## Patient information sheet for participation in a investigation project

Investigation project entitled: **Multicenter, observational International study to determine the natural history of patients with alpha-1 antitrypsin deficiency.**

Principal investigator: YOUR NAME

Department: YOUR DEPARTMENT AND CENTER

Promotor: YOUR DEPARTMENT AND CENTER AND Vall d’Hebron Research Institute (VHIR), Barcelona, Spain

**Objectives**:

We are asking for your participation in this investigation project the principal aim of which is to widen the knowledge on severe AAT deficiency by collecting clinical information on individuals with this infrequent disease. To do this, an International database with restricted access has been created to include clinical and functional information of the patients. The data collected will be statistically analysed and will be published for exclusively scientific purposes, while always guaranteeing patient confidentiality. Inclusion in this registry will not mean the performance of medical procedures or additional medical visits.

If you accept to participate in the study, the information obtained will help to better know the clinical evolution of patients with emphysema due to AAT deficiency and improve the treatment of these patients.

It is our intention to provide you with sufficient and correct information in order for you to decide whether to accept or not to participate in the study. Please read this information sheet carefully, and we will clarify any doubts you may have.

**Benefits**:

It is possible that you will not obtain any direct benefit from your participation in this study. However, greater knowledge of this disease could benefit other patients with AAT deficiency in the future and contribute to greater understanding and improvement in the treatment of this disease.

**Study procedures**

In this study no additional procedures to those included in the usual management of the diseases will be performed.

The study is based on the inclusion of information related to your disease in a NATIONAL (country) and International registry of patients with alpha-1 antitrypsin deficiency. This registry has been designed by the “European Alpha-1 Research Collaboration” (EARCO) and is promoted by the YOUR CENTER and Vall d´Hebron Institute of Research (VHIR).

The registry will gather information on a large number of patients with the same disease to better know its characteristics, natural history and prognosis. The information will be stored for a minimum of 25 years and/or until withdrawal of consent and will only be accessible to the data administrator and the VHIR. There are no risks derived from participation in the study; the data will not be rendered or shared with third parties or transferred but will be statistically analysed and may be published with exclusively scientific objectives after having been processed in order to avoid data cross-over. Patient confidentiality will always be guaranteed due to the fact that all the data are coded.

**Protection of personal data:**

According to the prevailing European and national laws on Personal Data Protection, the personal data obtained will only be the data necessary to fulfill the objectives of the study.

YOUR CENTER OR NATIONAL SOCIETY and the Fundación Hospital Universitario Vall d’Hebron-Institut de Recerca – “VHIR”- with NIF G-60594009, established at Paseo Vall d’Hebron 119-129, Edificio Mediterránea, 2nd floor Barcelona – 08035 is responsible for the personal data which you provide, and these data will be managed in a lawful, honest and transparent manner.

The objective a data management is to collect data for the study entitled: “**Multicenter, observational international study to determine the natural history of patients with alpha-1 antitrypsin deficiency.”**

The receiver of the data will be the VHIR or other authorized personnel who must maintain the confidentiality of the information according to prevailing legislation. In no case will the data be rendered to third parties without express previous consent by yourself, except according to legal obligation under the Regulation (EU) 2016/679 to persons who are legally entitled to request the data. Neither is international transfer of the data foreseen.

Any information of a personal nature which might be identifiable will be securely preserved by Dr. YOUR NAME or by an institution designated by him.

The legal basis of data management is the consent granted by yourself, and therefore, you may withdraw consent at any time. Notwithstanding this previous statement, if you do not wish to provide consent you will not be able to be included in the study. Automated, individualized decisions regarding the personnel data provided will not be made, including the elaboration of profiles. The personal data will only be used during the time deemed necessary, useful and pertinent to fulfilling the objective for which they were collected, and provided that you do not suppress or revoke consent they will be legally maintained or in the exercise or defense of possible claims.

You may at any time exercise your right to access, rectification, opposition, limitation, portability and suppression as well as withdraw consent.

In compliance with Regulation (EU) 2016/679, the VHIR has designated a Data Protection delegate, whose contact address is [dpd@ticsalutsocial.cat](mailto:dpd@ticsalutsocial.cat) .

The legal unit of the Fundación will resolve any doubts, complaints, clarifications, suggestions and will attend the exercising of your rights through the email address INCLUDE HERE YOUR LOCAL E\_MAIL [lopd@vhir.org](mailto:lopd@vhir.org) or by post.

You may also make claims before the competent Control Authority in regard to data protection.

**Voluntary participation and right to withdraw consent:**

Your participation in this study is voluntary, and you may decide not to participate or change your decision and withdraw consent at any time without this affecting the relationship with your physician or producing any detriment in your treatment.

If you require any further information on this study please contact the principal investigator Dr. YOUR NAME AND CENTER

Tel. YOUR CONTACT NUMBER

## Model of informed consent

|  |
| --- |
| Study title: Multicenter, observational international study to determine the natural history of patients with alpha-1 antitrypsin deficiency.  II\_\_\_\_\_(patient’s name and surname) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  I have read the information sheet given to me. I have been informed by the health professional named below:  -About the advantages and disadvantages of the study.  -About where my personal data will be obtained, stored and the processing the data will undergo.  -That my participation in the study is completely voluntary.  -That the data will be codified, limited and confidential.  -That I may at any time withdraw my consent, request suppression of my personal data and withdraw from the study with no explanation and without this having any repercussion on my medical care.  -That I have the right of access, rectification, opposition, limitation, portability and suppression of my personal data.  -That I understand the information received and have been able to make the questions I feel opportune to Dr. YOUR NAME  On signing the present document:  □ I f  Frreely give my consent, which I may withdraw at any time, and accept to participate in the study proposed.  □ I accept that the physicians involved in this study can contact me in the future if they consider it necessary to add new data.  □ I give my express consent to the management of my personal data according to the information contained in the section of Protection of Personal Data.  □ I give my express consent to be contacted for possible participation in future research studies in the field of alpha-1 antitrypsin deficiency  **Your city,\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_of \_\_\_\_\_\_\_\_\_\_\_\_\_, 20\_\_.**  **Participant**  **Date aName of NName of the signing participant (if over 14 years of age):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **ID number:\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Authorizing person (tutor or legal representative*): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*  Name of authorizing person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  ID number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Relationship with participant:\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature of authorizing person:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Declaration of physician/nurse (etc.) who has duly informed the participant.**  Name:  ID or Affiliation number:\_\_\_\_\_\_\_\_\_\_\_  Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**SECTION FOR WITHDRAWAL OR REVOCATION OF INFORMED CONSENT** (SIGNATURE OF PATIENT AND/OR FAMILY MEMBER/LEGAL REPRESENTATIVE)

I, ....................................................................................................................................or family member/legal representative*(if appropriate)*………………………………………… of the patient (name of patient)………………………………………………………………. withdraw/revoke consent to participate in the study, signed above.

This revocation of informed consent means that from the date on which this document has been signed medical data can no longer be collected without this being in detriment to the preservation of the data resulting from investigations performed previously.

Date of study withdrawal/revocation.........................................

Signature: