# **Information Collection Screenshots**

# Online submission form for the Genetic Testing Registry (GTR)

This document provides updated screenshots of the online form for the submission of genetic test information to the Genetic Testing Registry (GTR).

11/3/2021

# SECURE LOGIN SYSTEM



# **Testing Registry (GTR)!**

EXPIRATION DATE: 11/30/2021 Burden statement

To log in (or create a new account), please click the link "Sign in to NCBI" on the top right corner of this page. Make sure to always use the same log in

Here you will be able to register your laboratory and your clinical and research genetic tests. You can update your information at any time. The information entered here displays publicly at https://www.ncbi.nlm.nih.gov/gtr/.

The first time you log in you will see the GTR code of conduct and the AMA CPT code agreement before you reach your submission homepage.

To register your laboratory, click the button "Add a new lab". Once you submit your lab information, GTR staff will review it and contact you for more information.

When approved you will be able to register your clinical and research genetic tests manually by clicking the "Add a new clinical test" or "Add a new research test" or by using one of the two excel files available to register clinical tests in bulk. Please register your tests as represented in your lab's catalog. The more information you provide the more discoverable your test will be by GTR users.

Regardless of how many times you update your data, please submit your annual review once a year as this is a separate action. To submit your annual review, click the "Perform annual review" button to start it and the "Submit" button to finish and submit it.

There is a groups feature where multiple lab staff can work on the same lab and test records, please contact us at gtr@ncbi.nlm.nih.gov if you would like others in your lab to work on your GTR records.

For more information on how to submit to GTR: https://www.ncbi.nlm.nih.gov/gtr/docs/submit/

Please contact us at gtr@ncbi.nlm.nih.gov if you have questions or if you need any help.

Thank you for participating in GTR!



# **BURDEN STATEMENT**

S NCBI Resources  ☐ How To ☐		malheiro My NCBI Sign Out
GTR: GENETIC TESTING REGISTR'		
		Search
Advanced search for tests		
Overview ▼ Lab Submission ▼	Human Test Submission ▼ Microbe Test Submission ▼ Search	ı GTR ▼
	Search GTR Help Documents	Search GTR help documents

A Print this document

OMB NO: 0925-0651

EXPIRATION DATE: 11/30/2021

**Burden Statement:** 

Public reporting burden for this collection of information is estimated to vary from 18 minutes to 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0651). Do not return the completed form to this address.

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Submit Data	Genes & Expression	Nucleotide	Genome Data Viewer	NCBI on Facebook
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	Homology	Gene	Influenza Virus	Privacy Policy
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	Proteins	PubChem	Sequence Read Archive	
	Sequence Analysis			
	Taxonomy			
	Variation			

National Center for Biotechnology Information, U.S. National Library of Medicine 8600 Rockville Pike, Bethesda MD, 20894 USA

Policies and Guidelines | Contact









Last updated: 2021-11-10T17:08:11Z

# GTR CODE OF CONDUCT



# **Code of Conduct**

Test submitters providing test information to the Genetic Testing Registry (GTR) agree to abide by a code of conduct. Failure to honor this code of conduct may result in the removal of the submitter's test information from the GTR. Submitters agree to the following terms in the code of conduct:

- To uphold the integrity of the GTR through the submission of information that is accurate and not misleading.
- To assure the accuracy of the data at the time of submission and to review and, if necessary, update the submitted information at least once a year.
- To make no explicit or implicit claims that the National Institutes of Health, the Department of Health and Human Services, or the U.S. Government approves or endorses tests listed in, or any other information submitted to, the GTR.

To reference their participation in the GTR, test submitters may refer to the fact that information about their tests is available in the GTR and provide the relevant URL(s) but make no explicit or implicit claims that their tests listed in the GTR, or other information submitted to the GTR, have been approved or endorsed by the National Institutes of Health (NIH), the Department of Health and Human Services, or the U.S. Government. If this stipulation is not honored, NIH reserves the right to take action, including, in its sole discretion, removing the submitter's tests from the GTR.

In addition, users are encouraged to report any acts of inappropriate endorsement claims or any other breaches of this Code of Conduct on our Contact GTR page.

For microbe tests, submitters agree that they are submitting molecular or serologic microbe tests for microorganisms involved in human health and disease.

l agree

Disagree

# AMA CPT CODE LICENSE AGREEMENT



# **AMA CPT Code License Agreement**

# LICENSE FOR USE OF CURRENT PROCEDURAL TERMINOLOGY, FOURTH EDITION ("CPT®")

CPT only copyright 2012 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Registrants are defined as genetic test developers who are adding their tests to the National Center for Biotechnology Information's Genetic Testing Registry ("Genetic Testing Registry") as maintained by the National Library of Medicine.

Registrant, Registrant's employees and agents are authorized to use CPT codes and descriptors only as contained in the Genetic Testing Registry solely for Registrant's own use for the sole purpose of identifying and adding the appropriate CPT code(s) to their registered tests. Registrant acknowledges that the American Medical Associations (AMA) holds all copyright, trademark and other rights in CPT.

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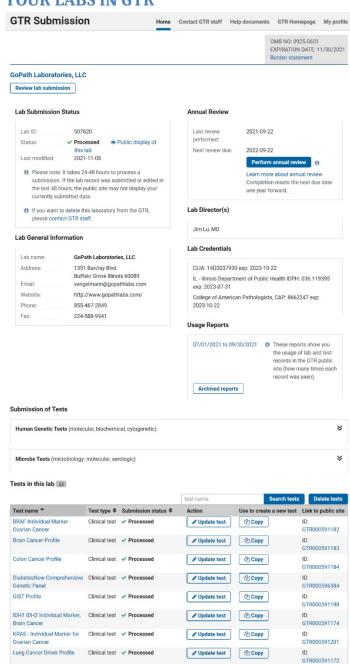
This Agreement will terminate upon notice if Registrant violates its terms. The AMA is a third party beneficiary to this Agreement.

Should the foregoing terms and conditions be acceptable to Registrant, please indicate your agreement and acceptance by clicking below on the button labeled "accept".

Accept

Skip

# YOUR LABS IN GTR



Clinical test 
Processed

Clinical test Processed

Clinical test Processed

Clinical test Processed

Mismatch Repair Proteins by Clinical test ✓ Processed

♥ Update test
 ☐ Copy

✓ Update test
 ✓ Copy

ID: GTR000591175

GTR000591263

GTR000591211

ID: GTR000591173

GTR000591213

Lung Cancer Expanded

LYNCHnow Extended

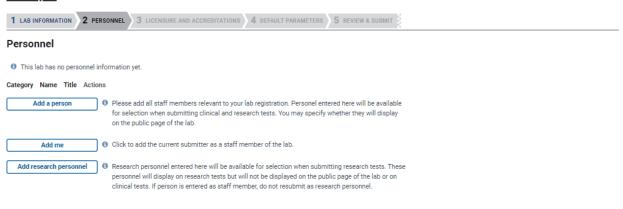
Melanoma Profile

OncoDefender CRC

If you have started submitting a lab in GTR but do not see it in this page, Please log in with the account you used to submit the lab or contact your group administrator to give you permission to access your records.

Other

# Example submission: SUB10192224



Save Cancel

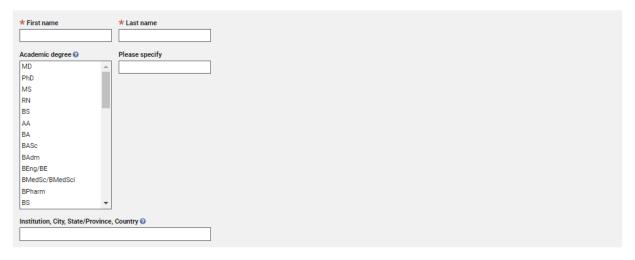
# Example submission: SUB10192224



# Add Research Personnel

★ Required field. ★ Completed field. Hover over ② to display help information.

Enter a Person responsible for the study (Minimal), a Study contact (Minimal) and Co-investigator(s) (Optional). Research personnel entered here will be available for selection when submitting research tests.



#### **Contact information**

 Email is REQUIRED for Person responsible for the study. NO contact information for this person will display publicly.

Either Email or Phone number are REQUIRED for Study contact(s). All contact information for Study contact will display publicly.

Contact information is optional for Co-investigator(s) and will NOT display publicly.

Email (ex. person@lab.com) ©	
Phone number: XXX-XXXX (U.S.A), +(country code)-AreaCode-XXXXXX ext XXXX (International)   ☐	
Fax number: XXX-XXXX (U.S.A), +(country code)-AreaCode-XXXXXX ext XXXX (International)	

Save

Cancel

GTR Submission		Home	Contact GTR staff	Help documents	GTR Homepage	My profile
Example submission: SUB101922	24					
1 LAB INFORMATION 2 PERSONNEL 3 LICENSURE AND ACC	REDITATIONS 4 DEFAULT PARA	METERS 5 REVIEW & SUBMIT				
Licensure And Accreditations				Hover ove	er 쥥 to display help	information.
Laboratory CLIA (or CLIP) Certification  3 Submission of clinical tests by US labs requires provision of CLI	A (or CLIP) number					
CLIA Certification # (e.g. 12D1234567)    Exp. Date (YYYY-MM  Add another CLIA certification  Add CLIP certification (applicable to DoD labs only)	-DD) <b>⊙</b>					
Laboratory State License(s)						
License name	License # <b>②</b>	Exp. Date (YYYY-MM-DD)	0			
Other Certification(s)/License(s) that the Lab Holds						
Name of certification/licensing body  Add another certification/license	License #	Exp. Date (YYYY-MM-DD)	•			

# **Example submission: SUB348876**

1 LAB INFORMATION 2 PERSONNEL 3 LICENSURE AND ACCREDITATIONS 4 DEFAULT PARAMETERS 5 REVIEW & SUBMIT

# **Summary**



Lab ID: 506435 Status: Not submitted, Last modified: 20:08.

Perform annual review

#### Lab information

 Name
 Example

 Institution
 Bethesda Maryland 21842

 Phone
 301-555-5555

 Email
 GTRlab@lab.com

 Types of service
 Affiliations

#### Personnel

Gregor Mendel Lab staff

Display this person's information on the GTR public site: Yes

Is this person the primary lab contact? Yes Is this person a lab director? Yes

Job title: Lab Director Professional certifications:

Contact information to be displayed on GTR public site:

Email: person@lab.com

Contact information for GTR staff to contact you about the submission:

Email: person@lab.com

# Licensure and accreditations

CLIA or CLIP certification CLIA: 12D1234567 Exp: 2023-12-01

State license(s) MD - Maryland Department of Health and Mental Hygiene DHMH: 1234567 Non-expiring

Other certification(s) College of American Pathologists, CAP: 112233 Exp: 2023-11-15

**Default parameters** 

Test contact policy Laboratory can only accept contact from health care providers. Patients/families are encouraged to discuss genetic testing options with

their health care provider.

Who can order test Genetic Counselor

Test-specific services Clinical Testing/Confirmation of Mutations Identified Previously

Order code: 234

Specimen source(s) Peripheral (whole) blood

Submit

Lab ID: 506435 Status: Not submitted, Last modified: 20:08.

# LIST OF TESTS

# GTR Submission Home Contact GTR staff Help documents GTR Homepage My profile OMB NO: 0925-0651 EXPIRATION DATE: 11/30/2021 Burden statement

# University of Minnesota Physicians Outreach Laboratory

Edit this lab

#### Lab Submission Status

Lab ID: 1130

Status: Unfinished at the Overview step

Last modified: 2021-10-15

If you want to delete this laboratory from the GTR, please contact GTR staff.

# Lab General Information

Lab name:	University of Minnesota Physicians Outreach Laboratory, University of
	Minnesota
Address:	Mayo Building, Room D210
	420 Delaware St SE
	Minneapolis Minnesota 55455
Email:	mbower1@fairview.org
Website:	https://mphysicians.org/outreach-laboratories
Phone:	612-273-8445
Faxo	612-273-8959

### Annual Review

Last review 2021-04-26
performed:

Next review due: 2022-04-26

Perform annual review (1) Learn more about annual review

Completion resets the next due date one year forward.

#### Lab Director(s)

Sophia Yohe, MD

#### Lab Credentials

CLIA: 24D0688128 exp: 2022-10-19
CLIA: 24D2043116 exp: 2023-04-14
College of American Pathologists, CAP: 1806001 exp: 2022-09-01

# Usage Reports



#### Submission of Tests



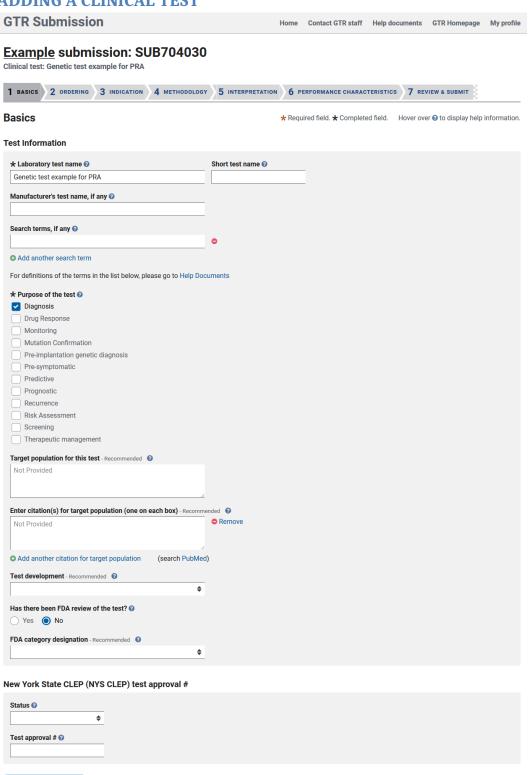
#### Tests in this lab 5

				test name	Search tests Delete tests
Test name *	Test type ♦	Submission status 🕏	Action	Action Use to create a new test	
Breast Actionable panel	Clinical test	✓ Processed		② Copy	ID: GTR000592961
Breast Expanded	Clinical test	✓ Processed		© Copy	ID: GTR000595973
New test	Clinical test	Unfinished			
PAH sequencing	Clinical test	✓ Processed		(건 Copy	ID: GTR000027152
PAX2 sequencing	Clinical test	✓ Processed		© Copy	ID: GTR000282123

If you have started submitting a lab in GTR but do not see it in this page, Please log in with the account you used to submit the lab or contact your group administrator to give you permission to access your records.

Submit a new lab

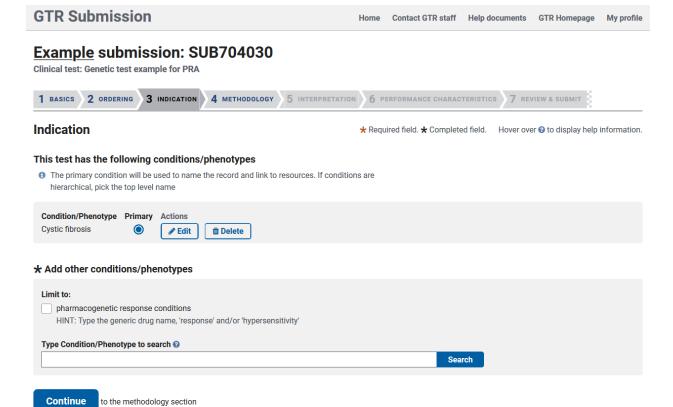
# ADDING A CLINICAL TEST



# Search AMA CPT code Search Show all Codes found:

Select

Cancel



Home Contact GTR staff Help documents GTR Homepage My profile

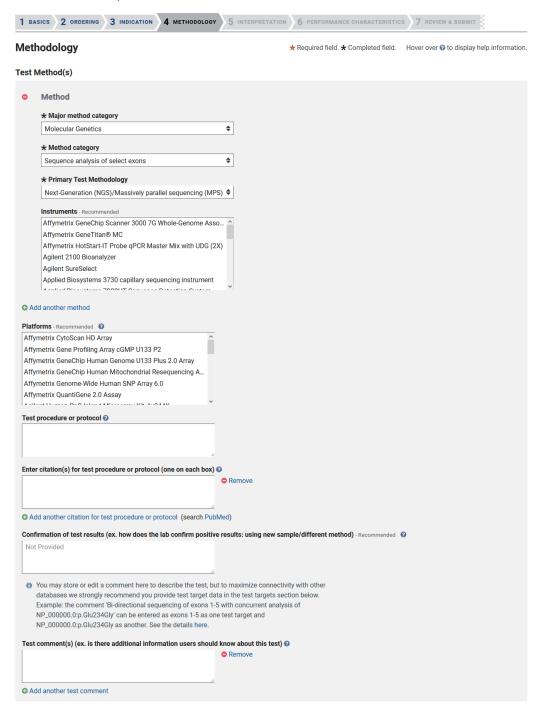
**GTR Submission** 

Save

Cancel

# **Example submission: SUB704030**

Clinical test: Genetic test example for PRA



# ★ Test Targets

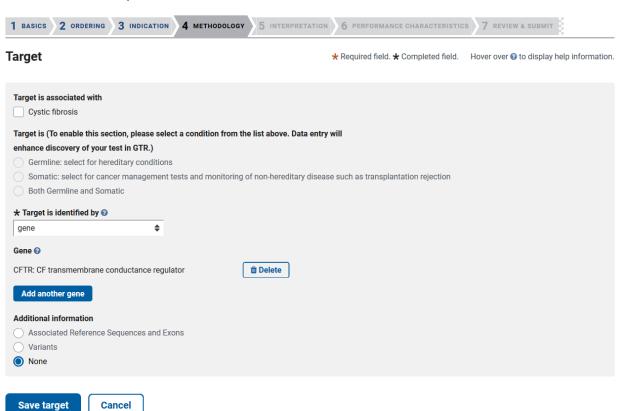
Please add a test target to continue. Each test only needs one condition-test target relationship.

Test must have at least one explicit condition-target relationship

Add test target

# Example submission: SUB704030

Clinical test: Genetic test example for PRA



GTR Submission

Home Contact GTR staff Help documents GTR Homepage My profile

Example submission: SUB704030

Clinical test: Genetic test example for PRA

1 BASICS 2 ORDERING 3 INDICATION 4 METHODOLOGY 5 INTERPRETATION 6 PERFORMANCE CHARACTERISTICS 7 REVIEW & SUBMIT

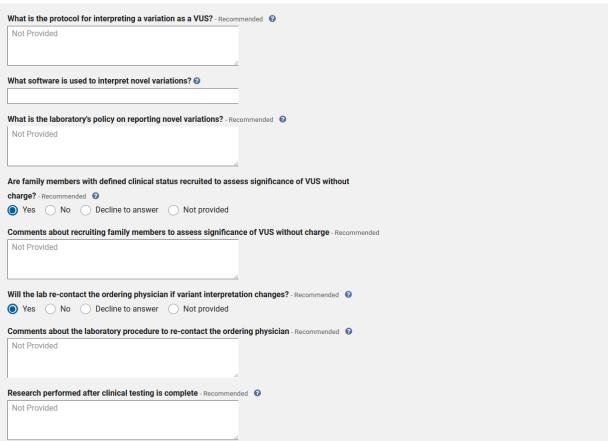
Interpretation

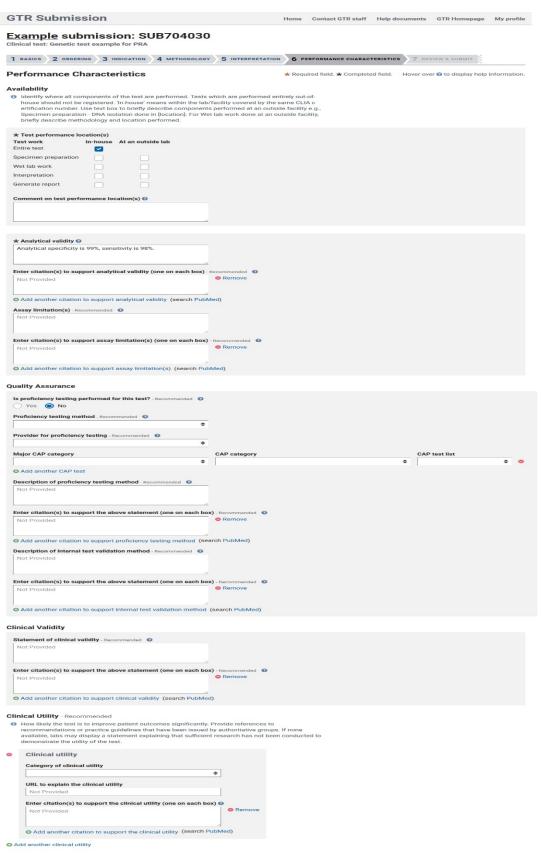
Hover over of to display help information.

# Upload Sample Reports



# Variants of Unknown Significance (VUS): Policy and Interpretation





# **Example submission: SUB704030**

Clinical test: Genetic test example for PRA

1 BASICS 2 ORDERING 3 INDICATION 4 METHODOLOGY 5 INTERPRETATION 6 PERFORMANCE CHARACTERISTICS 7 REVIEW & SUBMIT

#### Summary

# Submit

#### Basics

Name Genetic test example for PRA

Test purpose Diagnosis

Test-specific licenses License#:

# Ordering

Who can order the test Genetic Counselor
Informed consent required Decline to answer
Pre-test generic counseling required

Decline to answer

Post-test generic Decline to answer counseling required

Test-specific services Clinical Testing/Confirmation of Mutations Identified Previously

Custom mutation-specific/Carrier testing

Test-specific additional

Specimen source(s) Amniocytes

Amniotic fluid

Bone marrow

Contact policy Laboratory can only accept contact from health care providers. Patients/families are encouraged to discuss genetic testing options with

eir health care provider

# Condition/Phenotype: Cystic fibrosis

Mode of inheritance Autosomal recessive inheritance

Disease mechanism loss of function

# Methodology

Test method(s) Molecular Genetics, Sequence analysis of select exons, Next-Generation (NGS)/Massively parallel sequencing (MPS)

# Test target(s)

Target is germline

Identified by gene: CFTR: CF transmembrane conductance regulator

Reference Sequence(s)

Variant(s)

# Interpretation

Are family members recruited to assess

ye

Will the lab re-contact the ordering physician if variant interpretation changes

yes

#### Performance characteristics

Test performance Entire test: internal location(s)

Analytical validity Analytical specificity is 99%, sensitivity is 98%.

Proficiency testing is performed for this test?

no

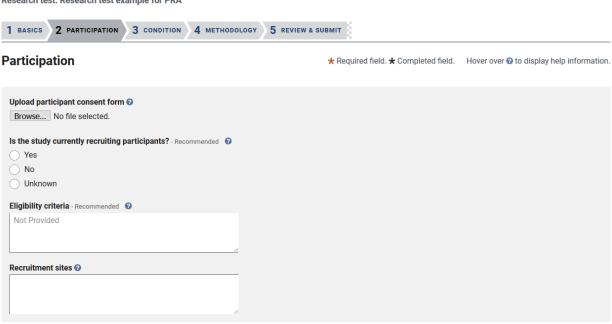
# Submit

# ADDING A RESEARCH TEST

OTD Oak and a single							
GTR Submission		Home	Contact GTR staff	Help docur	ments	GTR Homepage	My profile
Example submission: SUB704037 Research test: Research test example for PRA							
1 BASICS 2 PARTICIPATION 3 CONDITION 4 METHODOLO	OGY 5 REVIEW & SU	вміт					
Basics		* Requi	ired field. 🛨 Complete	d field. Ho	over ove	er ② to display help	information.
★ Laboratory test name ②  Research test example for PRA  ★ What is the purpose of the research test? ② ③ Contribute to generalizable knowledge  For the laboratory to generate data in order to make technical in	Short test name   mprovements to a test						
Study related to this test							
Research study name @	Short study name ②						
ClinicalTrials.gov identifier <b>②</b>	'						
URL for the study <b>②</b>							
If the study is approved by a research ethics committee (e.g., IRB),  Not Provided  What is the study type?   Interventional study (or Clinical Trial)  Observational study  Expanded access  Not applicable  ★ Study description   Example test for screenshots for PRA extension	, please provide the pro	otocol nui	mber - Recommended 4	<b>a</b>			
Enter citation(s) for study description (one on each box) @	• Remove						
◆ Add another citation for study description (search PubMed)  Study aims and hypotheses ◆							
Upload study protocol <b>②</b> Browse No file selected.							
Researchers							
★ Person responsible for the study ②     A M	•						
Research contact policy @							

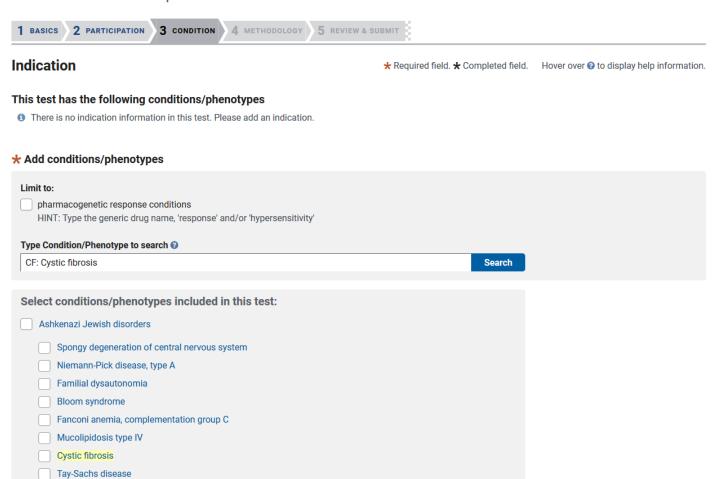
# **Example submission: SUB704037**

Research test: Research test example for PRA



# **Example submission: SUB704037**

Research test: Research test example for PRA



Do you want to add a novel condition not in GTR?

Add a novel condition

Continue to the methodology section

Gaucher's disease, type 1

Add selected conditions/phenotypes

Torsion dystonia

Hexosaminidase A deficiency, adult type

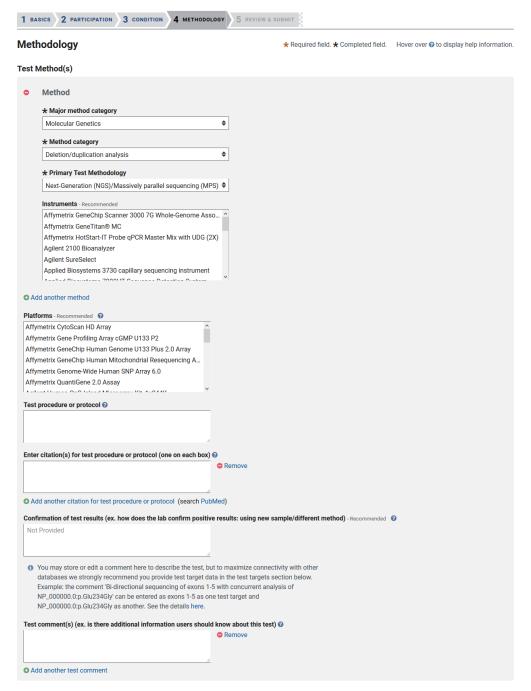
Juvenile (Subacute) Hexosaminidase A Deficiency

Cancel

Save

# Example submission: SUB704037

Research test: Research test example for PRA



# ★ Test Targets

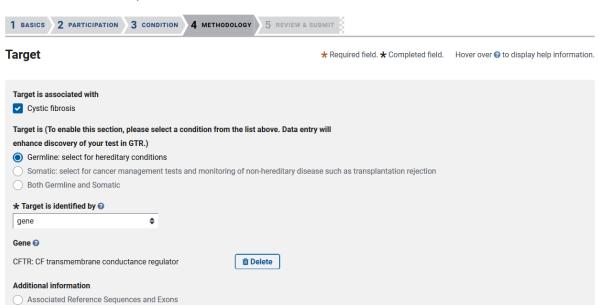
Please add a test target to continue. Each test only needs one condition-test target relationship.

Test must have at least one explicit condition-target relationship

Add test target

# **Example submission: SUB704037**

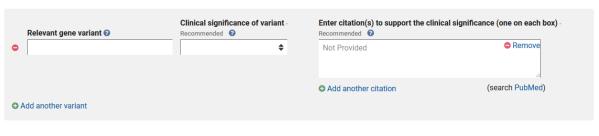
Research test: Research test example for PRA



# Variants

VariantsNone

Apply to: Cystic fibrosis



Save target Cancel

# Example submission: SUB704037

Research test: Research test example for PRA



# **Summary**



#### **Basics**

Name Research test example for PRA

Test purpose Contribute to generalizable knowledge

Study name

Study Description Example test for screenshots for PRA extension

Person responsible for the study

Study contact A M

Contact policy

# Participation

# Condition/Phenotype: Cystic fibrosis

Mode of inheritance Autosomal recessive inheritance

Disease mechanism loss of function

# Methodology

Test method(s) Molecular Genetics, Deletion/duplication analysis, Next-Generation (NGS)/Massively parallel sequencing (MPS)

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Reference Sequence(s)

Variant(s)

Submit