HOSPITAL MATERNOINFANTIL
UNIVERSITAT DE BARCELONA

Patient

Surname(s)……

First name……

Date of birth……

Disease diagnosis: ……

Informed consent: Participation in Rare Commons

Informing institution: **Sant Joan de Déu Hospital, Barcelona, Spain**……..

Person informing (name and national identification document number)……..

Relation to patient……

Introduction

As a group of researchers at the Sant Joan de Déu Hospital in Barcelona, we undertook the Rare Commons project (www.rarecommons.org) in order to build collaboration among patients and their carers, physicians, and researchers. This direct collaboration among the patients/parents/guardians of patients suffering rare diseases is a positively evaluated project that has earned the recognition of prestigious institutions such as the Center for Network Biomedical Investigation of Rare Diseases (CIBERER- ISCIII) and several patient associations.

The **Rare Commons project for rare diseases** aims, by means of the use of **new technologies and the Internet,** to create exhaustive databases that will allow for improved knowledge of the diseases in question, their natural courses, and their genotype/phenotype correlations, thereby enabling the formulation of clinical guides and diagnostic algorithms to permit early diagnosis—something that is sorely lacking today in the case of diseases with such low prevalence.

Methodology

The patient data will be collected via the Rare Commons (www.rarecommons.org) secure work platform and will be stored in a database at the Sant Joan de Déu Hospital, under terms specified in the applicable laws governing the protection of data.

In compliance with the **Organic Law 15/1999 of the 13th December**, the Sant Joan de Déu Hospital hereby states that the data will be included among the clinical and demographic data that pertain to the center.

The purpose of the data collection is to increase understanding of rare diseases based on the clinical information provided by patients and their attending physicians, by means of a mechanism of prior invitation and authorization of this participation given by the patients' families.

The information is intended for use by a group of researchers under the aegis of the Rare Commons platform at the Sant Joan de Déu Hospital working to advance knowledge and understanding of the diseases in question. This is the goal of the data collection. The patients and their families, in turn, will periodically receive general, anonymized descriptions of the information which will be of use to them in

*Law Concerning the Protection of Data of a Personal Nature (LOPD 15/1999) and Royal Decree 1720/2007

the management and control of the illness and the avoidance of side effects resulting from disease treatment.

Participants enjoy, at all times, the rights of opposition, access, rectification, and cancellation of their participation under terms laid out in said Organic Law 15/1999 of the 13th December. For the purpose of exercising these rights, and for any further clarification, they may write to the Client Attention Unit of the Hospital, at Paseo Sant Joan de Déu 2, 08950, Esplugues de Llobregat, Barcelona, Spain.

The Rare Commons team is committed to producing content that is both informative and in language comprehensible to the non-specialist for each of the areas affected by the disease. The process of collaboration on the part of the carer/patient is by means of a series of easy-to-complete questionnaires. Support in completing the questionnaires will be available from the Rare Commons team if needed.

The Rare Commons team requests that the carer/patient invite their referral physician to join in the project; without this invitation the physician will not have access to Rare Commons. If this participation is not desired by the carer/patient this decision will be respected and no further questions will be asked.

For additional information about the methodology please go to the following link http://www.rarecommons.org/es/como-trabajamos or contact us by email at rarecommons@hsjdbcn.org

Benefits

The careful analysis of the data collected will help us to expand knowledge and understanding of the rare diseases that are under study: their clinical and biochemical characteristics, their natural courses, and genotype/phenotype correlations. This expanded knowledge will also lead to the development of algorithms for suspicion and diagnosis of the diseases, guides for clinical practice in their treatment, and guidelines for therapeutic actions to be taken.
The study will enable the development of homogeneous, validated follow-up and treatment strategies. These will be published in freely available journal whenever possible, so that the information may be available to any and all physicians treating patients with the rare diseases in question, wherever they may be.

Risks and drawbacks

Your participation represents a commitment to collaborate, by means of a calendar designed to be as flexible as possible so as to adapt to your personal needs, in the filling out of a series of online questionnaires concerning the patient. It may be painful at times to recall difficult moments in the course of the disease in the patient. Our team of moderators is available at such times to provide needed support.

Voluntary nature of participation and termination of the study

Your participation in this study is **entirely voluntary**. You may decide not to participate any further and withdraw from the study at any time without having to offer any further explanation of your reasons for doing so. This will in no way affect your relationship with your physician, nor will it affect the patient's treatment in any manner. If you do decide to withdraw from participation in the study we would be grateful if you did so by directly notifying the Rare Commons team of your decision. The team, in turn,

may also end your participation in the study if they feel for any reason that the patient is not an appropriate candidate for study in terms of the inclusion and exclusion criteria (for example, if the diagnosis of the disease is not confirmed).

Consent

After having read the information made public by the Rare Commons platform regarding its aims and the end goals of its research, and after having been afforded the opportunity to ask any questions that I may have had concerning the study, I hereby **DO** ☐ / ☐ **DO NOT** give my consent to the investigators of the Rare Commons project conducting research on the above-mentioned disease to:

- use the available data to study the natural course, genotype/phenotype correlations, and other clinical characteristics of my disease or that of my child,
- store the data in a secure, supervised database governed by the laws on the protection of data* so that they may be used in future research,
- make the data and biomedical information obtained available to the greater scientific community,
- and keep me informed concerning the results of the investigation undertaken of my disease or that of my child.

I have been thoroughly informed about the implications of my participation in the study, I have fully understood the contents of the present document, and I accept the offer to participate voluntarily in the **Rare Commons project for families of patients suffering the above-specified disease.**

Signature of patient/father/mother/guardian…….

City: _____ Country: Date: _____

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