INFORMED CONSENT FORM

Consent Agreement

Sponsor / Study Title:	**FSHD Society / "BetterLife FSHD: A patient-driven health and research platform"**
Principal Investigator:	**Amanda Hill**
Telephone:	**(781) 301-6060, ext. 2200 (24-Hour)**
Address:	**FSHD Society** **1035 Bedford Street** **Suite 103 #1073** **Abington, MA 02351**

You are invited to join BetterLife FSHD, a health and research platform run by the FSHD Society. The FSHD Society is the world's largest patient organization for Facioscapulohumeral Muscular Dystrophy, or FSHD. We are dedicated to finding treatments and a cure for FSHD, as well as supporting patients and their families.

Before you agree to join BetterLife FSHD, it is important that you understand its goals, what is involved, and the benefits and risks to you. Please read the information in this form carefully. A copy of this form will be emailed to you and is available in your BetterLife account after you sign up. If you have any questions, you can contact the BetterLife team using the contact information on the top of this page.

[Only shown to a parent/guardian registering on behalf of a minor]: **If you are a parent or legal guardian joining BetterLife FSHD on behalf of your child, please understand that when "you" appears in the following information, it will refer to either you or your child.** If your child is age 7 or older, your permission and the permission of your child will be needed.

1. What are the goals of BetterLife FSHD?

BetterLife FSHD has two key goals:

#1. To help patients live a better life with FSHD.

#2. To speed and improve FSHD research and therapies.

When you join BetterLife FSHD, you will be asked to share data about your FSHD and your health. BetterLife uses this data to suggest resources we think will be helpful to you personally, such as articles, videos, or community groups. BetterLife also matches you to clinical trials and research studies that you may be a good fit for. And you can use BetterLife to track your FSHD progression and symptoms.

The data you share in BetterLife FSHD is made available to researchers working on FSHD.

However, your identity is always protected. Researchers use data from BetterLife to improve their understanding of FSHD and how it affects patients' lives. Researchers also use the data to design better treatments and clinical trials, improve clinical care, and help make sure patients can access treatments.

2. Who can join?

BetterLife FSHD is for anyone with FSHD living in the United States who is 1 year of age or older. However, anyone who is not an adult (18 years old in most states) must have permission from a parent or legal guardian to join. If you are not an adult, your parent or legal guardian should sign up for BetterLife with their information, then add you to their account.

3. How many people can join?

There is no limit to the number of people who can join BetterLife FSHD. However, we initially aim to enroll up to 5,000 participants in the United States.

4. What happens after I join?

After you register, you will create a profile for each person with FSHD, such as yourself and/or your child(ren). In each profile, you will be asked to fill out surveys with demographic data and data about your FSHD diagnosis and symptoms. It should take about 1 hour to register and complete these steps, but you do not have to do it all at one time.

Over time, we will ask for more data about your journey with FSHD. For example, we may ask you to respond to surveys about your pain, fatigue, or exercise. These surveys are optional, and you can respond whenever they are available in your profile. You will also have the option to connect your electronic medical records through your health provider, and the option to upload your genetic test results.

When you join, you will receive important communications about study operations, for example:

- Password reset, 2-factor authentication codes, or other system communications
- Notifications when/if your data is used in research
- Invitations to participate in further studies which you may be eligible for

You'll also receive helpful notifications and updates, which you can opt out of, including:

- Notifications of surveys availability and completion reminders
- Notifications when new community polls are posted
- A newsletter with study updates
- General marketing communications from the FSHD Society

You will also be added to the FSHD Society's contact database, along with a note that you registered for BetterLife.

How will my health data be used?
Your health data includes your responses to any questions or surveys in BetterLife FSHD, as well as your electronic health record and/or genetic test results, if you provide them. The BetterLife team will collect, use, and share your health data to achieve the two key goals:

#1. To help you live a better life with FSHD, we use your health data to generate personal insights and recommendations in your BetterLife FSHD dashboard. We also use your health data to customize your experience within BetterLife and to help us continually improve the platform.

#2. To speed and improve FSHD research and therapies, we use your health data to do research and we share your health data with other researchers. Researchers may include pharmaceutical, or biotechnology companies, academic institutions, hospitals, or other organizations involved in research and therapeutic development. We may also share your health data with government agencies or payor systems who make decisions about treatment approvals and access, for example, the Food and Drug Administration (FDA) or the Institute for Clinical and Economic Review (ICER). A steering committee reviews all requests for health data to make sure the request aligns with the goals of BetterLife and the requestor is trustworthy.

Before your health data is used, BetterLife removes your name and any personal information that could identify you, such as your address or phone number. Then, your health data is assigned a unique ID number. Only select BetterLife team members (including our third-party service provider, Lumiio) can link your personal information with your ID number. Researchers only receive your ID number, and they must agree not to try to figure out who you are. Your health data may also be linked with other data sources (for example, other FSHD studies or insurance claims databases) needed for research. Your identity may be needed to initially link these data sources but will always remain confidential.

Researchers and the BetterLife FSHD team may use your health data in reports, presentations, or publications. Your health data may be listed with your ID number, or it may be combined with other participants' data to create summary metrics, graphs, and charts. Summary graphs and charts contain only collective data, meaning it is not possible to see any one person's data.

5. Who will see my personal information?
Your personal information, such as your name and contact information, and the consent form signed by you may be looked at by those who have a legal right to see that information. This includes:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research participants like you.
- The Advarra Institutional Review Board (IRB), who is responsible for overseeing this study.
- The Principal Investigator and the rest of the BetterLife FSHD team (including Lumiio).

Your personal information will also go into the FSHD Society's contact database for marketing communications. We will never give your personal information to anyone else without your permission.

6. How will you protect my data?
There is a small risk that the data you share in BetterLife FSHD will be seen or accessed by someone who is not authorized. However, the FSHD Society is deeply committed to protecting your data and has taken all the necessary steps to reduce this risk.

To create BetterLife, the FSHD Society partnered with Lumiio, a leading provider of world-class data technology and services that empower research, healthcare, and patient advocacy. BetterLife FSHD is hosted on a secure data platform operated by Lumiio that complies with important research and privacy regulations for protecting participant data in research.

7. What are the possible discomforts and risks?
You may find it hard to answer some questions or be upset by them. You don't have to answer these questions. However, your answers can help us learn more about the impact of FSHD on your health and well-being. There is also a small risk that someone who should not see your data gets access to it. We do all that we can to protect your data, but absolute confidentiality cannot be guaranteed.

8. What are the possible benefits?
You may directly benefit from BetterLife FSHD in several ways:

1) You will receive resources that may help you manage your FSHD.
2) You may receive information about clinical trials and research studies that you may be a good fit for.
3) You can use BetterLife to help you track your FSHD progression and symptoms.

When you join BetterLife FSHD, you become part of a network of participants acting as citizen scientists. Your involvement improves our understanding of FSHD and helps support future research, therapeutic development, and clinical care, though this will not directly impact you right now.

9. Is taking part voluntary?
Yes, joining BetterLife FSHD is voluntary. You can choose to start and stop taking part at any time and without penalty or loss of benefits to which you are otherwise entitled.

If you no longer want to take part, you can withdraw your consent from your profile management page or contact the BetterLife team using the contact information on the first page of this form. You can choose to allow BetterLife to continue to use the data you already provided or to have your data deleted. However, data that was used and shared before you asked for it to be deleted cannot be retracted.

The BetterLife team can stop your participation at any time without your consent for the following reasons:

- If you provide false information,
- If we discover you are not eligible,
- If BetterLife FSHD is canceled, or
- For administrative reasons.

10. Can I take part in BetterLife and other research studies at the same time?
Yes! You can join BetterLife and take part in other research studies or clinical trials at any time.

11. What are the alternatives?
BetterLife FSHD is a unique platform that uses your health data to do research and provide you with helpful resources and personalized tools. We are not aware of alternative platforms like BetterLife FSHD. This study is for research purposes only; therefore, the only alternative is to not join BetterLife FSHD.

If you choose not to join, you can still be part of the FSHD Society community and access many related resources from our website (www.fshdsociety.org).

12. What if there is new information?
Any new information that is discovered and that may influence your decision to continue taking part in BetterLife FSHD will be provided to you.

13. Who is paying for BetterLife FSHD?
The FSHD Society pays for BetterLife FSHD. The BetterLife team shares the platform and data with researchers for a fee (including pharmaceutical or biotechnology companies, academic institutions, hospitals, FDA, ICER, and other organizations involved in research and therapeutic development), in accordance with the goals and data use described above. Proceeds are reinvested to continually improve BetterLife and to further the mission of the FSHD Society: finding treatments and a cure for FSHD and supporting patients and their families.

14. Will I receive payment?
No, you will not receive payment for joining BetterLife FSHD.

15. Does it cost anything to join?
No, there are no costs to join or take part in BetterLife FSHD.

16. Whom to contact about this study
During the study, if you have questions, concerns, or complaints about the study such as:

- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Principal Investigator's or study site's decision to withdraw you from participation.

Please contact the Principal Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, contact:

- By **mail**:

  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Advisor: Pro00079388.

A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Authorization to use and disclose your protected health information

If you decide to join BetterLife FSHD, the BetterLife team will use and share data about you, as described in this form. Data may come from your BetterLife records or from existing records kept by your doctor or other health care workers. Data may include:

- Name and demographic information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current medical records that are relevant to FSHD, including but not limited to medical history, other diagnosis(es), clinical assessments, laboratory or tissue studies, radiology studies, and procedure results.
- Genetic testing results or reports.
- Your answers to survey questions in BetterLife FSHD.

The BetterLife team may share data about you with authorized users. Authorized users may include:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research participants like you.
- The Advarra Institutional Review Board (IRB), who is responsible for overseeing this study.
- The Principal Investigator and the rest of the BetterLife FSHD team.
- Representatives of the FSHD Society.
- Outside individuals and companies, such as technology and data storage companies, that work with the BetterLife team and FSHD Society and need to access your information to conduct this study.

- Outside researchers who are approved by the steering committee to use BetterLife FSHD data, including pharmaceutical or biotechnology companies, academic institutions, hospitals, or other organizations involved in research and therapeutic development.
- Governmental agencies.
- Payor systems.

Your data will be used to conduct and oversee research, including to:

- Understand the characteristics, needs, and preferences of FSHD patients.
- Improve understanding of FSHD and how it affects patients' lives.
- Design better treatments and clinical trials.
- Improve clinical care.
- Ensure patients can access treatments.

Once your data has been shared with authorized users, it may no longer be protected by federal privacy law and could possibly be used or disclosed in ways other than those listed here. We will do everything we can to maintain the confidentiality of your information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You may revoke (take back) your permission to use and share data about you at any time by writing to the Principal Investigator at the address listed on the first page of this form. If you do this, you will not be able to stay in this study. No new data will be gathered after your written request is received. You can choose to allow BetterLife to continue to use the data you already provided or to have your data deleted. However, data that was used and shared before you asked for it to be deleted cannot be retracted.

☐ **I have read and understand the consent agreement**

You must agree to the following to register and join BetterLife FSHD:

I am an adult according to the laws of my state (in most states, this means you must be 18 years old; in Nebraska and Alabama, this means you must be 19 years old; in Puerto Rico, this means you must be 21 years old).	No	Yes
I understand the goals and nature of BetterLife FSHD, and I have no additional questions.	No	Yes
I give permission for the health data I enter in BetterLife FSHD to be used and shared. My personal information will be removed before use.	No	Yes
I understand that joining BetterLife FSHD is completely voluntary. I can change my mind at any time, I do not have to provide an explanation and I will not be penalized if I choose to stop taking part.	No	Yes

[Only shown to a parent/guardian registering on behalf of a minor]:

If you are registering on behalf of a child aged 7 or older: I attest that I am the parent or legal guardian of the child I am registering, and they have given me their assent (agreement) to include their information in BetterLife FSHD.

No	Yes

Signature

[Date/time stamp]