❖ **Number of the clinical study held by the IRCCS Foundation National Tumor Institute of Milan:**

Title of the clinical study:

Desmoid Fibromatosis during pregnancy: the effect of pregnancy on disease control and the effect of diagnosis on pregnancy histories.

A retrospective international observational multicenter study

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Form n. 1

INFORMATION FOR THE PATIENT
(Screening population)

This form will be given to you well in advance of your final decision.
It provides essential information on the clinical study you are asked to participate.
It's important for you to read this informational paper and discuss it with investigators before signing the consent to participate in the study
(Form n.2: "Informed Consent to Participate in the Study")
Only patients who accept and sign the consent can participate in the study.
The Patient can withdraw the consent to participate at any time.

The Disease.

Aggressive Desmoid Fibromatosis is a rare non-metastatic disease more common in women.
Due to its unpredictable behavior at the beginning, and due to its possible spontaneous regression, after diagnosis many patients are just under active clinical surveillance, postponing active treatments such as surgery, radiotherapy, chemotherapy etc. and only when there is a progression of the disease.
At the same time, an association between pregnancy and desmoid fibromatosis was observed: not rarely the diagnosis of desmoid fibromatosis occurs during pregnancy or immediately after.
Similarly in patients with diagnosis of fibromatosis (after surgery or not), another pregnancy may be the occasion of relapse or of progression of the disease. It is currently unknown the risk of a progression of the disease during pregnancy and there are very few studies available.

The clinical study.

This study aims to collect information on patients with a diagnosis of desmoid fibromatosis during their childbearing age, and those who were pregnant at the moment of the diagnosis or who had pregnancies afterwards. The purpose of the study is to analyze and to identify, if possible, specific risk factors and to clarify why pregnancy could be the reason of a progression or a recurrence of fibromatosis. At the same time, the purpose of the study is to verify if pregnancies occurred after a diagnosis of fibromatosis have somehow an increased risk from the point of view of obstetrics or during childbirth.
For patients who were not diagnosed with desmoid fibromatosis during pregnancy and for those who did not become pregnant after the diagnosis, it is possible to participate in the study by answering a short survey aimed at describing the broader population of desmoids patients during childbearing age and the consequent choices about fertility. This will be fundamental for the general interpretation of the study data. Participation in the study is on a voluntary basis and the patient can withdraw her consent at any time without explanation or without losing any rights.

Insurance coverage.

Due to the observational nature of the study, and given that we will be dealing with medical documents, the insurance policy stipulated by the Foundation guarantees appropriate coverage, in accordance with the current legislation.

Guarantees for the patient's protection involved in the clinical study.

- The conduct of this study has been approved by the Independent Ethics Committee at the Nation Tumor Institute of Milan.
- Patient participation in the study is totally free. This means that they can freely decide not to participate in the study, not to sign this consent, without prejudice in any way to the assistance they will receive in this institution later. Furthermore, Patients who agree to participate in a study can withdraw their consent at any time and are entitled to leaving the study immediately.
- Patient participation to this study does not involve additional cost connected to the participation of the study.
- Patients participating in the study receive an email containing the privacy policy with clinical managers contact details of the study (for all their needs during the study).
- A copy of Information Sheet and a copy of any Consent remain in the possession of Patient who agrees to participate in the study, sent by email.

- **Number of the clinical study held by the IRCCS Foundation National Tumor Institute of Milan:**

Title of the clinical study:

Desmoid Fibromatosis during pregnancy: the effect of pregnancy on disease control and the effect of diagnosis on pregnancies history.

A retrospective international observational multicenter study

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Form n. 2

INFORMED CONSENT
TO PARTICIPATION IN THE STUDY
(Screening population)

This form must be signed by you in case of participation in the clinical study.
It's important that you discuss with your investigators before signing this consent,
even according to the resume paper
(Form n.1 "Information for the patient).
Only patients who accept can participate in the study.
The Patient can withdraw the consent at any time.

I, the undersigned, with my full capacity of understanding and will,

1) **I declare to have been fully informed about the clinical study and to have read the Information Paper for the Patient, of which,**

on …../…../…….

I received a copy to keep (by e-mail),
and have adequately discussed it with investigators of the DF - DESMOID FOUNDATION - ITALIAN ASSOCIATION OF DESMOID TUMOR - ONLUS who are responsible for it at this institution,

on …../…../…….

in……..**;**

2) **I give my free and informed consent to take part in the clinical study in question:**

3) ❑ **I <u>authorize</u>**
❑ **I do not authorize**

<u>To provide to my general medicine Doctor</u>,

Dr. ……..……

<u>information about my participation to this clinical study.</u>

Patient's signature ……

Name ……

Date: …../…../…….

Signature of the legal Representative or of the tutor (if appropriate)

……

Name ……

Date: …../…../…….

Witness' signature *(if appropriate)* ……

Name ……

Date: …../…../…….

Witness' signature *(if appropriate)* ……

Name ……

Date: …../…../…….

Researcher's signature ……

Name ……

Date: …../…../…….

INFORMATION TO USERS
ABOUT THE PERSONAL DATA PROCESSING AND
DATA SPECIFIC CATEGORIES FOR CLINICAL RESEARCH PURPOSE

Number of the clinical study held by the IRCCS Foundation National Tumor Institute of Milan:

Clinical study code: " ……."

Clinical study title: Desmoid Fibromatosis during pregnancy: the effect of pregnancy on disease control and the effect of diagnosis on pregnancies history. A retrospective international observational multicenter study.

Dear Madam/Dear Sir,
pursuant to current national and European regulations on the personal data protection, in particular cause of Regulation (EU) 2016/679 of 27 April 2016 (General Data Protection Regulation, hereinafter also the "Regulation"), we inform You that:

1) Data Controller and DPO

DF - DESMOID FOUNDATION – Associazione Italiana Tumore Desmoide - ONLUS (after referred to as "Desmoid Foundation"), as promoter of the study in question is the owner of your data processing and works in collaboration in the experimental center with PI dott. Marco Fiore of IRCCS Foundation - National Cancer Institute of Milan, responsible for your data processing too. The data concerning you will be processed by each entity, for the areas of its competence and in accordance with the obligations established by law. The rights listed in this document may be exercised by contacting the promoter of the study:

- the owner of the treatment described here is DF - DESMOID FOUNDATION - ASSOCIAZIONE ITALIANA TUMORE DESMOIDE – ONLUS, based in Milan, via Giacomo Venezian n.1, 20133 (MI). The owner can be contacted to the registered office in Via Giacomo Venezian n.1, 20133 Milan (MI) or by e-mail to:
    - e-mail: info@desmoidfoundation.org
- the Data Protection Officer (or Data Protection Officer) can be contacted at the following addresses:
    - e-mail: info@desmoidfoundation.org
    - PEC: desmoidfoundation@selfpec.it

2) Data processed, legal basis of the processing and purpose

Desmoid Foundation directly acquires personal data and particular categories of data (including data relating to health, its origin, its lifestyles) which it processes in paper and computer form, for clinical research purposes, as described in the study, with the aim of promoting the prevention and improvement of therapeutic treatments;
by consenting to the treatment described here, your data may be used for the purpose of improving

knowledge of oncological diseases, developing new treatments, medical devices and diagnostic methods to ensure better patient care.
Your consent to the data processing for the purposes of this study is free and optional and your failure to provide it will not preclude you from accessing other medical/health services requested and prescribed by oncologists and/or other specialists.
Your consent may be revoked at any time, in which case the revocation will have value only for the future, remaining valid for the processing carried out up to that moment.

3) Nature and consequences of data providing

As mentioned above, your consent to the data processing for the study purposes is free and optional but is a necessary and indispensable condition to be able to participate in this study.

4) Processing methods and storage times

Your data will be processed with suitable technical and organizational security measures.
They will be processed without specifying your name but associated with an identification code (pseudonymisation). This is to avoid identifying you directly when the study data will be used. Only the doctor and authorized persons will be able to link this code to your name.
The data you provide will be kept as long as necessary for clinical research purposes. In the field of scientific research, in fact, constant technological development makes it possible to obtain new and very important results thanks to the analysis of data which, due to the lack of current medical and technological knowledge during initial collection, could not be examined. Furthermore, with the progress of the research activity, data collected, even in very ancient periods, could be useful for new studies. The conservation of your data therefore represents an essential phase for research.

5) Subjects authorized to process, responsible and data communication

For the purposes outlined above, your data will be processed by authorized personnel duly designated by Desmoid Foundation, such as: healthcare, technical, administrative personnel and any external companies that perform on behalf of and authorized by the Desmoid Foundation, in Italy, in the European Union or in non-EU countries.
In the latter case, the transfer to each of these countries will take place on the basis of the legitimacy of the transfer in relation to each state or on the basis of the consent given by you.
The promoter will take all possible measures to ensure compliance with current legislation in relation to the information collected.
The updated list of third parties including analysis laboratories is available and at your request the doctor who will follow you can provide it to you.
The data, also processed by electronic tools, will be disseminated only in aggregate form and therefore in an absolutely anonymous way and may be published in scientific and/or statistical journals or disclosed during scientific conferences.

6) Exercise of rights

At any time you will be able to access data concerning you, know how they were acquired, check if they are exact, complete, updated and well-kept and assert your rights to request the rectification of your data, as well as the limitation of the processing that concerns you, as required pursuant to and within the limits of Articles 15, 16, 18 of the Regulation. You may also exercise the right to object to your data processing pursuant to and

within the limits of art. 21 of the Regulation and request your data portability, within the limits of art. 20 of the Regulation.
You also have the right to withdraw your consent at any time, without prejudice to the lawfulness of the processing based on consent before the withdrawal.
These rights can be exercised by contacting the Data Controller as indicated in point 1. Pursuant to art. 77 of the Regulation, if you believe that the processing related to you violates the legislation on the personal data protection, you have the right to lodge a complaint with the Italian Data Protection Authority or with the supervisory authority of the EU Member State in which he habitually resides, works or in the place where the alleged violation occurred.

GIVING CONSENT*

I consent to my personal data processing and those belonging to particular categories for clinical research activities related to the pathology for which I have contacted this Institute.	YES ❒ NO ❒
I consent to my personal data transfer and those belonging to particular categories outside the European Union for the research purposes within the limits and in the manner indicated in the information provided to me with this document.	YES ❒ NO ❒

** In the case of a minor, the consent is expressed by the parent(s) exercising parental responsibility.*

** In special cases, consent is given by the tutor/support administrator.*

TO CONSENT AND FINALIZE YOUR PARTICIPATION IN THE STUDY, IT'S MANDATORY TO CONFIRM YOUR IDENTITY. THERE ARE 2 OPTIONS:

1) SEND A COPY OF YOUR IDENTITY DOCUMENT ON THE OFFICIAL WHATSAPP NUMBER OF THE DF – DESMOID FOUNDATION – ITALIAN ASSOCIATION TUMORE DESMOIDE ONLUS: + 39 3518279997

2) PRINT THE PDF PRIVACY POLICY CONSENT AND SEND IT BACK SIGNED TO THE EMAIL info@desmoidfoudation.org OR TO DEDICATED WHATSAPP NUMBER + 39 3518279997

*** FAILURE TO SEND THE PHOTO OF YOUR IDENTITY DOCUMENT OR THE SIGNED PRIVACY POLICY CONSENT WILL RESULT IN EXCLUSION FROM THE CLINICAL STUDY**