FAGPR System User Guide

Patient/Proxy Portal

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Pulse Infoframe Inc.
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1 OVERVIEW OF FAGPR SYSTEM

The intended overarching objectives of the Friedreich’s Ataxia Global Patient Registry (FAGPR) website solution implementation and use are:

“Improve health outcomes and experiences of care through routine data collection to facilitate timely reporting to researchers and industry partners about outcomes and experiences that matter to patients.”

The FA Global Patient Registry (FAGPR) is an open-ended patient registry for Friedreich’s Ataxia (FA) that collects quality, real-world data to provide further understanding of FA and needs for its treatment. The FA Global Patient Registry has been launched by global FA advocacy parties to be the sole international registry for this disease.

The goals of the registry include:

- understand FA from the point of view of patients and caregivers
- connect patients and families to opportunities for PRO research and clinical trials of potential new therapies

2 PATIENT/PROXY ACCESS TO E-CONSENT

2.1 REGISTERING IN THE FAGPR SYSTEM

Registration Screen is where the patient or their proxy will enter the information required. Select the preferred language from the drop down and indicate if you are patient or registering on behalf of a patient. Please note choices (arrow). If you are using one email (username) to register several patients, either minor children or legal adults, choose the option “I am registering on behalf of a patient”.

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Example: Legal Guardian Registration screen

When you select the option to “Register as legal guardian” this screen will appear for you to complete:
If you are going to be PROXY for more than one participant you will need to follow the following to register:

Preferred Language
 French

I am a patient registering for myself - this choice is for any patient who is a legal adult and for anyone assisting an adult patient with registration.

I am registering on behalf of a patient - this choice is for parents and legal guardians of any patient who is a minor.

Register new patient with current account
Continue new registration
If you are a PROXY for more than one participant this is the log-in screen that will prompt you to select the patient for whom you are completing information:

Once you have completed registration you will see this:
2.2 EMAIL TO ACTIVATE ACCOUNT

Once you have registered your information into the FAGPR system you will receive an Email similar to the one below which will give directions to activate your account and create the password you will use in accessing the FAGPR system. The email you used for registration will be your username.

2.3 LOG IN

You will then be re-directed to the FAGPR system login page. For the first time you access you will be required to create a password. If you already are registered click the sign in link.
Once you create your password for the first time, you will be re-directed back to the login page.
2.4 PASSWORD RECOVERY
If you cannot remember your password note the “Forgot Password” link on the Log in page. Click on this link and then follow the email instructions to reset your password.

2.5 ELECTRONIC CONSENT
All patients will be presented an electronic consent form on the patient portal providing appropriate information about the system, and the privacy and use of your submitted data so participants can make
an informed decision about their participation in the FAGPR system. By signing the electronic consent, you are agreeing to the collection of your personal health information and use of your data by appropriate research entities in a de-identified form.

If you choose to consent/opt in, you will be agreeing to participate in survey collection outlined in the FAGPR system. If you decide to withdraw your consent/opt out, you will no longer be asked to complete surveys and no further information will be collected.

Please read through the consent thoroughly and ensure you fully understand the purpose of the FAGPR system and what you are being asked to do. If you have any questions, please contact the FAGPR coordinators at FAGPR@curefa.org.

In addition to consent, if a minor patient is between the age of 12 and the legal age of their country (for example 18), there will be an assent form listed under the consents section.

The minor patient is expected to read and complete that assent form. The minor patient won’t have a login, so it will be done under their proxy’s login.

If you are comfortable and ready to proceed, use the DocuSign function, which is a secure way to electronically sign and provide your consent to participate in the FAGPR system. Check the box with the statement, “I agree to use electronic records and signatures”. Once that box is checked the CONTINUE button will activate:

You will find the signature box at the bottom of the form. Please click “Accept electronic signature below” to enter your signature.
Docusign will create a signature template for you; you do not need to print the form to sign. Please click “ADOPT AND SIGN” to use the signature template.

You must then select “FINISH” in order for your signed consent to be saved and then you may close the form.

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Note: Please select the Finish button to complete the consent, and then select the close button. You have the option to print the signed form for your records, if you wish (see below for instructions). There are multiple options where you can choose to print the signed consent by choosing the “OTHER ACTIONS”.

You can confirm your consent has been signed on the patient dashboard. The button next to the consent form will turn from red to green when the form is signed.

The consent form (and assent form for children age 12 to 18) must be signed before you will be able to complete the Patient Profile or the survey forms.
To review the consent document and print or save for your records go to CONSENTS on the dashboard. In the upper right select the VIEW MORE button.

This is the screen after VIEW MORE was selected. Notice the icons which allow you to download or print the Consent Form for your records.
2.6 Log Out
You may log out of the system by navigating to the upper right hand corner of the panel and click on the “Logged in” area. There will be a drop down – Settings and Log out. Select Log out to complete your session.

2.7 Settings
This screen populates when the SETTINGS option is selected. There are areas that are available to edit if necessary as well as having the option to “Withdraw from Registry” (see Section 5 for further instructions). Save changes or cancel the activity.
3.0 Your Dashboard and Entering Your Information

3.1 Your Dashboard

Once you complete the consent process, and any time you log in to the FAGPR system, you will be directed to your dashboard which will give you information about your account and survey completion status.

This is the first section of the “Dashboard” which displays the welcome message and Consent status.

This the next section of the “Dashboard” showing Profile and surveys:
3.2 ENTERING YOUR INFORMATION AND VIEWING ASSIGNED SURVEY SETS

To enter your patient profile information: At the dashboard select “Patients” and “Profile”. This is the first page section that you will see.

3.2a Entering Identification
Please note that you must use the scroll bar to navigate the lower portions of the profile page. Once you select the “Next” button the data you have entered in the form will be saved.
Once you have saved the identification information by selecting NEXT you will see the RESEARCH section that requires completion.

Enter your information under each of the following headings:

3.2 b Research
This is where you will enter the required information about preferences for contact about research participation and willingness to donate biospecimens. Remember to scroll down to complete the entire form. When you have completed the information click the “Next” button to save.
4 COMPLETING SURVEYS

You may be assigned multiple survey with different due dates. Assigned surveys will be open for you to submit two weeks prior to the due/expiry date. You will receive an email when a new survey is due for updates. You can then login to the FAGPR system and navigate to the survey page. The following is an example of the survey schedule:

- Survey/Questionnaire (order and timeline)
- FA Diagnosis - Fill only once
- FA Medical History – Annually
- FA Functional Mobility – Annually
- FA Quality of Life – Annually
- FA Health Economics – Annually

The four (4) Annual Form opens 1 month before anniversary; You will receive a reminder email to update your survey forms one month before the anniversary date, on anniversary date, and one month after the survey form opens for updates.

Select > Forms>Surveys from the dashboard. In this screen you will see the FA surveys with a pencil icon. Click on this icon to gain access to the questionnaire. Research surveys that you can complete will be available and indicated with the pencil icon.

Any new research survey that is posted in the FAGPR will have ethics review board approval and be approved by the FAGPR scientific review committee.
This is the view when the FA Diagnosis form is selected:

When you have completed the information on the form (ensure to scroll down to visualize the entire form) select the **Submit Form** button.
You will receive confirmation that the submission was successful:

Finally, **Close** the form: If you have clicked to submit the form, you must choose “OK” on the pop-up menu. Currently, each of the annual survey forms is only accessible for updates annually.
From the Surveys tab you can view previous submissions, see the due date of upcoming surveys, and open and submit surveys that are currently available to be completed. Double click on the survey to open it. This screen represents the selected survey and its content. Note the directives at the top left of the panel which describe how to print or save the information.

You can view your previous submissions for a specific survey set by clicking the spyglass + icon.

The pencil icon indicates open surveys that you can fill out or update.
5 Withdrawing Consent or Opting Out of FAGPR

If you decide that you no longer wish to participate in the FAGPR, you are able to withdraw your consent to participate in surveys. You are also able to change the option to be contacted about research study participation without withdrawing from FAGR entirely if you wish that the survey data be available to FA researchers.

To delete your access to the FAGPR system, go to SETTINGS in your patient profile screen accessible from the upper-right corner of the screen.
This screen represents the area to select to begin the withdrawal from the registry.

Here you can select “Withdraw consent”.

- By withdrawing your consent, you are opting out of participating in the FAGPR System.
- By confirming your withdrawal, you will be logged out and will no longer be able to login.
- You can rejoin and re-consent at any time by contacting the registry coordinator via email: FAGPR@curefa.org

Once you click the “Withdraw” button this screen will appear to remind you about the implications of withdrawing.
Once your consent to participate is withdrawn, previously entered data and completed survey responses will remain in the FAGPR system and may be used in aggregated reports. No further data can be entered from the point of consent withdrawal and you will no longer have access to the FAGPR system. You will no longer receive reminder notifications from the FAGPR system.

After withdrawal, the patient will receive an email containing a link to download their data. The link is available for 2 months.

6 ACCESSING ADDITIONAL INFORMATION / HELP

NOTE: If you are having issues with your account, contact FAGPR@curefa.org