

**RESEARCH PARTICIPANT INFORMATION AND
CONSENT TO PARTICIPATE IN FTD REGISTRY RESEARCH
Part 1 – Understanding your Participation (Canada)**

TITLE: FTD Disorders Registry: Implementation of a web-based patient and caregiver research registry for Frontotemporal degenerative disorders

PROTOCOL NO.: FTDDR-001v1
WIRB® Protocol #20160472

SPONSOR: FTD Disorders Registry, LLC

INVESTIGATOR: Dianna K. Hughbanks-Wheaton, MS, PhD, CHES
FTD Disorders Registry, LLC
637 Carolina St.
San Francisco, California 94107
United States

**STUDY-RELATED
PHONE NUMBER(S):** Dianna K. Hughbanks-Wheaton, MS, PhD, CHES
888-840-9980 (Monday – Friday 8:30 AM to 5:30 PM; Central Time)

You are being asked to take part in research as part of your enrollment in the FTD Disorders Registry. The purpose of FTD Registry research is to improve our understanding of Frontotemporal Degeneration (FTD) disorders, increase awareness, and promote additional research.

You are being asked to participate in research because you are an individual diagnosed with an FTD disorder, or you are a caregiver or family member of a person diagnosed with one of the FTD disorders.

The following information is provided to help you understand the purpose of FTD Registry research. Please take your time to read the information carefully, if you have questions please contact the Registry Director at director@ftdregistry.org or 888-840-9980.

What is a Registry?

A Registry is an electronic database of information about individuals with a specific disorder or medical condition. Registries are often created by patient groups, researchers, or medical professionals to collect information into a central location.

What is the FTD Disorders Registry?

The FTD Registry will collect information from people diagnosed with FTD, their caregivers and family members. Participation in research is voluntary. If you choose to participate in this study you may withdraw at any time. Research will include surveys to help us understand disease impact on persons diagnosed and their families. Research may also include studies by clinicians and scientists who want to analyze data stored in the registry, submit their own surveys, or gather information for clinical trial planning. All participant data will be 'de-identified' (made anonymous) by removing your name or other personal identifiers and replacing with a code.

How does the Registry de-identify your information?

To register, you create a research account with a login name and a password. Next you will fill out an online form that asks for your legal name at birth, date of birth (year, month, day), city of birth, and physical gender at birth. This information is used to assign a Global Unique Identifier (GUID) that is an alpha-numeric code. The GUID replaces your personal contact information and is linked to your data so that it is now de-identified. Only the Registry Director has access to this code and your contact information.

The Registry will not maintain nor report data in a way that an individual can be identified by their answer. Groups of de-identified data will be combined (called 'aggregate data') for analysis. This aggregate data will be available to the community and to researchers.

You will be asked to update your Registry information at least once per year or a change in your status.

In order to complete your profile, you may be asked by the Registry Director to login and respond to unanswered questions in the survey or upload information. If the Registry Director is unable to reach you for updates, your account may become inactive.

Your participation in this registry has no set time limit. You can stop participating in the registry at any time.

Am I eligible to participate in Registry research?

To participate, you must be a person diagnosed with an FTD disorder, a family member of someone diagnosed with FTD, or caregiver of a person diagnosed with FTD. You must be at least 18 years old (19 in those states or provinces where the age of majority is 19). If you live in British Columbia or Quebec, the subject must be the one who provides consent.

What will happen if I take part in Registry research?

If you agree to participate in Registry research you will be asked to complete a series of 3 intake surveys. The surveys will ask about things like when were you diagnosed with FTD, what impact the disease has had on you or your family, what tests you are willing to take if you enroll in a clinical trial. These basic intake surveys will take less than 30 minutes each to complete for most people. The intake surveys will create an FTD profile for you in the Registry database. You may be asked to participate in additional research surveys based on your FTD profile.

As a research participant you may also be invited to participate in additional study activities, these additional studies may have a separate consent form and will be explained in detail so that you may determine if you would like to be part of it.

The FTD Disorders Registry is not a treatment study. Your alternative is to not participate.

What are the benefits to you for participating in the Registry?

Participation in the FTD Disorders Registry may not benefit you personally, medically or financially. However, your participation may benefit you and others with FTD by helping researchers to improve their understanding of these rare and debilitating disorders.

Collected data may help speed research to find potential treatments, and facilitate other medical advances to improve the outlook for individuals diagnosed with FTD disorders. In addition, participants can choose to receive updates about clinical research studies or trials for which they may be eligible.

Are there any risks, inconveniences or discomfort?

The risks of taking part in the FTD Disorders Registry are low. By participating in the Registry and looking at summarized data contributed by all participants, you may learn information that is difficult or upsetting to you. You may find some of the questions asked in the surveys embarrassing, difficult or uncomfortable to answer. It is important to recognize that each person with an FTD disorder is unique, and the answers are important to learn about FTD.

Loss of private or confidential information is also a risk, but it is a low risk. To keep this risk low, your information is stored in a secure online database. This database uses a security system with many safeguards and protections.

To minimize the risk of loss of private or confidential information, only the Registry Director will have access to information that identifies you. Information that might identify you, such as your name and address, will not be shared with anyone else. If you have remaining questions or concerns please visit our Privacy & Confidentiality page or contact the Registry Director at (director@ftdregistry.org).

You can decide to leave the Registry any time you want.

Taking part in the research is completely voluntary—it is your choice. You may decide not to participate or decide to join or participate in research, but later change your mind. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your part in FTD Registry research may be stopped at any time by the Registry Director or sponsor without your consent for any reason.

If you decide to withdraw, you must provide reasonable notice to the Registry Director to delete your profile information. Please understand that information already shared in a research study or survey cannot be removed or retrieved even if you leave the Registry.

What happens to the information collected in the FTD Disorders Registry?

Scientists, health care providers, the sponsor, regulatory agencies such as the U.S. Food and Drug Administration (FDA), Health Canada, the Institutional Review Board (IRB) and other appropriate professionals can request access to the de-identified data stored in the Registry. Approvals of such requests are made by the FTD Disorders Registry Scientific Advisory Board (SAB). The SAB is made up of medical and scientific professionals who guide the policies of the Registry. The Registry will never release any personal information such as name, address, email, or phone number. Before your information is shared, it is “de-identified” to remove information that would allow someone to locate or identify you.

This information is shared so the research can be conducted and properly monitored. The people receiving this information may not be required to protect it and your information may be redisclosed without your permission. If you do not provide permission to use your information you cannot be in the study.

Confidentiality will be respected and no information that discloses the identity of the participant will be published without consent unless required by law. However, records identifying the participant may be given to and inspected by Health Canada/PHAC senior officials, and the REB members, for the purpose of monitoring the study.

Confidentiality and the Collection, Use and Disclosure of Your Personal Information

This consent form also tells you about your privacy rights. If you sign this form, you will be giving your permission for the collection, use and disclosure of your personal information for the purposes of this study.

If you decide to be in this study, the study doctor and study staff will collect information about you. This may include your name or initials, date of birth, gender, ethnic origin, medical history and health-related information such as results of laboratory tests, x-rays and physical examinations and medical records. The information collected from you will be kept for 25 years as required by law.

When possible, the information sent to the sponsor and those working for the sponsor will not identify you directly. Other indirect identifiers will be used instead. Your personal information will be used to confirm your eligibility for this study, to assess the results of this study, for purposes of safety and to meet legal and regulatory requirements.

For the purposes set out above, the study doctor and study staff may share and disclose information about you to the sponsor. "Sponsor" includes any persons or companies contracted by the sponsor to have access to the research information during and after the study.

The information will be given to Health Canada. It may also be given to the U.S. Food and Drug Administration (FDA) and governmental agencies in other countries where the study drug may be considered for approval. Information, including your medical records, which identifies you and the consent form signed by you will be looked at and/or copied for research or regulatory purposes by:

- the sponsor;

and may be looked at and/or copied for research or regulatory purposes by:

- Health Canada;
- the FDA;
- governmental agencies in other countries; and
- Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

There may be other circumstances where your information may be disclosed if required by law or for your benefit in the event of an emergency.

You have access rights to your information and the possibility to correct your information according to local law and procedures. You can discuss this with your study doctor. There is no expiration for your permission. You may take away your permission to collect, use and share information about you at any time by providing reasonable notice to the study doctor. If you do this, you will not be able to stay in this study. No new information about you will be gathered after that date. However, the information about you that has already been gathered may still be used and given to others as described in this form.

What will we show you about your/your loved one's health information, and on the questions you answered?

We do not provide participants in the Registry with specific health or medical information related to their care or that of other participants. If you take part in a specific research study as a result of being in the FTD Disorders Registry, the scientists may share results with you. If scientists learn anything interesting about FTD using data from the FTD Disorders Registry we will post these results on the Registry website.

Cost and Compensation

There are no costs to join the FTD Disorders Registry. You will not be paid for taking part in the Registry.

Who "owns" the data in the Registry?

The FTD Disorders Registry LLC is the guardian of the information contained within the FTD Disorders Registry. The LLC is a not-for-profit corporation set up just for the purpose of building and maintaining this as a resource to the community.

You will be asked to give your informed consent electronically after you have completed reading Part 1 - "Understanding your Participation"

The Registry provides a form that describes your participation. This form is called "informed consent". Persons diagnosed with an FTD disorder who understand the informed consent form (and who do not have a legally authorized representative) are eligible to join the Registry on their own. Persons diagnosed who have indicated their willingness to participate in research with their caregiver or family can have their data entered with the help of their care partner. If you/or your care partner answer "yes" to the questions regarding participation, you will have "consented". Please take the time you need to make your decision and discuss it with your family, friends and caregivers. You can print a copy of the informed consent if you choose.

Problems or Questions?

If you have any research-related problems or questions, concerns or complaints about the FTD Disorders Registry or about your rights as a Registry member, contact the Registry Director by email (director@ftdregistry.org) or by phone (888-840-9980).

If you have any questions or complaints about your rights as a participant or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

Manager, Research Ethics Board Secretariat
70 Colombine Driveway
9th Floor, Room 941C
Brooke Claxton Building, Postal Locator: 0909C
Tunney's Pasture
Ottawa, Ontario, K1A 0K9
Phone number (613) 941-5199
Email: REB-CER@hc-sc.gc.ca

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Please acknowledge that you have read Part 1- "Understanding your Participation" by checking the box.

 Yes

PARTICIPATE IN FTD REGISTRY RESEARCH ADDENDUM

PART 2 - Informed Consent Agreement

TITLE: FTD Disorders Registry: Implementation of a web-based patient and caregiver research registry for Frontotemporal degenerative disorders

PROTOCOL NO.: FTDDR-001v1
WIRB® Protocol #20160472

SPONSOR: FTD Disorders Registry, LLC

INVESTIGATOR: Dianna K. Hughbanks-Wheaton, MS, PhD, CHES
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637 Carolina St.
San Francisco, California 94107
United States

STUDY-RELATED PHONE NUMBER(S): Dianna K. Hughbanks-Wheaton, MS, PhD, CHES
(888) 840-9980 (Monday – Friday 8:30 AM to 5:30 PM; Central Time)

Please read the main Consent Information Sheet titled, “Part 1 – Understanding your Participation” prior to reading “Part 2 – Informed Consent Agreement”. Please read this information carefully. Take as much time as you need. If you have questions, please ask them. You can send your questions via email to the Registry Director (director@ftdregistry.org) or call the Director (888-840-9980). You may choose to wait until your questions are answered before deciding to participate in the Registry.

You are a volunteer. You 12

, or a caregiver or family member of a person diagnosed with one of the FTD disorders. There will be no penalty if you decide not to participate. You can consent to participate and later decide to withdraw your consent; however, you will be required to inform the Registry Director, so that your profile can be updated and closed.

If you agree to participate in the Registry, you will be asked to complete a series of short enrollment surveys about your life and health. The surveys will ask about such things as demographic information, disease progression, medications, family history, and how the disease affects your life. Each survey should only take about 20-30

minutes. You do not have to complete all the surveys at one time.

You will be asked to update your Registry information at least once per year or as your health changes. In order to complete your profile, you may also be asked by the Registry Director to login and respond to unanswered questions in the survey or upload relevant information. If the Registry Director is unable to reach you for updates, your account may become inactive.

Informed Consent

For the purpose of this document “I” and “you” refer to the registrant:

- *the person affected by an FTD disorder*
- *or the care partner providing the information on behalf of the affected individual*
- *or the caregiver or family member or friend of a person affected, who also wants to participate in research and are consenting for themselves.*

“The registry” refers to the FTD Disorders Registry.

All of the following questions must be answered in order to participate in registry research.

1. The registry has been fully explained to me. I have read and understand the “Understanding my Participation” document and this “Informed Consent Agreement”. I also know how to access both documents in the future if I want to review them. I have had the opportunity to ask questions of the Registry Director.

All my questions have been answered to my satisfaction.

Yes

2. I understand that my participation in the registry is entirely voluntary. Should I change my mind and wish to withdraw my data from the registry, I understand that I will be free to do so without having to provide any explanation.

Yes

3. Your information will be saved in the registry using a global unique identifier code – also called the GUID. The code is used so others don’t know who you are. The

registry has processes in place to protect your identity. The registry may share your coded de-identified information with other registries or databases, such as the ARTFL or LEFFTDS clinical research networks or with qualified researchers. This information may be used for research or to plan clinical trials.

I give permission for my de-identified information to be shared with other approved registries and databases and qualified researchers.

Yes

4. The registry may get information about a clinical trial for which I might be eligible. I would like to be contacted with this information.

(Please note that even if the coordinators of a clinical trial believe that you might be eligible for the trial, based on the data about you stored in the registry, it is still possible that later on it will turn out that you do not meet the trial inclusion criteria. Please also be aware that if we inform you about the existence of a trial, this does not imply that we endorse it. In order to participate in any trial, you will need to fill out a separate informed consent form.)

Yes

5. It is important that the registry information be up to date. We will contact you once or twice a year to ask about changes in your medical condition or contact profile. We may also send you electronic forms to fill out each year. I give the FTD Disorders Registry permission to contact me with this information.

Yes

6. Please choose the CONSENT option that applies to you:

- Consent as an adult participant with FTD (if the person with FTD can provide his/her own consent).
- Permission by care partner or Legally Authorized Representative (if the person with FTD is 18 years or older and cannot provide his/her own consent). Please note that subjects in British Columbia and Quebec must be able to consent for themselves.
- Adult participant (18 years or older [19 years or older in the states and provinces where the age of majority is 19]) who is a caregiver or family member of a person with FTD.
- Care partner or Legally Authorized Representative for the participant with FTD that has passed away.

7. If you are acting as a care partner or Legally Authorized Representative for the participant with FTD, please affirm that you have permission to act on their behalf, and that we may contact you directly with questions regarding their account.

- Yes
- Not Applicable

By signing this form, I agree that:

- This study has been explained to me. Yes No
- All my questions were answered. Yes No
- Possible harm and discomforts and possible benefits (if any) of this study have been explained to me. Yes No
- I understand that I have the right not to participate and the right to stop at any time. Yes No
- I understand that I may refuse to participate without consequence. Yes No
- I have a choice of not answering any specific questions. Yes No
- I am free now, and in the future, to ask any questions about the study. Yes No
- I have been told that my personal information will be kept confidential. Yes No
- I understand that no information that would identify me will be released or printed without asking me first. Yes No
- I understand that I will receive a signed copy of this consent form. Yes No

For future research projects: (if applicable)

- I agree that my data may be used for future testing in similar research projects.

Yes No

Consent: By checking this box, I the person diagnosed, (or care partner or legally authorized representative for the adult person diagnosed), or a caregiver or family member of a person diagnosed with FTD, am indicating that I have read Understanding Your Participation and the Informed Consent Agreement for the FTD Disorders Registry, that I understand the risks and benefits of participation, and that I agree to participate in the registry.

Yes

You agree that your response to check box above serves as your electronic signature and that you are consenting to participate in research. Your acceptance of the consent agreement will be electronically recorded together with the date and time. You may print and/or save a copy of this consent form for your records.

Yes

Signature

Please sign all, or a portion of your name within large signature window using your mouse or touch pad. Then type your full name in the smaller signature widow below.

Sign name using mouse or touch pad

Signature of

Date

Please select today's date with the help of the calendar.

