Consent to Participate in the Fibrous Dysplasia and McCune-Albright Syndrome Patient Registry And to Share Data for Future Research Purposes

Adult consent for Study Participants over age 18

Title: Fibrous Dysplasia and McCune Albright Syndrome Patient Registry

Principal Investigator: Kiran Murty

Telephone: 917-513-2169 (24 Hours)

Address: **Fibrous Dysplasia Foundation**
2885 Sanford Ave SW #40754
Grandville, MI 49418

Experimental Research Subjects Bill of Rights

California law, under Health & Safety Code 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. The list includes the right to:

1. **Be informed of the nature and purpose of the experiment.**

2. **Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.**

3. **Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.**

4. **Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.**

5. **Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.**

6. **Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.**

7. **Be given an opportunity to ask any questions concerning the experiment or the procedures involved.**

8. **Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.**

9. **Be given a copy of the signed and dated written consent form.**

10. **Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.**

Definitions

For the purpose of this Consent form, "Study Participant" refers to the person diagnosed with fibrous dysplasia or McCune Albright Syndrome (FD/MAS). Registry information will be collected on patients who are diagnosed with FD/MAS. "You" refers to the person providing the information. The reference of "we" in this document refers to the research organization Fibrous Dysplasia Foundation.

Research Data Sharing

A patient Registry collects and stores patient medical information, family history and other relevant information for use in medical research.

You are invited to provide personal and medical information in an online questionnaire format by answering surveys and uploading medical information. This data and related information is to be stored (banked) in a research data database or Registry where it can be used for future research projects. The data collected in this Registry will be used by researchers to study FD/MAS with the following objectives and goals:

1) Develop an understanding of the form FD/MAS takes in the population, including the scope of medical symptoms patients experience, the disease progression, and how the disease impacts the patient's quality of life.
2) Understand how FD/MAS is currently being diagnosed and treated, including monitoring practices, and how particular treatments affect health outcomes.
3) Understand the economic burden of FD/MAS on patients and their families as well as other barriers to care.

4) Identify what doctors need to know about patients and caretakers, what caretakers need to know about doctors and patients, and what patients need to know about caretakers and doctors.
5) Provide information to researchers that can be used to develop clinical effectiveness research, clinical trials or other research.
6) Provide a convenient online platform for patients and/or caregivers to learn about other opportunities to be involved in research or clinical trials.
7) Support the FD/MAS medical community in developing clinical recommendations and standards of care for patients.

In order to decide whether or not you wish to allow your data to be used for future research, you should know about the risks and benefits to make an informed decision. This form gives you information about the Registry and how the data may be used. Once you understand the data collection and sharing process, you will be asked if you wish to take part; if so, you will be asked to electronically agree to participate.

The Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is sponsored by the Fibrous Dysplasia Foundation (FDF) and there is no cost to you to participate. The registry is on a platform provided by the National Organization for Rare Disorders (NORD). The FDF owns and controls what happens to the data in the registry. In the unforeseeable event that the FDF would not be able to continue the FD/MAS Repository program the study will be considered to have ended. All *de-identified* data (defined below) previously transferred to the National Organization for Rare Disorders (NORD) will be maintained and will be governed by existing Informed Consent language; all *identifiable* and *re-identified* information will be destroyed.

The Principal Investigator (PI) for the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is a member of the Board of Directors, Kiran Murty. He is supported by the following sub-PIs who also function collectively as the Registry Oversight Committee: Dr. Alison Boyce, Dr. Andrea Burke, Cindi Brandt Levin and Amanda Konradi, PhD. The PI and sub-PIs are subject to change; however, the PI will always be on the Board of Directors of the Fibrous Dysplasia Foundation and sub-PIS always will be closely affiliated with the FDF. Should the PI or sub-PIs change, all participants will be informed of the change.

How Your Data Gets Into the Registry

The data obtained from you for this Registry will be sent to the registry by you, via upload, data entry, and other forms of communication. This data will include your name, date of birth, diagnosis, treatment information, general medical information and other information. Study coordinators may edit your records or add notes or comments to your records based on the data you've supplied or authorized to be shared with the study.

How Your Data Is Stored and Used for Future Research

The goal of the Registry is to share medical and other FD/MAS-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, subject to an approval process through the FD/MAS Advisory Committee. 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.

All data that you provide will be stored on secured computers and servers and protected with encryption and passwords. Although we take measures to protect your privacy and confidentiality, because your disease is rare, there is a small risk you may be identifiable from the information in the registry.

Risks and Inconveniences

There are no physical risks to you for allowing your data to be stored or used in future research studies. In the unlikely event that someone outside the research team views your information however, there is a risk of breach of confidentiality (see the Confidentiality 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 chance of this happening is very small. We have protections in place to lower this risk. There can also be a risk in uncovering 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 not likely to benefit you personally, medically or financially. However, participation may help members of your family and others with fibrous dysplasia and McCune Albright Syndrome or other diseases by increasing the understanding of your disease/condition and other diseases. Having an available registry of information about fibrous dysplasia and McCune Albright Syndrome may help speed up research, such research could eventually help researchers to learn whether or how treatments work, or help medical professionals improve how they treat the disease. Participants may also receive information about opportunities

to participate in research and clinical trials, as well as information about medical advances and other news from the registry.

Alternative

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

Economic Considerations

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.

Confidentiality

All identifiable information that is obtained in connection with this Registry will remain confidential. The Registry aims to share detailed medical and other information with researcher while protecting your privacy. One way the Registry protects your information is to remove your name, address and other "identifying" information from our medical information before providing it to researchers. This information is "de-identified" because it has had all the personal identifiers removed including your name, address, or other information that identifies you or your family. Your Registry information will be labeled with a code number and stored on secured computers and servers and protected with encryption and passwords. Only authorized people who work in the Registry will have access to the key to the code and will be able to identify you if needed. When the results of future research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent is obtained. The Registry will not share your identifiable information with anyone outside the Registry (unless you give permission to share it). Approved researchers and clinicians will be allowed to see only the de-identified information. Approved researchers and clinicians may use de-identified information to conduct research, including research unrelated to FD/MAS. They may also search the de-identified information to find patients for their studies. If a patient looks like a good match for a researcher's study, the Fibrous Dysplasia Foundation Registry or Registry's agent will contact you if you have given us permission to contact you about research studies.

Your de-identified Fibrous Dysplasia and McCune Albright Syndrome Patient Registry information may be shared with other databases such as the Global Rare Disease Patient Registry Data Repository (GRDR). This will allow more researchers to use the information to do research. The de-identified information collected and compiled by the Registry belongs to the FD/MAS community. The Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is the guardian of the information contained within the Registry.

Third parties may seek access to data in the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry. Third parties may include, but are not limited to, researchers or companies conducting retrospective studies or conducting research and/or clinical trials on new therapies.

Third parties will only be granted access to registry information upon review and approval of the Advisory Board. Such approvals shall be obtained prior to providing access to registry information; shall be based upon considerations of scientific quality and validity; shall be granted for research studies related to FD/MAS; and shall be documented. Third parties seeking access to registry information for retrospective studies will only have access to anonymous information identifiable only by the assigned unique identifier. Third parties seeking access to registry information for the purpose of determining eligibility for participation in a research study or clinical trial must demonstrate evidence of IRB approval of the research study for which access is being requested. Before any data is released, researchers must first apply to the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry Oversight Committee. This committee will review the project for its reliability and validity and compliance with ethical principles.

You will be asked to update your Registry information periodically by completing questionnaires, called surveys. You may be asked to update some surveys more frequently. Based upon your preference for how you would prefer to be contacted, the Registry will contact you to remind you to update your data. The Registry may also ask you to upload your genetic test results and other blood work or test results. Your Registry account can be updated whenever there is a change in your health, change in treatment, or new symptom.

Research results will not be returned to you or your doctor. If research results are published, your name and other personal information will not be given.

Representatives from the National Institutes of Health, Food and Drug Administration, NORD or Hummingbird IRB may inspect study records during auditing procedures to be sure that the Registry is being protected according to regulations and policies. However, these individuals are required to keep all information confidential.

User Submitted Content

NORD and the Fibrous Dysplasia Foundation have the right to edit and delete any portion of the Website.

Use of the Data/Information Contained on the Website

All data collected by NORD and Fibrous Dysplasia Foundation may be combined and shared with other NORD organizations or outside researchers. You are responsible for the accuracy of the data and its content. NORD and its affiliated organization will protect the data to the extent possible and as described in this consent.

Consent from International Users of the Platform

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. 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.

Voluntary Participation and Withdrawal

Participating in this Registry is voluntary. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled, (such as your health care outside the study, the payment for your health care, and your health care benefits). You are free to choose not to allow your data to be used in research and if you do decide to participate, you are free to change your mind at any time, but the researchers may still use the data shared with them before you changed your mind in order to complete the research that has already started. The researchers will anonymize the data by archiving all identifiers and links to identifiers so that it cannot be associated with you, but the researchers will not destroy the data. Information that has already been shared with the GRDR or sent to an external research project for a specific study prior to your request for removal cannot be retrieved, removed or altered.

If you withdraw your permission or do not wish to participate, this will involve no penalty or loss of benefits to which you are otherwise entitled. This will not harm your relationship with your doctors who may be involved with the Registry or FD/MAS.

This form and your permission will never expire unless you change your mind and withdraw it. You may withdraw your permission by telling the Registry staff in writing to:

Kiran Murty
registry@fibrousdysplasia.org
Fibrous Dysplasia Foundation
2885 Sanford Ave. SW #40754
Grandville, MI 49418

Privacy Rights

The health-related information that we gather about you in this study is personal. The researchers are required by law to protect the privacy of information known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of your PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a possibility that information about you could be used or disclosed in a way that it will no longer be protected.

By signing this form, you give permission for the Registry to store and use and/or disclose the information in this Registry database. You have a right to refuse to participate. Your health care outside the study, the payment for your health care, and your health care benefits will not be affected if you do not sign this form. You do not give up any of your legal rights by agreeing to participate in this registry.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider sharing your information and the consent form carefully – as long as

you feel is necessary – before you make a decision. Please contact the Registry staff as listed above.

An Institutional Review Board, for the purpose of protecting your rights, has reviewed this Registry. An institutional review board is a group of people who are responsible for protecting the rights and welfare of people who participate in studies. For questions about your rights as a Study Participant in this Registry or to discuss other study related concerns or complaints with someone who is not part of the Registry team, you may contact Hummingbird IRB at 1-855-447-2123 (toll free). Review and approval of this Registry by Hummingbird IRB is not an endorsement of the Registry or its outcome.

Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

I want to be involved in a clinical trial. If I register, is this guaranteed?
Although one of the main goals of the registry is to make it easier for patients to participate in clinical research, there is no guarantee that an individual patient will be eligible for a particular trial or contacted about a clinical trial. Even if you are contacted about possible eligibility based on your information in the registry, you may or may not meet the study requirements.

Please also be aware that if the registry informs you about a trial, this does not imply that the registry endorses it. Each study you enroll in will require that you sign an informed consent form for that study. Please make sure to thoroughly discuss any study you are considering with the research staff before signing its informed consent form.

I don't want to be involved in a clinical trial. Should I still register?

Absolutely. We hope that you are still willing to register even if you don't want to take part in a clinical trial. Your information may be useful to researchers who are trying to learn more about patients with Fibrous Dysplasia and McCune Albright Syndrome.

Authorization

I have read (or someone has read to me) this Consent and Authorization Form to provide data for future research purposes and have decided to donate my data to the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry. The general purposes of registry participation, details of my involvement and possible hazards and inconveniences have been explained to my satisfaction. By checking "yes" to the choices below, I give permission for the described uses and disclosures of my information. I understand that I will receive an electronic a copy of this consent/authorization form.

Because of the way data is collected and saved, to participate in this study, the participant or person agreeing must be willing to agree to permitting data to be shared as described. If you cannot agree to this, please do not participate in the study.

CHECK all that apply

I am authorized to submit information to this registry because the information is about me, I am an adult eighteen years of age or older, and I do not have a legal guardian.	Yes ☐ No ☐
I understand that participation in the registry is voluntary and that I can decide to withdraw at any time.	Yes ☐ No ☐
I understand that the registry consists of independent surveys and I am under no obligation to complete them all.	Yes ☐ No ☐
I am willing to regularly be contacted by the registry to update or correct my health information.	Yes ☐ No ☐
I understand that my personal information will be protected and saved in the registry using a code. However, there is a very small risk that my identity could be revealed.	Yes ☐ No ☐
I am willing to provide my *de-identified* information to be shared with other databases such as the Global Rare Disease Patient Registry Data Repository (GRDR).	Yes ☐ No ☐
I understand that my *identifiable* information will not be released unless the Registry staff contact me to obtain my consent.	Yes ☐ No ☐
I understand that I am under no obligation to participate in other studies, should I be contacted to give consent.	Yes ☐ No ☐
I understand that I may not personally benefit from participating in the registry or from the use of de-identified medical information in any research study.	Yes ☐ No ☐
I understand that I can withdraw from the registry at any time and archive my identifiable information.	Yes ☐ No ☐
I also understand that any of my information provided to researchers before withdrawing cannot be removed.	Yes ☐ No ☐
I understand that I will be informed if there is any breach in the computer systems that contain my data.	Yes ☐ No ☐
I understand that the questions I am asked may make me uncomfortable.	Yes ☐ No ☐
I understand that my participation in the registry does not guarantee my involvement in any clinical trials.	Yes ☐ No ☐
I understand that I can obtain further information about the study by contacting registry@fibrousdysplasa.org or PI.registry@fibrousdysplasia.org.	Yes ☐ No ☐

I understand that I can inquire about my rights as a participant in the registry by contacting Hummingbird IRB: info@HummingbirdIRB.com	Yes ☐ No ☐
I wish to consent to participate in the Registry.	Yes ☐ No ☐

Consent to Participate in the Fibrous Dysplasia and McCune-Albright Syndrome Patient Registry
and to Share
Data for Future Research Purposes

Consent for persons with a Legally Authorized Representative (LAR) who is unable to consent for him or herself

Title: Fibrous Dysplasia and McCune Albright Syndrome Patient Registry

Principal Investigator: Kiran Murty

Telephone: 917-513-2169 (24 Hours)

Address: **Fibrous Dysplasia Foundation**
2885 Sanford Ave SW #40754
Grandville, MI 49418

Experimental Research Subjects Bill of Rights

California law, under Health & Safety Code 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent. The list includes the right to:

1. **Be informed of the nature and purpose of the experiment.**

2. **Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.**

3. **Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.**

4. **Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.**

5. **Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.**

6. **Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.**

7. **Be given an opportunity to ask any questions concerning the experiment or the procedures involved.**

8. **Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.**

9. **Be given a copy of the signed and dated written consent form.**

10. **Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.**

As the guardian or authorized representative for the participant, we encourage you to discuss the registry with the participant to the extent compatible with their understanding. If the participant has any questions about the registry, please feel free to contact the registry staff.

Definitions

For the purpose of this Consent form, "Study Participant" refers to the person diagnosed with fibrous dysplasia or McCune Albright syndrome FD/MAS. Registry information will be collected on patients who are diagnosed with FD/MAS. "You" refers to the person providing the information, who may be a family member or guardian who is legally responsible for the care and health of the patient. The family member or guardian inputting survey responses on behalf of the Study Participant is referred to as the respondent. The reference of "we" in this document refers to the research organization, Fibrous Dysplasia Foundation.

Research Data Sharing

A patient registry collects and stores patient medical information, family history and other relevant information for use in medical research.

On behalf of the Study Participant, you are invited to provide personal and medical information in an online questionnaire format by answering surveys and uploading medical information. This data and related information is to be stored (banked) in a research data database or Registry where it can be used for future research projects. The data collected in this Registry will be used by researchers to study FD/MAS with the following objectives and goals:

1) Develop an understanding of the form FD/MAS takes in the population, including the scope of medical symptoms patients experience, the disease progression, and how the disease impacts the patient's quality of life.
2) Understand how FD/MAS is currently being diagnosed and treated, including monitoring practices, and how particular treatments affect health outcomes.
3) Understand the economic burden of FD/MAS on patients and their families as well as other barriers to care.
4) Identify what doctors need to know about patients and caretakers, what caretakers need to know about doctors and patients, and what patients need to know about caretakers and doctors.
5) Provide information to researchers that can be used to develop clinical effectiveness research, clinical trials or other research.
6) Provide a convenient online platform for patients and/or caregivers to learn about other opportunities to be involved in research or clinical trials.
7) Support the FD/MAS medical community in developing clinical recommendations and standards of care for patients.

In order to decide whether or not you, on behalf of the Study Participant, wish to allow the Study Participant's data to be used for future research, you should know about the risks and benefits to make an informed decision. This form gives you information about the Registry and how the data may be used. Once you understand the data collection and sharing process, you will be asked if you, on behalf of the Study Participant, wish to take part; if so, you will be asked to electronically agree to participate.

The Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is sponsored by the Fibrous Dysplasia Foundation (FDF) and there is no cost to you to participate. The registry is on a platform provided by the National Organization for Rare Disorders (NORD). The FDF owns and controls what happens to the data in the registry. In the unforeseeable event that the FDF would not be able to continue the FD/MAS Repository program the study will be considered to have ended. All *de-identified* data (defined below) previously transferred to the National Organization for Rare Disorders (NORD) will be maintained and will be governed by existing Informed Consent language; all *identifiable* and *re-identified* information will be destroyed.

The Principal Investigator (PI) for the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is a member of the Board of Directors, Kiran Murty. He is supported by the following sub-PIs who also function collectively as the Registry Oversight Committee: Dr. Alison Boyce, Dr. Andrea Burke, Cindi Brandt Levin and Amanda Konradi, PhD. The PI and sub-PIs are subject to change; however, the PI will always be on the Board of Directors of the Fibrous Dysplasia Foundation and sub-PIS always will be closely affiliated with the FDF. Should the PI or sub-PIs change, all participants will be informed of the change.

How Study Participant Data Gets Into the Registry

The data obtained from you, on behalf of the Study Participant for this Registry will be sent to the registry by you, via upload, data entry, and other forms of communication. This data will include

your name, date of birth, diagnosis, treatment information, general medical information and other information. Study coordinators may edit your records or add notes or comments to your records based on the data you've supplied or authorized to be shared with the study.

How Study Participant Data Is Stored and Used for Future Research

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

When the Study Participant's information is stored, we are careful to try to protect the Study Participant's 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 the Study Participant's information in a de-identified manner. De-identified means that the researchers will use the Study Participant's information without knowing his/her identity. In some cases, they may use some identifying information about the Study Participant for research purposes, subject to an approval process through the FD/MAS Advisory Committee. At times, the researchers will use the information with a code, instead of the Study Participant's name; the code would allow results of the research to be linked back to the Study Participant.

All data that you provide will be stored on secured computers and servers and protected with encryption and passwords. Although we take measures to protect your privacy and confidentiality, because your disease is rare, there is a small risk you may be identifiable from the information in the registry.

Risks and Inconveniences

There are no physical risks to you or the Study Participant for allowing the Study Participant's data to be stored or used in future research studies. In the unlikely event that someone outside the research team views the Study Participant's information however, there is a risk of breach of confidentiality (see the Confidentiality section for an explanation of how the 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 the Study Participant's information could be misused. The chance of this happening is very small. We have protections in place to lower this risk. There can also be a risk in uncovering genetic information. New health information about inherited traits that might affect the Study Participant or his/her 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 the Study Participant based on his/her genetic information. However, it does not protect the Study Participant 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 not likely to benefit you (or the Study Participant) personally, medically or financially. However, participation may help members of the Study Participant's family and others with fibrous dysplasia and McCune Albright Syndrome or other diseases by increasing the understanding of the Study Participant's disease/condition and other diseases. Having an available registry of information about fibrous dysplasia and McCune Albright Syndrome may help speed up research, such research could eventually help researchers to learn whether or how treatments work, or help medical professionals improve how they treat the disease. Participants may also receive information about opportunities to participate in research and clinical trials, as well as information about medical advances and other news from the registry.

Alternative

On behalf of the Study Participant, you do not have to participate in this study so your alternative is to say "no".

Economic Considerations

Neither you nor the Study Participant will receive any payments for allowing the Study Participant's information to be stored in the Registry.

The Study Participant's information will only be used for research. Should one of the researchers use the Study Participant's medical information to develop a commercial product, neither you nor the Study Participant should expect to receive any financial gain from these efforts.

Confidentiality

All identifiable information that is obtained in connection with this Registry will remain confidential. The Registry aims to share detailed medical and other information with researchers while protecting the Study Participant's privacy. One way the Registry protects the Study Participant's information is to remove his/her name, address and other "identifying" information from our medical information before providing it to researchers. This information is "de-identified" because it has had all the personal identifiers removed including the Study Participant's name, address, or other information that identifies the Study Participant or the Study Participant's family. The Study Participant's Registry information will be labeled with a code number and stored on secured computers and servers and protected with encryption and passwords. Only authorized people who work in the Registry will have access to the key to the code and will be able to identify you or the Study Participant if needed. When the results of future research are published or discussed in conferences, no information will be included that would reveal you the Study Participant's identity unless your specific consent is obtained. The Registry will not share your or the Study Participant's identifiable information with anyone outside the Registry (unless you give permission to share it). Approved researchers and clinicians will be allowed to see only the de-identified information. Approved researchers and clinicians may use de-identified information to conduct research, including research unrelated to FD/MAS. They may also search

the de-identified information to find patients for their studies. If a patient looks like a good match for a researcher's study, the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry or Registry's agent will contact you if you have given us permission to contact you about research studies.

Your and the Study Participant's de-identified FD/MAS Registry information may be shared with other databases such as the Global Rare Disease Patient Registry Data Repository (GRDR). This will allow more researchers to use the information to do research. The de-identified information collected and compiled by the Registry belongs to the FD/MAS community. The Fibrous Dysplasia and McCune Albright Syndrome Patient Registry is the guardian of the information contained within the Registry.

Third parties may seek access to data in the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry. Third parties may include, but are not limited to, researchers or companies conducting retrospective studies or conducting research and/or clinical trials on new therapies. Third parties will only be granted access to registry information upon review and approval of the Advisory Board. Such approvals shall be obtained prior to providing access to registry information; shall be based upon considerations of scientific quality and validity; shall be granted for research studies related to FD/MAS; and shall be documented. Third parties seeking access to registry information for retrospective studies will only have access to anonymous information identifiable only by the assigned unique identifier. Third parties seeking access to registry information for the purpose of determining eligibility for participation in a research study or clinical trial must demonstrate evidence of IRB approval of the research study for which access is being requested. Before any data is released, researchers must first apply to the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry Oversight Committee. This committee will review the project for its reliability and validity and compliance with ethical principles.

You will be asked to update your and the Study Participant's Registry information at least once per year by completing questionnaires, called surveys. You will be asked to update some surveys more frequently. Based upon your preference for how you would prefer to be contacted, the Registry will contact you to remind you to update your and the Study Participant's data. The Registry may also ask you to upload the Study Participant's genetic test results and other blood work or test results. Your Registry account can be updated whenever there is a change in the Study Participant's health, change in treatment, or new symptom.

Research results will not be returned to you or the Study Participant's doctor. If research results are published, your and the Study Participant's name and other personal information will not be given.

Representatives from the National Institute of Health, Food and Drug Administration, National Organization of Rare Disorders and from Hummingbird IRB may inspect study records during auditing procedures to be sure that the Registry is being protected according to regulations and policies. However, these individuals are required to keep all participant information confidential.

Voluntary Participation and Withdrawal

Participating in this Registry is voluntary. Refusing to participate will involve no penalty or loss of benefits to which you/the Study Participant are otherwise entitled, (such as health care outside the study, the payment for your health care, and health care benefits). On behalf of the Study Participant you are free to choose not to allow the the Study Participant's data to be used in research and if the Study Participant does participate, you are free to change your mind at any time, on behalf of the Study Participant, but the researchers may still use the information collected before you changed your mind in order to complete the research that has already started If you remove your permission, the researchers will anonymize the data by archiving all identifiers and links to identifiers so that it cannot be associated with you or the Study Participant, but the researchers will not destroy the data.. Information that has already been shared with the GRDR or sent to a researcher for a specific study prior to your request for removal cannot be retrieved, removed or altered.

If you withdraw your permission or decide against participation, this will involve no penalty or loss of benefits to which you/or the Study Participant are otherwise entitled. This will not harm your or the Study Participant's relationship with the Study Participant's doctors who may be involved with the Registry or FD/MAS.

This form and your permission will never expire unless you change your mind and withdraw it. You may withdraw your permission by telling the Registry staff in writing to:

Kiran Murty
registry@fibrousdysplasia.org
Fibrous Dysplasia Foundation
2885 Sanford Ave. SW #40754
Grandville, MI 49418

Participation of minors and adults unable to consent

Registry information will be collected on patients who are diagnosed with a form of FD/MAS. Patients over the age of 18 who understand the consent form and legally provide their own consent (and thus do not have a legal guardian) are eligible to join the Registry on their own. Otherwise, the legal guardian or parent of the patient must sign the consent form for the patient to join. When a minor Study Participant becomes 18 (and if they are able), consent will be obtained directly from them for continued participation.

Privacy Rights

The health-related information that we gather about the Study Participant in this study is personal. The researchers are required by law to protect the privacy of information known as protected health information (PHI). All reasonable efforts will be made to protect the confidentiality of the Study Participant's PHI, which may be shared with others to support this research, to conduct public health reporting, and to comply with the law as required. Despite these protections, there is a

possibility that information about you could be used or disclosed in a way that it will no longer be protected.

By agreeing to participate in this registry. you give permission on behalf of the Study Participant for the Registry to store and use and/or disclose the information in this Registry database. You have a right to refuse to participate. The Study Participant's health care outside the study, the payment for his/her health care, and his/her health care benefits will not be affected if you do not sign this form. You do not give up any of your or the Study Participant's legal rights by signing this form.

User Submitted Content

NORD and Fibrous Dysplasia Foundation have the right to edit and delete any portion of the Website.

Use of the Data/Information Contained on the Website

All data collected by NORD and the Fibrous Dysplasia Foundation may be combined and shared with other NORD organizations or outside researchers. You are responsible for the accuracy of the data and its content. NORD and its affiliated organization will protect the data to the extent possible and as described in this consent.

Consent from International Users of the Platform

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. 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.

GETTING ANSWERS TO YOUR QUESTIONS ABOUT THE STUDY

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider sharing your/the Study Participant's information and the consent form carefully – as long as you feel is necessary – before you make a decision. Please contact the Registry staff as listed above.

An Institutional Review Board, for the purpose of protecting your/the Study Participant's rights, has reviewed this Registry. An institutional review board is a group of people who are responsible for protecting the rights and welfare of people who participate in studies. For questions about the rights of the Study Participant in this Registry or to discuss other study related concerns or complaints with someone who is not part of the Registry team, you may contact Hummingbird IRB at 1-855-447-2123 (toll free). Review and approval of this Registry by Hummingbird IRB is not an endorsement of the Registry or its outcome.

Do not agree to participate unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

The Study Participant wants to be involved in a clinical trial. If I register, on behalf of the Study Participant, is this guaranteed?

Although one of the main goals of the registry is to make it easier for patients to participate in clinical research, there is no guarantee that an individual patient will be eligible for a particular trial or contacted about a clinical trial. Even if you are contacted on behalf of a Study Participant about possible eligibility based on information in the registry, the Study Participant may or may not meet the study requirements.

Please also be aware that if the registry informs you about a trial, this does not imply that the registry endorses it. Each study you enroll in on behalf of the Study Participant will require that you sign an informed consent form for the Study Participant for that study. Please make sure to thoroughly discuss any study you are considering on behalf of the Study Participant with the research staff before signing its informed consent form.

The Study Participant does not want to be involved in a clinical trial. Should I still register on behalf of the Study Participant?

Absolutely. We hope that you are still willing to register on behalf of the Study Participant even if the Study Participant does not want to take part in a clinical trial. The information you provide on behalf of the Study Participant may be useful to researchers who are trying to learn more about patients with Fibrous Dysplasia and McCune Albright Syndrome.

Authorization

I have read (or someone has read to me) this Consent and Authorization Form to provide data for future research purposes and have decided to allow the Study Participant's data to be included in the Fibrous Dysplasia and McCune Albright Syndrome Patient Registry. The general purposes of registry participation, details of involvement and possible hazards and inconveniences have been explained.. By agreeing to the choices below, I give permission on behalf of the Study Participant for the described uses and disclosures of the Study Participant's information. I understand that I will receive a copy of this consent/authorization form.

Because of the way data is collected and saved, to participate in this study, the participant or person agreeing must be willing to agree to permitting data to be shared as described. If you cannot agree to this, please do not participate in the study.

Please reference the following sections of the consent form for details on how data collected in this study will be used.

- How Study Participant Data gets into the registry
- How Study Participant Data is stored and used for future research
- Confidentiality

- Voluntary Participation and Withdrawal
- Privacy Rights

CHECK all that apply

I am authorized to submit information to this registry, either because the information is about someone for whom I am the legal guardian or parent.	Yes ☐ No ☐
I understand that participation in the registry is voluntary and that I can decide to withdraw at any time.	Yes ☐ No ☐
I understand that the registry consists of independent surveys and I am under no obligation, on behalf of the patient, to complete them all.	Yes ☐ No ☐
I am willing to regularly be contacted by the registry to update or correct the patient's health information.	Yes ☐ No ☐
I understand that the patient's personal information will be protected and saved in the registry using a code. However, there is a very small risk that the patient's identity could be revealed.	Yes ☐ No ☐
I am willing to provide the patient's *de-identified* information to be shared with other databases such as the Global Rare Disease Patient Registry Data Repository (GRDR).	Yes ☐ No ☐
I understand that the patient's *identifiable* information will not be released unless the Registry staff contact me to obtain my consent.	Yes ☐ No ☐
I understand that the patient is under no obligation to participate in other studies, should I be contacted to give consent.	Yes ☐ No ☐
I understand that the patient may not personally benefit from participating in the registry or from the use of de-identified medical information in any research study.	Yes ☐ No ☐
I understand that I can withdraw the patient from the study at any time and archive our identifiable information.	Yes ☐ No ☐
I also understand that any of the patient's information provided to researchers before withdrawing cannot be removed.	Yes ☐ No ☐
I understand that I will be informed if there is any breach in the computer systems that contain the patient's data.	Yes ☐ No ☐
I understand that the questions I am asked may make me or the patient uncomfortable.	Yes ☐ No ☐
I understand that my participation in the registry does not guarantee my involvement or the patient's involvement in any clinical trials.	Yes ☐ No ☐

I understand that I can obtain further information about the study by contacting registry@fibrousdysplasa.org or PI.registry@fibrousdysplasia.org.	Yes ☐ No ☐
I understand that I can inquire about my rights or the patient's rights as a participant in the registry by contacting the Hummingbird IRB: info@HummingbirdIRB.com	Yes ☐ No ☐
I wish to consent for the patient to participate in the Registry.	Yes ☐ No ☐