CONSENT TO ACT AS A STUDY PARTICIPANT IN THE DESMOID TUMOR RESEARCH FOUNDATION PATIENT REGISTY AND TO SHARE DATA FOR FUTURE RESEARCH PURPOSES

Adult consent for Study Participants over age 18

Title: Desmoid Tumor Research Foundation Patient Registry

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Sponsor: The Desmoid Tumor Research Foundation

Key Information

You are invited to take part in a research study for individuals with Desmoid Tumor (s). We hope that this form will help you decide whether or not to participate, but you can also call or e-mail the study staff at the contacts above if you have any other questions.

Things you should know:

We are doing this research to collect data from Desmoid Tumor patients that will further the understanding of the disease, its course, and outcomes over time.

If you choose to participate, you will be asked to set up an account at dtrf.iamrare.org and begin completing online surveys from any web-enabled electronic device at any time. This will take approximately an hour or more depending on how many questions you answer and how much information you share.

While there are no physical risks, other potential risks include breach of confidentiality and mis-use of your data.

Participating in the study may not help you directly, but your time and information may help others with Desmoid Tumor (s) in the future.

It is up to you whether to participate in this study, and you can stop at any time. Please take time to read this entire form and ask questions before deciding whether to take part. Detailed information about your participation in this study follows.

Purpose of this Informed Consent Document

This document will give you the information so you can decide if you want to join this study or not. This consent document is structured to follow the framework provided by federal regulations. While we hope the information we provide will answer most of your questions, it may not answer them all. If you have any remaining questions, please contact the Principal Investigator at the phone number or e-mail listed above.

Definitions

For the purpose of enrolling in this registry, a legal adult is defined as a person who is at least 18 years of age, the age of majority in their state, province or country, and able to consent for themselves. On this Consent form, "Study Participant" refers to the person of legal age diagnosed with desmoid tumor(s) (also known as aggressive fibromatosis) who is able to enter information about themself. Registry information will be collected on patients who are diagnosed with desmoid tumor(s). "You" refers to the person reading this form and providing the information. The reference of "we" in this document refers to the research organization the Desmoid Tumor Research Foundation (DTRF). Institutional Review Board (IRB) is an independent group that reviews research proposals to make sure they properly protect participants.

Study Aims

The data collected in this Registry will be used by researchers to study desmoid tumors with the following objectives and goals:

1) To characterize and describe the desmoid tumor patient population as a whole and to gain a better understanding of the spectrum of clinical variants in individuals with desmoid tumors of all stages.
2) To understand the changes of desmoid tumors over a lifetime as well as to gain information on clinical practice patterns and variations over the course of treatment.
3) To facilitate the development of best practice and management guidelines and recommendations to optimize care, improve quality of life and outcomes and standards of care.
4) To provide information regarding ongoing research studies and clinical trials. Study Participants may consent to be contacted by researchers for recruitment into IRB approved studies.

How Your Data Gets Into the Registry

The data obtained from you for this Registry will be sent to the data bank along with the following information, which will be entered into a computer (the database) that is used for research purposes.

Data entered into the Registry may include, but is not limited to:

> Name, date of birth, diagnosis, treatment (past and proposed), general medical information, the CTNNB1 or the APC gene mutations (if known), blood level results, tumor location, number of recurrences, other tumor expression markers.

How You Provide Your Data

A patient Registry collects and stores patient medical information, family history and other relevant information for use in medical research. We will be asking you to give us your information by filling out surveys online and uploading medical documents related to your history and experience with Desmoid Tumor. We will store your information so that it can be combined and compared with information from others and used for research.

You always have access to the data you enter in the registry via the participant dashboard. You can also view charts and graphs derived from the combined data contributed to the registry by other Study Participants. This combined data will not reveal Study Participant identities.
We will ask you to enter your information using online surveys on a secure internet site.
At registration you were asked to provide basic information about yourself such as name, date of birth, and residence. That information will also be considered research data.

You will be asked about demographics such as race, ethnicity, and education status.
We will ask for specific information related to your history with the disease. This may include questions about diagnosis, treatment, genetic mutations, and lab results.

You will be asked to update your registry information at least once per year, and you may be asked to update some surveys more frequently. Periodically, The Desmoid Tumor Research Foundation may add additional new surveys for you to complete. We may contact you to remind you to update surveys, finish incomplete surveys, or complete outstanding surveys.

In addition to reminding you about surveys, we may ask you to upload new test results or other medical information and may contact you to clarify data you have entered. Registry staff may also notify you of major changes to the study or changes in the Institutional Review Board (IRB) of record. You can update your information in the registry whenever there is a change to your health, your treatment, or if you develop new symptoms.

We may reach out to you by phone or e-mail, and the registry may automatically generate reminders that will be sent to you by e-mail. After you agree to participate, you will be able to choose what kind of contacts you want to receive, like notice of opportunities to donate specimens or participate in other research studies. You will be able to change these preferences whenever you want by logging into your registry account.

You can view and revise your study opt-ins at any time by logging into your registry account. Select your name and the DTRF Patient Registry. Then, click the button labeled 'Consent/Opt-ins' followed by the button that says 'Opt-Ins'.

The registry cannot provide medical advice or answer specific medical questions. For resources that support people with Desmoid Tumor (s), please visit the Sponsor web site at dtrf.org. For medical assistance, contact your doctor's office.

How We Use Your Data

The goal of the Registry is to share medical and other desmoid tumor-relevant information with scientists and other researchers, while protecting the Study Participant's privacy.

When your information is stored, we are careful to try to protect your identity from discovery by others. Strict security safeguards are in place to reduce the chance of misuse or unplanned release of information.

Whenever possible, the researchers will use your information in a de-identified manner. De-identified means that the researchers will use your information without knowing your identity. In some cases, they may use some identifying information about you for research purposes which is subject to an approval process through the DTRF Patient Registry Advisory Board. At times, the researchers will use your information with a code, instead of your name; the code would allow results of the research to be linked back to you.

This registry is maintained by the National Organization for Rare Disorders, Inc. (NORD ®), a patient advocacy organization dedicated to individuals with rare diseases and the organizations that serve them. As owners of the IAMRARE platform, designated NORD staff will have access to all the data that you enter on the platform, including identifiable data. Identifiable data is any information that can link a participant to a research study and reveal their identity. Identifiable data may include information such as name, medical record numbers, and home address. It may also include indirect information that, when combined, may make it possible to identify a person. This would include information such as age, city, zip code, or gender. Some of this data will be used to set up a Global, Unique Identifier (GUID) for each Study Participant on the NORD platform. Information needed for this ID comes from your Participant profile. The GUID will help to link data across studies, within and outside of the NORD platform, without sharing your identifying information. Linking of data by using the GUID will only be done with approval of the Registry Advisory Board where it is scientifically important to the research. Please read the paragraphs that follow for additional information on how your data might be shared and how your identity is protected. In addition to platform maintenance activities, after notifying the DTRF, NORD may conduct IRB-approved research across different rare diseases using registry data. In all cases, your privacy will be protected in any publications using data from the registry.

The registry is overseen by the DTRF Patient Registry Advisory Board, a committee that may include scientists, doctors, and patients. The Advisory Board has been involved since the early planning of the registry and continues to advise on the development of surveys. They review any reported problems or breaches of confidentiality to make sure they are appropriately reported and resolved.

The Advisory Board is responsible for reviewing all applications or requests for registry data to be sure that the proposed project has scientific merit and will be valuable to the community. They will also be responsible for deciding what specific data will be given to researchers. This will be limited to only the data needed to answer their research question.

The Advisory Board will choose whether to release grouped data or individual data. No information that would directly link data to the participant will be included in the released data and the data will be de-identified. De-identification means your name, all dates and your address will be removed from the data, and only a randomly assigned identification code will be included.

Any researcher who applies to receive registry data will need to have their project approved by an IRB. The application requires that the researcher describes things such as the aims of the research, how the data will be analyzed, who the Principal Investigator is, and how they will protect the confidentiality of the data. They will need to sign a Data Confidentiality Agreement and promise not to share the data with anyone else. They must agree not to try and identify participants or share information in a way that people could be identified.

Outside researchers may ask the Advisory Board to advertise their study to registry participants for recruitment purposes. The registry staff will not give outside researchers your contact information. If this request is approved, the registry staff will provide you with study details and how to contact the researcher. It will be up to you if you decide to participate in this study or not. You can also decide not to receive information about outside studies by editing your opt-ins.

The Advisory Board may determine that it would be valuable to include the registry data on a data sharing platform. An example of this is the FDA-sponsored Rare Disease Cure Accelerator – Data and Analytics Platform (RDCA-DAP). Any data shared with a data sharing platform will be de-identified.

A member of the Advisory Board may conduct their own research outside of the registry. They may wish to have access to the data or inform participants of a clinical trial or research study in which they are personally involved. They are required to apply for access as an independent researcher. They will remove themselves from the discussion and voting process concerning their own research.

Risks and Inconveniences

There are no physical risks to you for allowing your data to be stored or used in future research studies. The registry surveys may ask questions that you find unpleasant or uncomfortable, such as the impact of Desmoid Tumor (s) on your daily life, your economic status, or mood. While some questions (marked with a red asterisk [*]) require responses, where the information may be sensitive, you can choose 'Prefer not to answer.'

As with any information you provide electronically, there is a risk of breach of confidentiality (see the How We Use Your Data section for an explanation of how your information is protected). In the event that there is a breach in the Registry's computer system, you will be notified.

There is a risk that your information could be misused. The Advisory Board reviews ongoing and new research to help prevent misuse. The chance of this happening is very small. We have protections in place to lower this risk. There can also be a risk in disclosing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Very rarely, employers, health insurance companies, and others could misuse health or genetic information. There is a federal law called the Genetic Information Nondiscrimination Act (GINA) that, in general, makes it illegal for health insurance companies, group health plans, and most employers, except those with fewer than 15 employees, to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. There may be other risks we are not aware of at this time.

Benefits

Participation in the Registry is voluntary and may not result in direct benefit to you (or the Study Participant) personally, medically or financially. However, we hope the research results will help people with desmoid tumors in the future. We hope that the information we learn in future research studies will increase our knowledge of human health and that this information will lead to better prevention, diagnosis and treatments in the future.

Alternative

You do not have to participate in this study, so your alternative is to say no.

Cost and Payment

It should not cost you anything to participate in the Desmoid Tumor Patient Registry other than the costs of internet access. You will not be paid for the information you provide. You will not receive any payments for allowing your information to be stored in the Registry.

Your information will only be used for research. Should one of the researchers use your medical information to develop a commercial product, you should not expect to receive any financial gain from these efforts.

Privacy Rights

Your participation in the DTRF Patient Registry is private. The DTRF will not inform unauthorized individuals that you are participating in this study. They will only contact you using the contact methods and information that you provide.

Confidentiality

You will be asked to provide two types of information in the registry. The first type of information includes details that can be used to identify you, such as your name, address, birthdate and sex. The other type of information includes details about your health and wellbeing that by themselves cannot be used to identify you. For example, questions may ask about a symptom or a treatment received.

All identifiable information that is provided to the registry will remain confidential. The DTRF and NORD staff will have access to this data as needed to provide registry support and maintenance.

Data may be provided to approved researchers. The goal is to provide these researchers with the minimum data necessary to accomplish their research study. When the results of research conducted with data from the registry are published or reported, no information that could identify you will be disclosed.

Representatives from NORD and the IRB that oversees this registry may review study records during auditing procedures. This is to ensure that the registry is protected according to regulations and policies. NORD staff may also access this registry to provide technical support. These representatives must keep all information confidential.

Voluntary Participation and Withdrawal

It is up to you whether or not you want to participate in this registry. If you choose not to, you won't be penalized in any way. You won't lose any benefits you might otherwise be entitled to, and your health care will not be affected. If you decide not to participate or choose to withdraw from the registry, that decision won't harm your relationship with your doctors, even if they are involved with the DTRF Patient Registry or with the Desmoid Tumor Research Foundation.

There may be other registries that serve individuals with Desmoid Tumor (s). You are free to provide data to any such registry instead of, or in addition to, the DTRF Patient Registry. There may be other research opportunities, including clinical trials, for individuals with Desmoid Tumor

(s). You may choose to participate in any research projects whether or not you participate in this registry.

If you choose to participate in the DTRF Patient Registry, that permission will not expire, but you can change your mind at any time. To withdraw from the registry, log into your registry account. Select your name and the DTRF Patient Registry. Then, click the button labeled 'Consent/Opt-ins' followed by the button that says 'Revoke'. You may also withdraw by contacting the registry staff directly by e-mail at: registry@dtrf.org.

Withdrawing your consent means that the registry will no longer contact you and that you will not be asked to submit new information. However, researchers may continue to use data that has already been shared by the registry and the registry will continue to share data that you provided before you withdrew. If you no longer want your data to be shared, even in a form that does not identify you, you should contact the registry directly by phone or e-mail, as described above, and request that your data be removed from the registry.

If You Live Outside the United States

The DTRF Patient Registry is maintained on servers that are physically present in Canada. For persons living outside the United States who choose to share information about themselves, the same protections for privacy and confidentiality are offered as in the United States; in addition, as explained below, residents of the European Union and Switzerland have additional rights related to personal information. By signing this consent, you acknowledge that you are disclosing information that would otherwise be private. Privacy laws in your country may have different protections than those provided in the United States.

For persons who are residents of the European Union and Switzerland, transfers of your personal information outside of the European Union and/or Switzerland, will comply with the General Data Protection Regulation under an appropriate transfer mechanism provided for by that regulation, including the use of standard data protection clauses adopted by the European Commission. Please be aware that, under the General Data Protection Regulation, the European Commission is permitted to issue a decision that the data protection laws of a third country are adequate to the protection of personal information and that, to date, the European Commission has not done so with respect to the United States.

For persons who are residents of the European Union and Switzerland, processing of personal information will also be undertaken in such a manner as to ensure the rights of data subjects provided for by the General Data Protection Regulation. Specifically, registry participants who are residents of the European Union and Switzerland are entitled to:

- Request to obtain access to and rectification or erasure of personal data;
- Receive personal data in a portable, readily-accessible format;
- Restrict or withdraw permission for the processing of personal information; or
- Lodge a complaint with an appropriate supervisory authority.

Please note that the rights to erase personal data or restrict or withdraw permission for the processing of personal information are subject to limitations provided for by Article 17 of the General Data Protection Regulation, namely, that such rights may be limited as necessary to protect the public interest in the area of public health or for archiving purposes in the public and scientific interest.

Getting Answers To Your Questions About The DTRF Patient Registry

We have used some technical terms in this form and talked about issues in research and data sharing with which you may not have been familiar. Take as long as you need to consider this information and decide if you want to share your personal and medical information with the registry. If you have any questions or want anything explained further, please contact the DTRF Patient Registry registry@dtrf.org or contact the PI, Kelly Mercier, Ph. D at kelly@dtrf.org. It is our responsibility to answer your questions.

An Institutional Review Board, for the purpose of protecting your rights, has reviewed this Registry. To discuss study-related concerns or complaints with someone who is not part of this registry team, please contact North Star Review Board at 877-673-8439 (toll free) or info@northstarreviewboard.org. You may want to contact the IRB if:

- You have questions about your rights as a Study Participant in this registry;
- You have questions, concerns, or complaints that are not being answered by the research team;
- You are not getting answers from the research team;
- You cannot reach the research team; or
- You want to talk to someone else about the research.

Please do not sign this form unless you have had all your questions answered.

Authorization

The following statements are intended to:

- Make sure that you have had the time and opportunity to consider whether you want to participate in this registry;
- Have had your questions answered; and
- Agree to participate in the study as described.

You will be asked to acknowledge:

- That you have read the consent form and have no further questions about the registry and your participation;
- That you wish to provide personal data to the registry for the purposes of the Study;

- That you allow for your data to be used for future research; and
- That you are of legal age.

This is a web-based form. Your digital signature is the same as if you had signed your name to a paper document. By answering "Yes" to all of the following statements, you are giving your consent to participate in the DTRF Patient Registry. After signing, a copy of the consent form will be e-mailed to you. If you cannot comfortably answer "Yes" to these statements, please do not check the consent boxes in the following section.

1. I have read this Consent and Authorization Form to provide my personal and medical data to be shared for the purpose of research. All my questions about the DTRF Patient Registry have been answered to my satisfaction, and I understand the purpose of the registry and the risks of participation.

   Yes ___ No ___

2. I wish to provide my research data to the DTRF Patient Registry for the purposes described above under Study Aims.

   Yes ___ No ___

3. I wish to provide my research data to the DTRF Patient Registry for future research within recognized ethical standards for scientific research, as described under How We Use Your Data.

   Yes ___ No ___

4. I acknowledge that I am at least 18 years of age, the age of majority in my state, province or country, and able to provide consent for myself.

   Yes ___ No ___

Permission for contact includes the following statements:

- Interest in hearing about other studies from the Desmoid Tumor Research Foundation
- Interest in hearing about clinical trials
- Interest in donating specimens or DNA (biobanking) for future research
- Interest in genetic testing
- Interest in learning more about the Desmoid Tumor Research Foundation
- Interest in signing up for a Desmoid Tumor Research Foundation patient newsletter