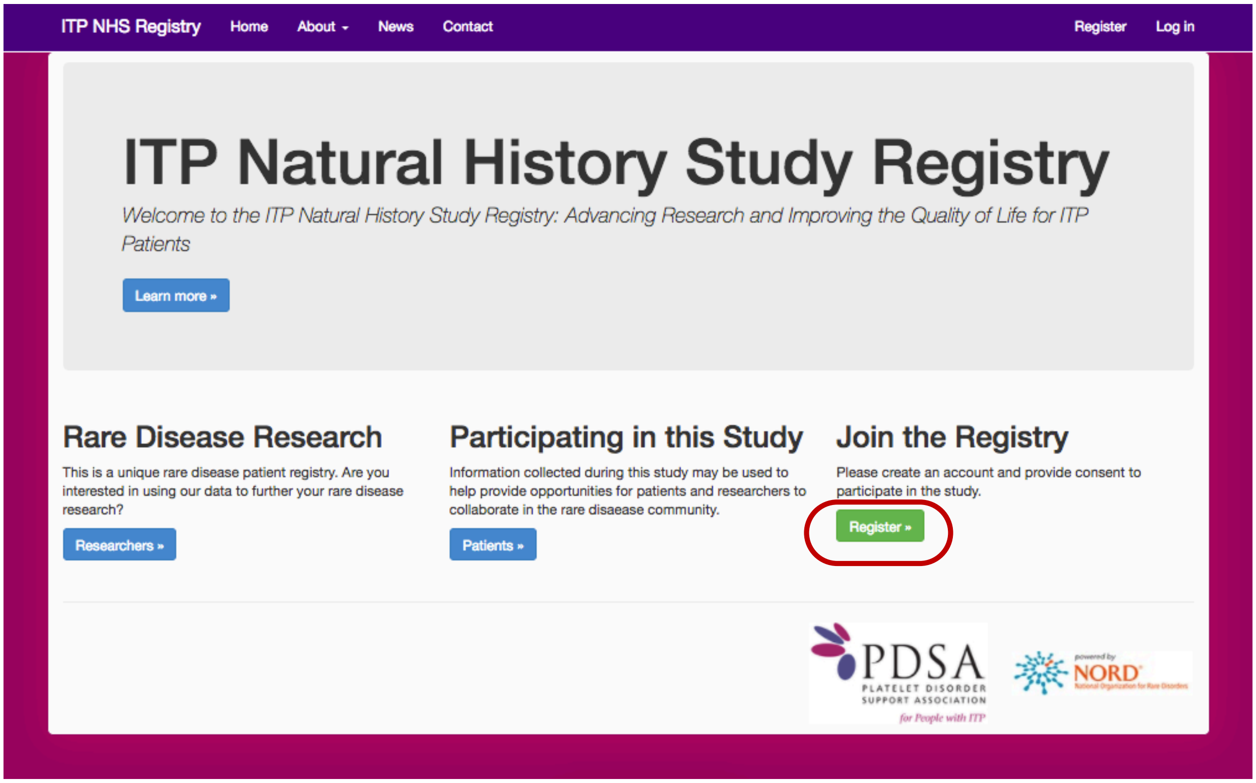
ITP Natural History Study Registry

Procedure for Registering, Consenting and completing Surveys

1. Go to the **ITP NHS Registry** website at: **itpstudy.iamrare.org**.



ITP Natural History Study Registry

Welcome to the ITP Natural History Study Registry: Advancing Research and Improving the Quality of Life for ITP Patients

Rare Disease Research

This is a unique rare disease patient registry. Are you interested in using our data to further your rare disease research?

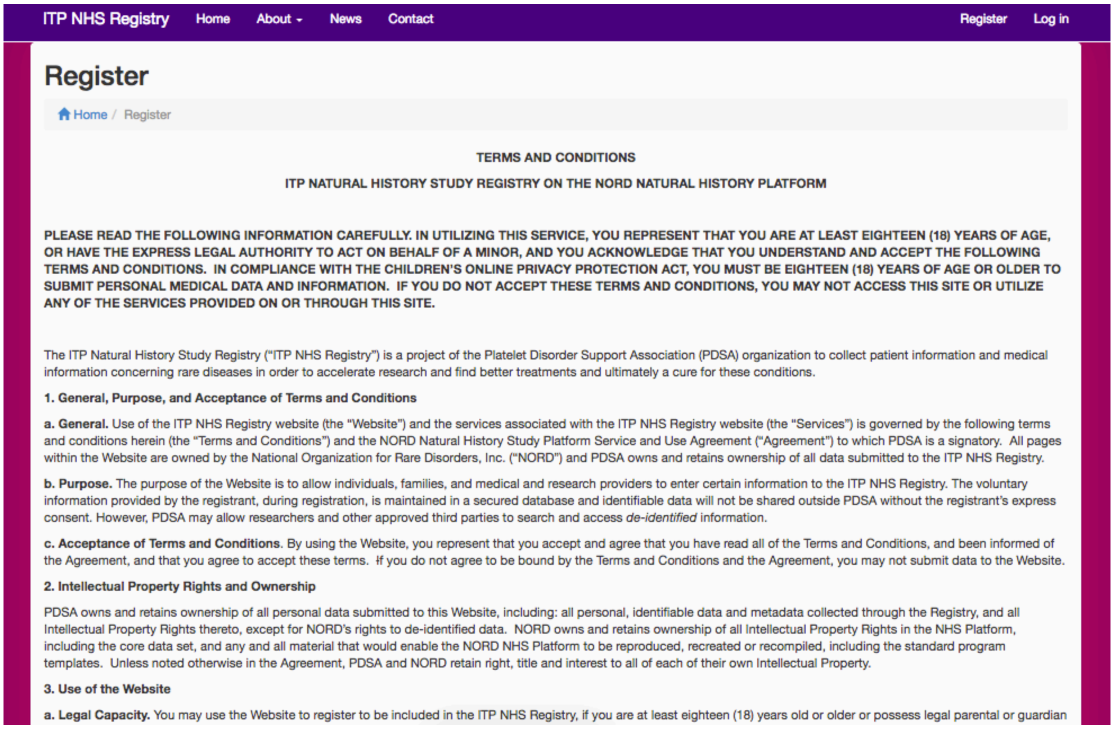
Participating in this Study

Information collected during this study may be used to help provide opportunities for patients and researchers to collaborate in the rare disaease community.

Join the Registry

Please create an account and provide consent to participate in the study.

2. Click on the green **Register** button.
3. Read the **"Terms and Conditions"** document.



Register

TERMS AND CONDITIONS

ITP NATURAL HISTORY STUDY REGISTRY ON THE NORD NATURAL HISTORY PLATFORM

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY. IN UTILIZING THIS SERVICE, YOU REPRESENT THAT YOU ARE AT LEAST EIGHTEEN (18) YEARS OF AGE, OR HAVE THE EXPRESS LEGAL AUTHORITY TO ACT ON BEHALF OF A MINOR, AND YOU ACKNOWLEDGE THAT YOU UNDERSTAND AND ACCEPT THE FOLLOWING TERMS AND CONDITIONS. IN COMPLIANCE WITH THE CHILDREN'S ONLINE PRIVACY PROTECTION ACT, YOU MUST BE EIGHTEEN (18) YEARS OF AGE OR OLDER TO SUBMIT PERSONAL MEDICAL DATA AND INFORMATION. IF YOU DO NOT ACCEPT THESE TERMS AND CONDITIONS, YOU MAY NOT ACCESS THIS SITE OR UTILIZE ANY OF THE SERVICES PROVIDED ON OR THROUGH THIS SITE.

The ITP Natural History Study Registry ("ITP NHS Registry") is a project of the Platelet Disorder Support Association (PDSA) organization to collect patient information and medical information concerning rare diseases in order to accelerate research and find better treatments and ultimately a cure for these conditions.

1. General, Purpose, and Acceptance of Terms and Conditions

a. General. Use of the ITP NHS Registry website (the "Website") and the services associated with the ITP NHS Registry website (the "Services") is governed by the following terms and conditions herein (the "Terms and Conditions") and the NORD Natural History Study Platform Service and Use Agreement ("Agreement") to which PDSA is a signatory. All pages within the Website are owned by the National Organization for Rare Disorders, Inc. ("NORD") and PDSA owns and retains ownership of all data submitted to the ITP NHS Registry.

b. Purpose. The purpose of the Website is to allow individuals, families, and medical and research providers to enter certain information to the ITP NHS Registry. The voluntary information provided by the registrant, during registration, is maintained in a secured database and identifiable data will not be shared outside PDSA without the registrant's express consent. However, PDSA may allow researchers and other approved third parties to search and access *de-identified* information.

c. Acceptance of Terms and Conditions. By using the Website, you represent that you accept and agree that you have read all of the Terms and Conditions, and been informed of the Agreement, and that you agree to accept these terms. If you do not agree to be bound by the Terms and Conditions and the Agreement, you may not submit data to the Website.

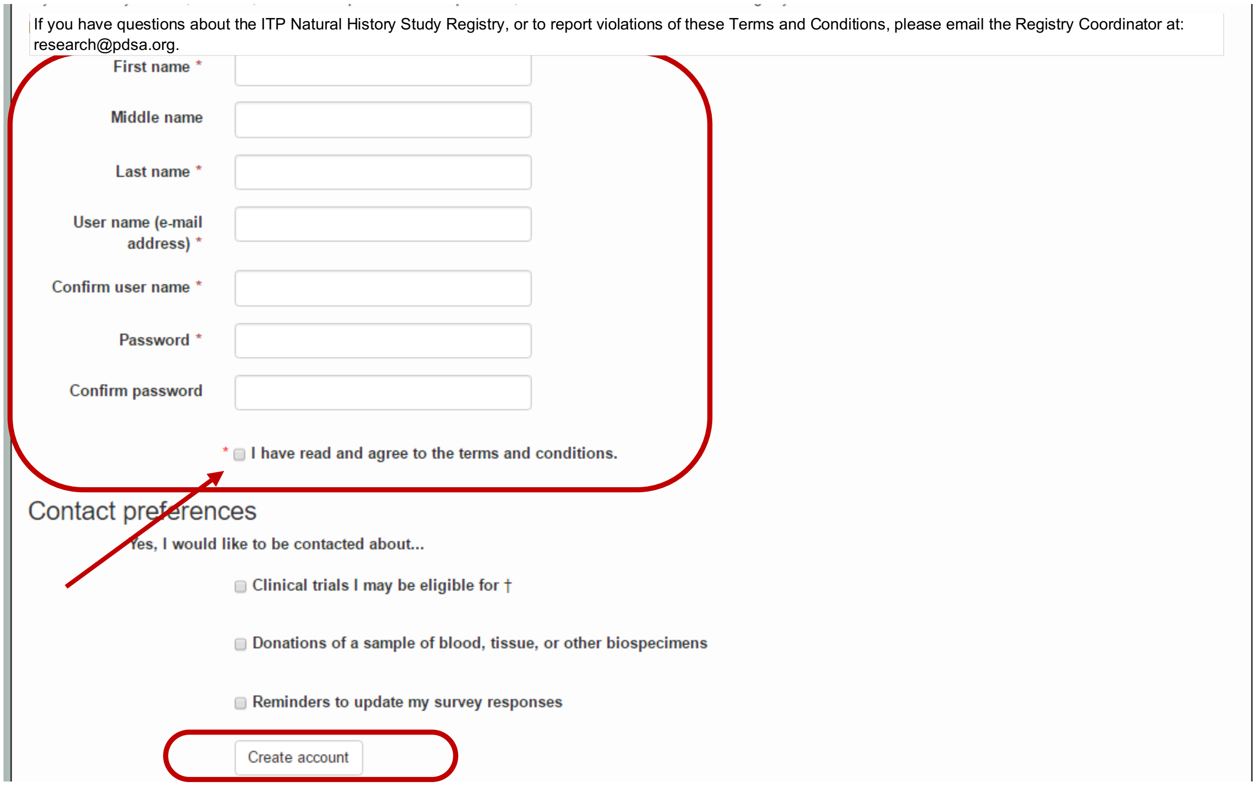
2. Intellectual Property Rights and Ownership

PDSA owns and retains ownership of all personal data submitted to this Website, including: all personal, identifiable data and metadata collected through the Registry, and all Intellectual Property Rights thereto, except for NORD's rights to de-identified data. NORD owns and retains ownership of all Intellectual Property Rights in the NHS Platform, including the core data set, and any and all material that would enable the NORD NHS Platform to be reproduced, recreated or recompiled, including the standard program templates. Unless noted otherwise in the Agreement, PDSA and NORD retain right, title and interest to all of each of their own Intellectual Property.

3. Use of the Website

a. Legal Capacity. You may use the Website to register to be included in the ITP NHS Registry, if you are at least eighteen (18) years old or older or possess legal parental or guardian

4. Fill in the requested information.
5. Agree to the Terms and Conditions
6. **Opt-in or out** of reasons to be contacted by study personnel
7. Click **Create Account** button



If you have questions about the ITP Natural History Study Registry, or to report violations of these Terms and Conditions, please email the Registry Coordinator at: research@pdsa.org.

First name *

Middle name

Last name *

User name (e-mail address) *

Confirm user name *

Password *

Confirm password

* ☐ I have read and agree to the terms and conditions.

Contact preferences

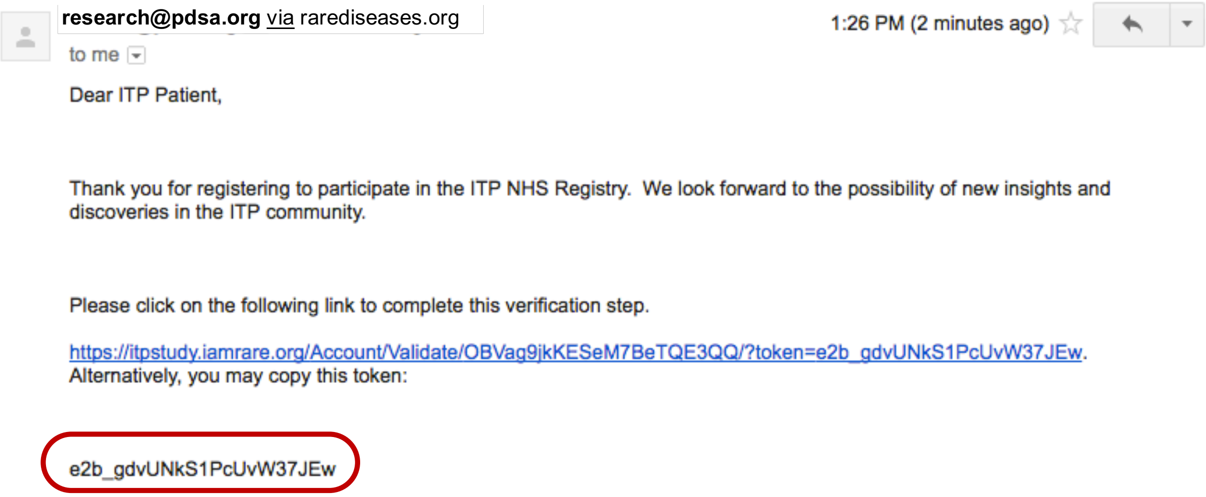
Yes, I would like to be contacted about...

☐ Clinical trials I may be eligible for †

☐ Donations of a sample of blood, tissue, or other biospecimens

☐ Reminders to update my survey responses

8. A confirmation email will be sent to the email address that was provided during registration. Confirm registration by copying the **Confirmation Token** from your email.



research@pdsa.org via rarediseases.org

1:26 PM (2 minutes ago)

to me

Dear ITP Patient,

Thank you for registering to participate in the ITP NHS Registry. We look forward to the possibility of new insights and discoveries in the ITP community.

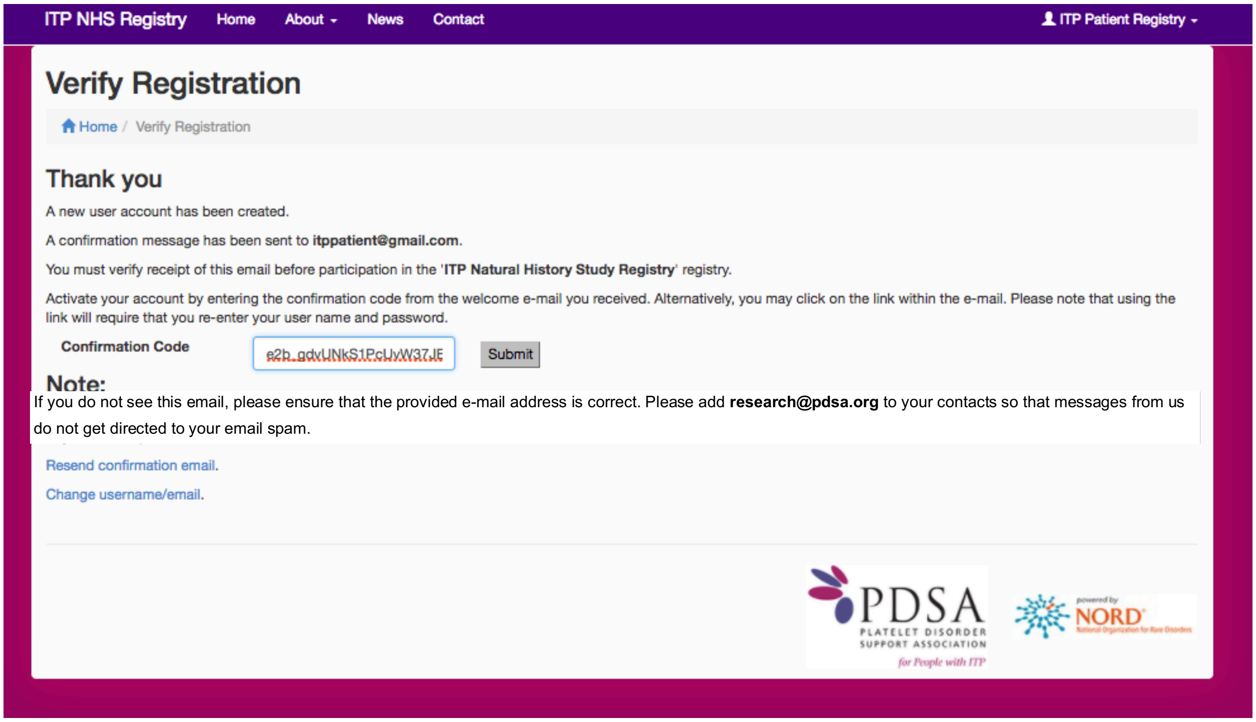
Please click on the following link to complete this verification step.

https://itpstudy.iamrare.org/Account/Validate/OBVag9jkKESeM7BeTQE3QQ/?token=e2b_gdvUNkS1PcUvW37JEw.
Alternatively, you may copy this token:

e2b_gdvUNkS1PcUvW37JEw

9. Paste the confirmation token into the "**Confirmation Code**" field. Click **Submit**.

a. If the confirmation email has not been received after a few minutes, click **“Resend confirmation email”** at the bottom of the page. Be sure to check spam folders for the email confirmation.



Verify Registration

Home / Verify Registration

Thank you

A new user account has been created.

A confirmation message has been sent to **itppatient@gmail.com**.

You must verify receipt of this email before participation in the '**ITP Natural History Study Registry**' registry.

Activate your account by entering the confirmation code from the welcome e-mail you received. Alternatively, you may click on the link within the e-mail. Please note that using the link will require that you re-enter your user name and password.

Confirmation Code e2b_gdvUNkS1PcUyW37JE

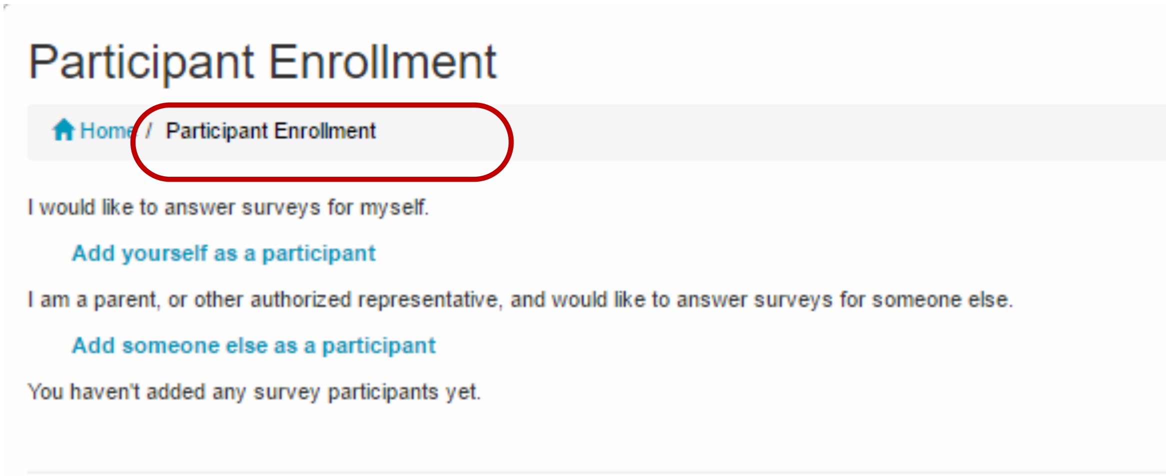
Note:

If you do not see this email, please ensure that the provided e-mail address is correct. Please add **research@pdsa.org** to your contacts so that messages from us do not get directed to your email spam.

Resend confirmation email.

Change username/email.

10. Click on **“Participant Enrollment.”**
11. Select the appropriate **Option** for granting consent.



Participant Enrollment

Home / Participant Enrollment

I would like to answer surveys for myself.

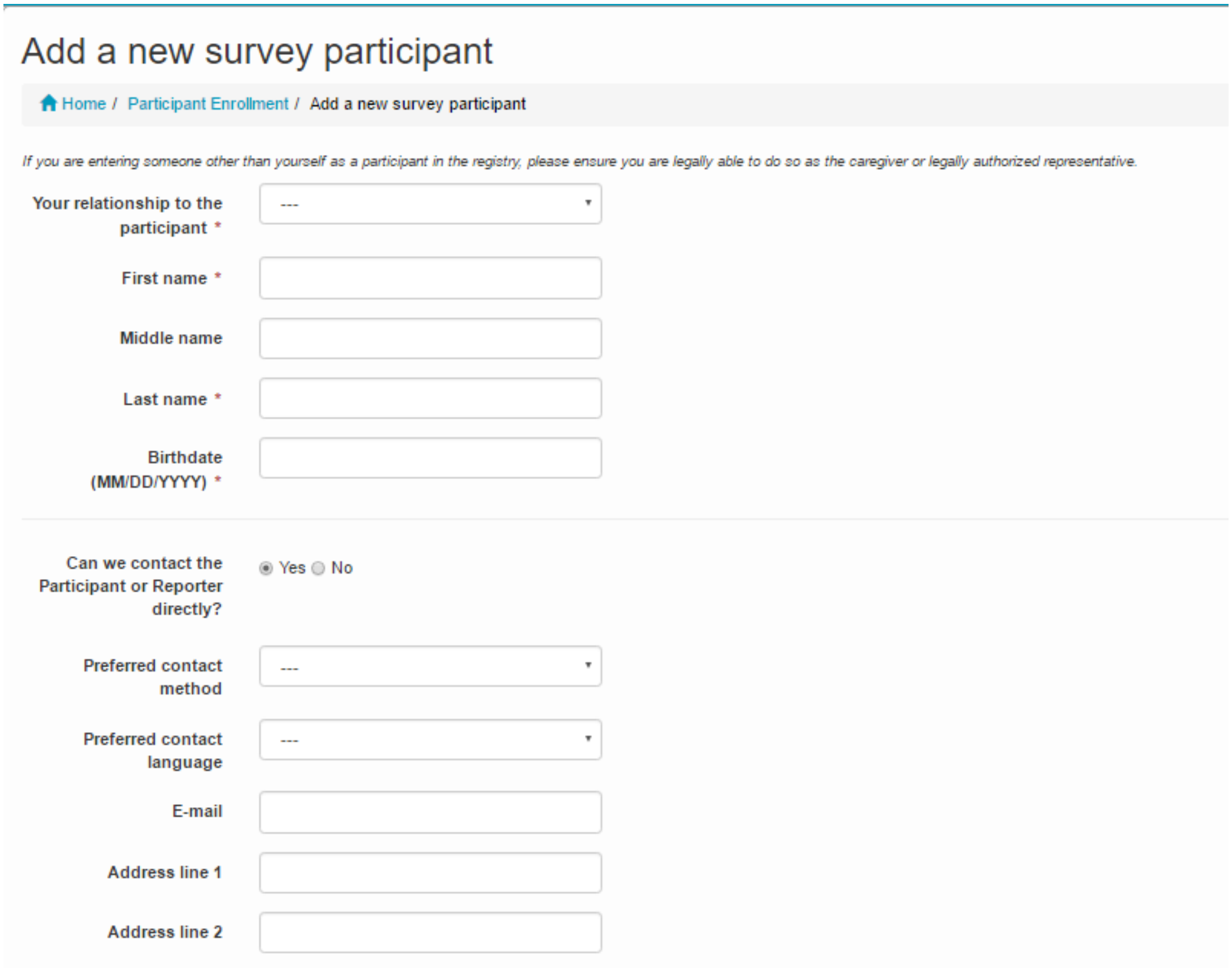
Add yourself as a participant

I am a parent, or other authorized representative, and would like to answer surveys for someone else.

Add someone else as a participant

You haven't added any survey participants yet.

12. Fill in the fields as they apply to the **Study Participant**.



Add a new survey participant

Home / Participant Enrollment / Add a new survey participant

If you are entering someone other than yourself as a participant in the registry, please ensure you are legally able to do so as the caregiver or legally authorized representative.

Your relationship to the participant * ---

First name *

Middle name

Last name *

Birthdate (MM/DD/YYYY) *

Can we contact the Participant or Reporter directly? ● Yes ○ No

Preferred contact method ---

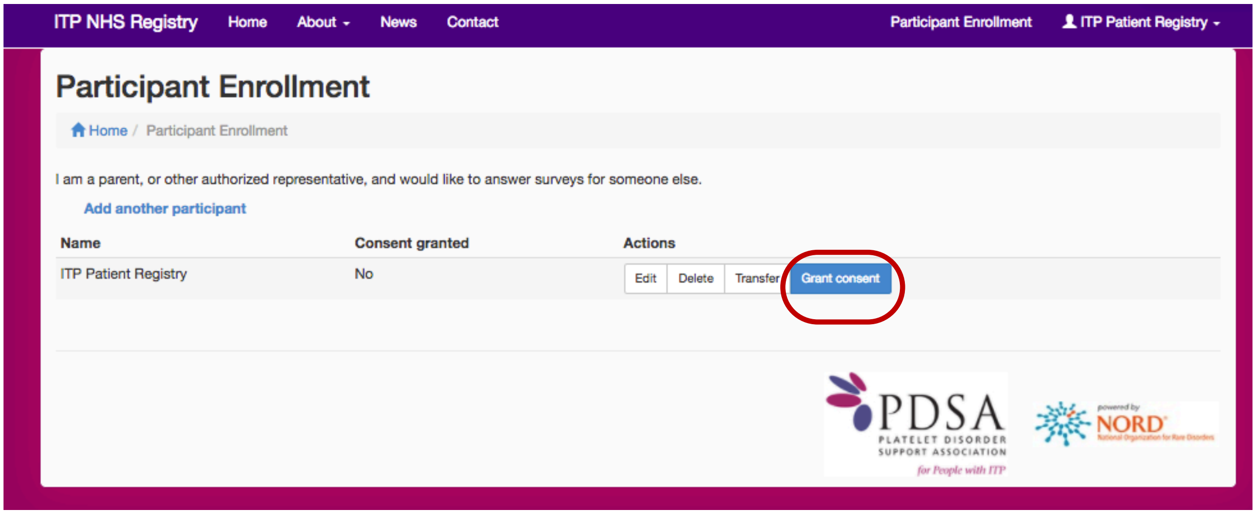
Preferred contact language ---

E-mail

Address line 1

Address line 2

13. Grant Consent for participation in Registry by clicking on **“Grant Consent.”**



Participant Enrollment

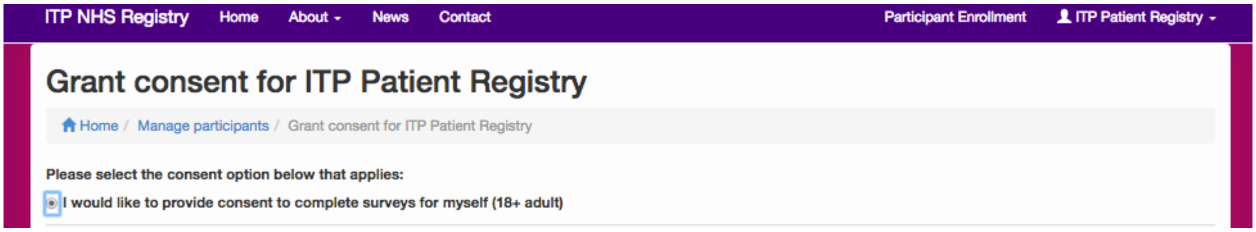
Home / Participant Enrollment

I am a parent, or other authorized representative, and would like to answer surveys for someone else.

Add another participant

Name	Consent granted	Actions
ITP Patient Registry	No	Edit Delete Transfer Grant consent

14. Select consent option (dependent on whether patient is 18+ or a Legally Authorized Representative "LAR")



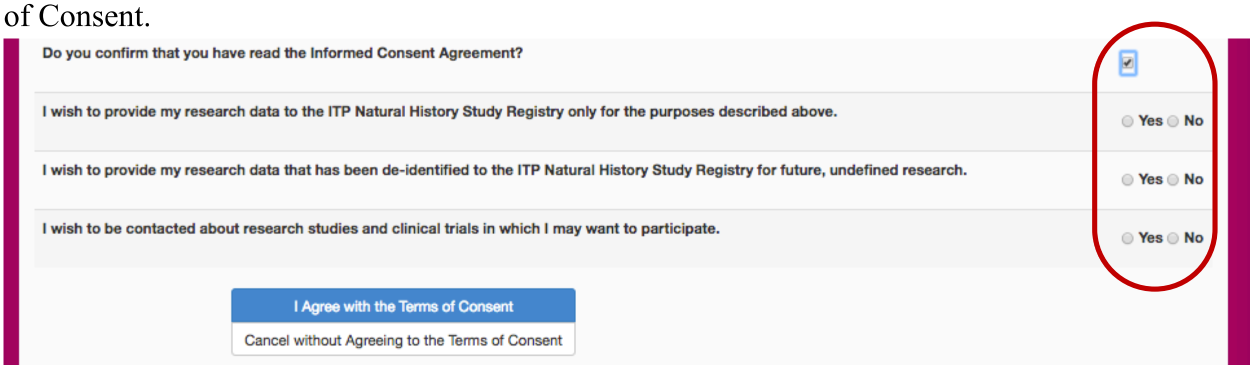
Grant consent for ITP Patient Registry

Home / Manage participants / Grant consent for ITP Patient Registry

Please select the consent option below that applies:

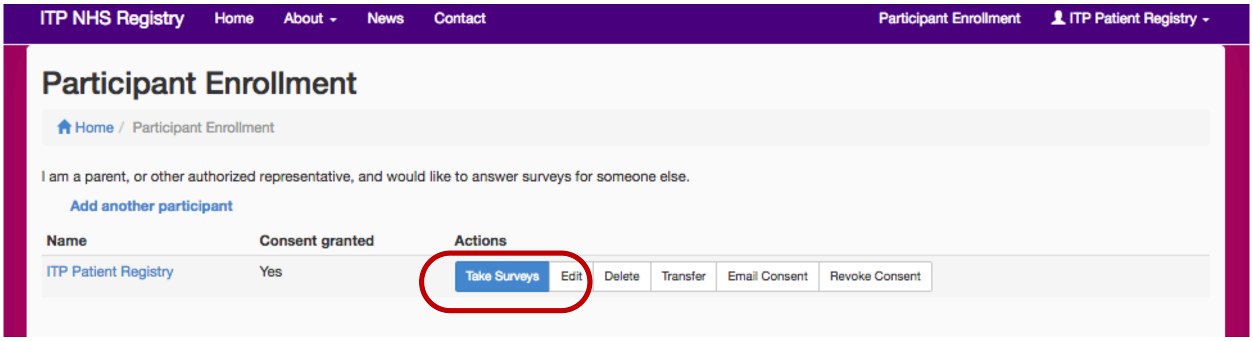
● I would like to provide consent to complete surveys for myself (18+ adult)

15. Read consent thoroughly. Once you have read the entire agreement, select box that confirms you have read the agreement. Next, answer the three questions below regarding study communication preferences. When finished, select whether you agree with Terms of Consent.



Do you confirm that you have read the Informed Consent Agreement?	☑
I wish to provide my research data to the ITP Natural History Study Registry only for the purposes described above.	○ **Yes** ○ **No**
I wish to provide my research data that has been de-identified to the ITP Natural History Study Registry for future, undefined research.	○ **Yes** ○ **No**
I wish to be contacted about research studies and clinical trials in which I may want to participate.	○ **Yes** ○ **No**

16. You will receive an email with a copy of your consent form. On the registry site, select "Return to Participant Enrollment"
17. Access Surveys by clicking on **"Take Surveys."**



Participant Enrollment

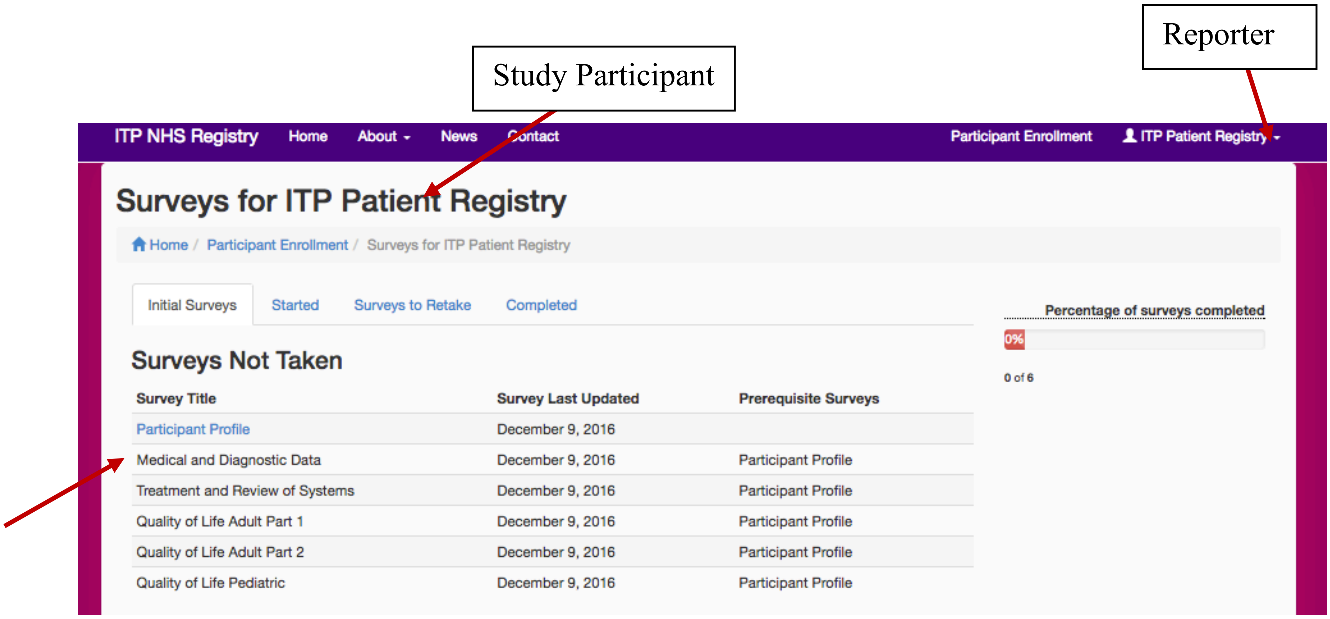
Home / Participant Enrollment

I am a parent, or other authorized representative, and would like to answer surveys for someone else.

Add another participant

Name	**Consent granted**	**Actions**
ITP Patient Registry	Yes	Take Surveys Edit Delete Transfer Email Consent Revoke Consent

18. Complete the **surveys** applicable to the **Study Participant**. For example, and adult would not complete the Quality of Life Pediatric survey.
    a. **NOTE: The Reporter is listed in the top right hand corner of the page and the Study Participant is listed on the left side of the page**. If someone is answering surveys for him or herself, both the Reporter and Study Participant fields will reflect the same name.


Reporter

Study Participant

Surveys for ITP Patient Registry

Home / Participant Enrollment / Surveys for ITP Patient Registry

Percentage of surveys completed

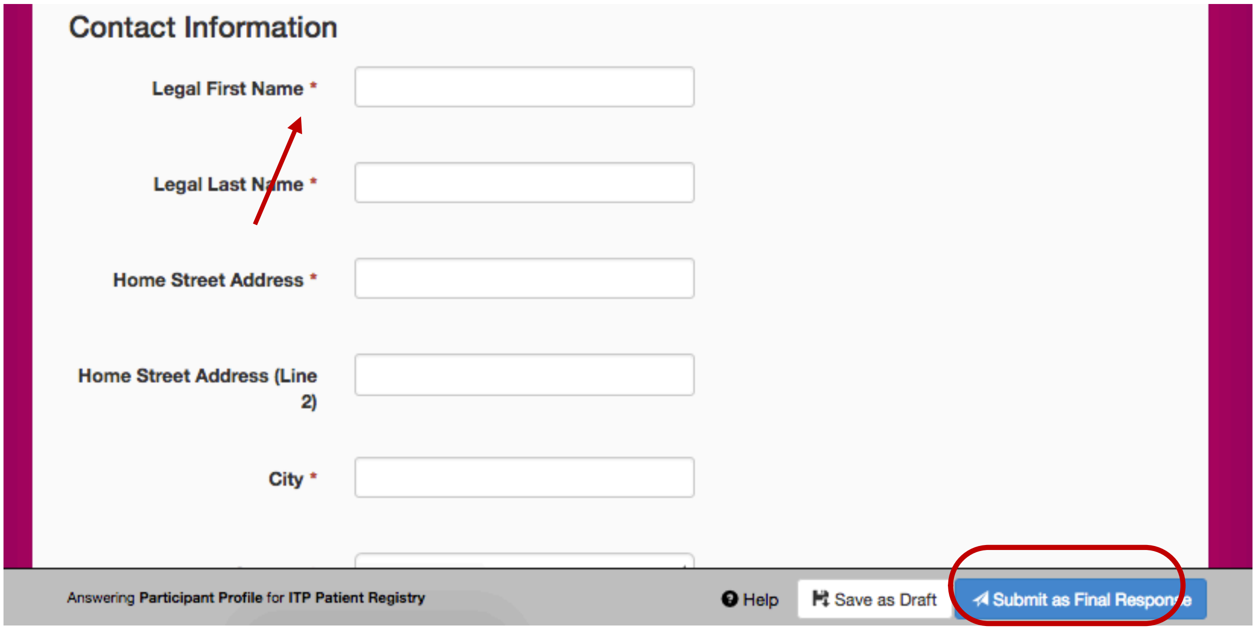
0%

0 of 6

Surveys Not Taken

Survey Title	Survey Last Updated	Prerequisite Surveys
Participant Profile	December 9, 2016	
Medical and Diagnostic Data	December 9, 2016	Participant Profile
Treatment and Review of Systems	December 9, 2016	Participant Profile
Quality of Life Adult Part 1	December 9, 2016	Participant Profile
Quality of Life Adult Part 2	December 9, 2016	Participant Profile
Quality of Life Pediatric	December 9, 2016	Participant Profile

19. Under **"Survey Title"** click on the name of the survey to open the survey. Complete the survey. Questions marked with a red * are require a response.


Contact Information

Legal First Name * ☐

Legal Last Name * ☐

Home Street Address * ☐

Home Street Address (Line 2) ☐

City * ☐

Answering **Participant Profile** for **ITP Patient Registry**

20. When each Survey has been completed, click on the **Submit as Final Response** button. If not completed, Surveys can be saved as drafts by clicking the **Save as Draft** button.