' representatives as well as members with legal and ethical expertise. It ensures that the request for data use aligns with the purposes of the registry and its policy.  The Registry Data Access Committee may provide data access to **clinical researchers from within or** outside <please name the ERN>**, patient organisations, and the pharmaceutical industry** in order to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases**.** Also, registry data may be shared with **health authorities, policy makers and regulators** to inform their decisions on rare disease health policy and approval of medicines. |
| **Data use for commercial purposes**  Companies might request access to data stored in the registry to perform research aimed to develop new therapies for your child/the patient’s condition. For example, the registry can inform companies how many patients live with a certain disease and help find patients in clinical trials of new therapies.  Typically, the results of this research will become property of the company that may also use them for further **commercial purposes** and to patent. Your child/the patient will not acquire any rights over these results, own them in any way, or be entitled to share any future financial benefit derived from this research.  You may choose if you want to allow the use of the data of your child/the patient for commercial research. |
| **Data transfers outside the EU**  Data without any personally identifiable information may also be forwarded to researchers working in countries outside the EU, where the General Data Protection Regulation (GDPR) does not apply. In this case, a written agreement will be set up to ensure that the data is processed in compliance with the GDPR. You may choose if you want to allow the transfer of the data of your child/the patient to non-EU countries to contribute to projects directly aligned with the aims of this registry within a framework compliant with GDPR. |
| **Future changes in data collection**  To gain more insight on the condition of your child/the patient we may need additional data in the future. This information will be published on the registry website <Please include the URL of the registry website>.  <The part of this section on future changes in data collection is optional, at ERN discretion>  In the event a disease-specific subregistry exists for your **<**please precise disease/group of diseases>, more detailed clinical data will be collected. Such subregistries are of great importance to better understand the precise nature of rare diseases. More information on the available subregistries can be found on the registry website.  Furthermore, we may request additional data from existing databases/registries, such as <indicate the databases/registries, including other ERN registries>. You may choose if you want to allow the linking of the data of your child/the patient with additional data as described above. |
| **Re-contacting to participate in research projects**  In the future, research projects on the diseases and conditions covered by this registry may be proposed. You may choose if you want to be re-contacted by the medical doctor of your child/the patient to participate in such studies. If you agree to be contacted, you are free to refuse, without any prejudice, participation in the proposed studies after you have been fully informed. The current care of your child/the patient will not change in any way if you choose not to give your consent. |

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| **WHAT ARE THE BENEFITS?**  While there is no direct benefit from participating in this registry, the knowledge about the disease will be improved. This may benefit your child/the patient and other patients suffering from the same disease.  The participants may benefit by facilitated access to clinical studies aimed to prevent and treat the disease. |
| **Communication of research results**  The results of the research will be communicated through <please include information on how the results will be communicated (e.g., registry website [The information about projects given access to registry data is publicly available on the registry website.], OR information provided by the patient’s medical doctor upon request, OR publication in scientific journals where personal data are not provided, etc.)>. The privacy of the data your child/the patient’s data will always be protected as described below. |
| **Incidental findings** <Optional section, please delete if no incidental findings are expected >  It is possible that during an investigation using data submitted to the registry an abnormality will unexpectedly be discovered that is directly relevant relevant to the personal health of your child/the patient or to the health of your family members/the patient family members. We call this an incidental finding. To make a sound choice, it is important that you weigh up the pros and cons of using this information. On the one hand, medical measures may be available that can be taken in time if the findings are known. However, there can also be disadvantages to knowing about a health risk. Especially if no effective medical interventions are available, the knowledge about potential future health problems can cause psychological distress. Some findings, such as a hereditary predisposition for a disorder, may mean that some of your family members/family members of the patient **are exposed to the same health risks.**  You are asked to give your consent to be informed by the medical doctor of your child/ of the patient about any incidental finding that is directly relevant to the personal health of your child/the patient or to the health of your family members/the patient family members. |

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| **PROTECTION** |

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| WHAT ARE THE RIGHTS OF THE REGISTRY PARTICIPANT?  * + - You decide whether to let your child/the patient participate in the registry. Please take as much time as you need to make this decision. You do not have to sign anything. You can decline participation without giving any reasons. Your child/the patient will receive the same treatment irrespective of whether or not you agree to participate in this registry.     - You have the right to give or withhold your consent at any time. If you consent today, you may modify or withdraw your consent later, without any prejudice. The medical doctor of your child/the patient will explain how your consent can be modified and how the data can be removed from the registry if you wish so. Please be informed that, to guarantee the validity of any research performed, data already processed cannot be deleted. However, this data will not be used in new research projects after withdrawal.     - You are entitled to receive further information about the purposes for which the data of your child/the patient will be processed and who will have access to it. You can also request to access the data of your child/the patient at any time.     - The hospital where your child/the patient is treated is the “data controller” responsible for the **local protection** of confidential patient data. If you have any concerns about the way in which the data of your child/the patient is processed, you would like more information or to exercise your rights, you may contact the Data Protection Officer, or you may raise a complaint to the relevant data protection authority. You can find contact details of the local Data Protection Officers at the registry website <please include link towards the registry website - alternatively add information about local DPO here>. They have the duty to ensure the data is processed safely and to notify you if a breach of data security occurs. Any inquiries should be addressed by the Data Protection Officer within 30 days.     - For all data submitted to the **central registry database**, the < include the name and place of the central registry office> and its principal investigator <please include the name of the custodian and responsible person for data protection, storage, use and access> is responsible for the protection of the data, its storage, use and access: <please include the contact details of the custodian and responsible person for data protection, storage, use and access>.     - <For the parent version> When your child will reach legal majority, the hospital will approach your child again to check whether he/she wishes to stay in the registry. |

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| HOW WILL DATA BE SECURED?  * + Participation in the registry will be kept strictly confidential and all information will be handled through very secure electronic systems. As the registry involves collecting information from many centres, the system will be password protected and only persons specifically involved with the registry will have access.   + The registry users and administrators will not be able to contact you because the name of your child/the patient, address and hospital number will not be recorded. All your child/the patient’s data will be pseudonymised before being stored in the registry. This means that all identifiers that relate to your child/the patient will be removed and replaced by a pseudonym[[3]](#footnote-4). Only the medical doctor of your child/the patient can link the pseudonym to your child/the patient. Therefore, the risk of re-identification by unauthorized persons is minimal.   + In all publications emerging from the registry, it will be ensured that it is not possible to identify an individual patient, e.g., by providing data in tables or presenting age categories rather than the real age.   + A pseudonymisation service will be used for this purpose. It allows to identify duplicate registration of patients, linkage between registries and other data resources, keep data protected and preserve the possibility of re-contacting by the medical doctor in charge.   + The registry data will be stored on a secure server in <please include information on storage location OR Cloud service name used with the location of its servers holding the registry data> for …. <please include information on storage duration OR the criteria to define it (e.g., minimum or maximum time, until the research objectives have been met, which may be several decades from now OR As the registry is designed to look at long term outcome, the data shall be stored indefinitely, even after the registered person has passed away**)>**. The data will be kept in the database for at least <Please include the number of years>. |
| COULD PARTICIPATION IN THE REGISTRY CAUSE ANY HARMS?  * + Participating in this observational registry will not cause any health risks.   + Even though the registry has processes in place to ensure your child/the patient’s personal information is protected, there is a remote risk the data could be matched with information you have already authorized in publicly available databases such as ancestry websites or public rare disease registries with identifiable information. To minimize this risk, researchers asking for access to registry data will confirm in writing not to try to identify you by any means, applying their duty of professional secret. |

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| **ADDITIONAL INFORMATION** |

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| **Costs** Participation in this registry will not entail any costs for your child/the patient. |
| **Insurance**  <please include information about insurance taken for the registry activities if applicable, as requested by some Ethics Committees – otherwise, please delete this paragraph> |
| **Ethics Committee Approval**  This Informed Consent Form has been reviewed and approved under the number <Ethics Committee/ IRB number> by [name of the (local) Ethics Committee/IRB |

If you have any other question about the registry, please contact: **<**please include the name and the contact details of the reference person for the ERN>

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| INFORMED CONSENT  Patient First and Last Name:………………………………………………..………………………………..………  Date of Birth (dd/mm/yyyy):: .. .. / .. .. / .. .. .. .. ID number:………………………………………………  I am the parent I am the legal representative[[4]](#footnote-5)  Parent/ Legal Representative First and Last Name: …………………………………………………………… |

I have read the information sheet about the <name of the registry>.

I have been given the time and opportunity to ask questions about the objectives of the registry and the use of the data of my child/the patient and that I have solved all my doubts with the medical doctor.

I understand that the participation of my child/the patient is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting the future medical care of my child/the patient.

I approve that the data of my child/the patient will be stored in the <name of the registry>, used for non-profit purposes and shared with approved users to improve the delivery of healthcare as described above.

I consent to the processing of my child/the patient pseudonymized data for the purposes described above.

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| **The following consent conditions are optional. Please indicate your preferences by writing your initials in the relevant box. If you leave the boxes empty, we assume you agree to the statements.** | | |
| **YES** | **NO** |  |
|  |  | **I CONSENT** that the pseudonymized data of my child/the patient may also be **used** **to support commercial projects** aimed to improve healthcare. |
|  |  | **I CONSENT** that the pseudonymized data of my child/the patient **may be transferred to non-EU countries, in compliance with GDPR,** to support projects aimed to improve healthcare. |
| Optional, at ERN discretion |  | **I CONSENT** that the pseudonymized data of my child/the patient may be **linked to existing databases/registries** to improve healthcare. |
|  |  | **I WOULD LIKE TO BE CONTACTED** by the medical doctor of my child/the patient about any **research project and/or clinical study related to my child/the patient’s condition.** |
|  |  | **I WOULD LIKE TO BE INFORMED** by the medical doctor of my child/the patient **about any incidental finding** that is directly relevant to my personal health or to the health of my family members. |

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| **PARENTS/LEGAL REPRESENTATIVE**  Date and Signature: | **MEDICAL DOCTOR / AUTHORISED WITNESS**  Full name:  Position:  Date and Signature: |

**Please keep one copy of this Informed Consent Form in case records and hand one copy to the person who has signed this form.**

1. Adult for whom you are legal guardian [↑](#footnote-ref-2)
2. including the European General Data Protection Regulation (GDPR), Reg. (EU) 2016/679; the Declaration of Helsinki 2013; the International Ethical Guidelines for Biomedical Research Involving Human Subjects CIOMS-WHO (2016); the Oviedo Convention and its Additional Protocol on human rights and biomedicine, concerning biomedical research (2005); the [“standard contractual clauses for the transfer of personal data to third countries” (EU) 2021/914](https://eur-lex.europa.eu/legal-content/DE-EN/TXT/?from=DE&uri=CELEX%3A32021D0914) and **…. <please include any other applicable law>** [↑](#footnote-ref-3)
3. A pseudonym is a sequence of letters and numbers that replaces all identifiers that relate to a patient; the data of the patient is then called “pseudonymised data”. These identifiers can only be retrieved, from the pseudonym, by the authorised health care professionals enrolling the patient in the registry. [↑](#footnote-ref-4)
4. *Patients not able to consent by their own (age or legally incompetent or mentally incompetent) must be also involved in the process of information to the extent permitted by their comprehension grade and maturity. The age to which the capacity of consent for processing of data is recognized, varies according to the national legislations. Once minors reach the legal age of maturity, they will be asked to provide their consent to continue participating in the registry. The need to ask for consent to all persons holding the parental responsibility of the patient depends on the national regulations. People holding the parental responsibility of the patient, shall sign this consent in different (duplicated) documents.*  [↑](#footnote-ref-5)