





# **Paper Application Process**

Please email your completed application and study recommendation letter to <a href="https://www.harvard.edu"><u>UDN@hms.harvard.edu</u></a> for processing. If you do not have the ability to submit your application please call the UDN Helpdesk at 1-844-746-4836.

To apply online, go to http://undiagnosed.hms.harvard.edu/apply.

If you have any questions, please contact the UDN Helpdesk:

Phone: 1-844-746-4836

Email: UDN@hms.harvard.edu

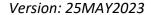


Diseases Network	Version: 25MAY2023
Are you the applicant or legal guardian of the applicant?	
<ul> <li>Yes</li> <li>No- Please review the information on this page with the applicant or the agreeing to the fields on this page, you are confirming that the applicant or agrees to the information.</li> </ul>	
Name:	
Relation to applicant:	
Directions	
Please read the following consent form carefully. The consent form refers t applying to the Undiagnosed Diseases Network (UDN) and "you" refers to	
Introduction	
We invite you to take part in a research study supported by the National Ins(NIH).	stitutes of Health
<ul> <li>First, we want you to know that:</li> <li>Taking part in this research is entirely voluntary.</li> <li>You may choose to not take part, or you may withdraw from the stude ither case, you will not lose any benefits to which you are otherwise.</li> <li>You may receive no benefit from taking part. The research may give may help in the future.</li> </ul>	e entitled.
Second, some people have personal, religious, or ethical beliefs that may I medical or research treatments they would want to receive (such as blood have such beliefs, please discuss them with your health care providers or referred you agree to the study.	transfusions). If you

While the UDN has access to state-of-the-art research resources to help diagnose patients, it is important to remember that the UDN is a research study. Participation in the UDN does not replace the long-term, longitudinal care you receive at home. Your care team at home will remain responsible for treatment and management.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at the Undiagnosed Diseases Network (UDN), or with your family, friends, or your personal doctor or other health professional.

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#### **About the Study**

#### Why is this study being done?

The Undiagnosed Diseases Network (UDN) is a group of medical and research centers across the United States. The purpose of the UDN research study is to diagnose people with unnamed conditions and improve our ability to care for people with rare and undiagnosed diseases.

#### What is involved in the study?

To apply to the UDN, you will likely spend an hour or more completing the information on this web site and speaking with your health care provider. Once you complete your application, it will be given to one of the UDN medical centers. The medical center may contact you and ask you to send some of your medical records. It may take you a couple of hours or many hours to collect and send your records to the medical center. Medical information, including photographs, about you will be shared with health care providers in the UDN.

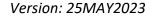
We cannot accept everyone into the UDN. In order to determine which people to accept, we ask applicants to send us a letter from a health care provider. Sometimes we also request medical records that describe their disease and medical test results. We also ask for the applicant's name, contact information, and some additional information, like race and gender. If you apply and provide this information but are not accepted into the UDN, we will keep this information. Keeping your information will allow us to evaluate our admission process. We may publish some of this information in papers about the UDN. All of these papers would discuss the UDN applicants as a whole and would not include any of the information that could identify you, like your name or birth date. If you are accepted into the UDN you will be asked to sign a consent form for the entire study.

If you are not accepted into the UDN, there is no process to request for someone else to review your application. If you have new medical information, you can ask the UDN medical center to review your application again. However, there is no guarantee that the decision will change.

If you are accepted into the UDN, you may need to spend several more hours obtaining additional medical records and speaking with the medical center staff. You may need to travel to one of the UDN medical centers to be seen by a team of doctors, nurses, and other people who work at a hospital. During the evaluation, you would be looked at by multiple doctors. We would ask you questions about your health and the health of your family. After the evaluation, you would likely talk to people at the medical center regularly about updates of the testing.

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☐ I have read and understand this section.

#### **Risk and Benefits**





# What are the risks of applying to the UDN?

The risks of applying to the UDN and sending information about your condition are:

- 1. *Use of information:* Some people are concerned that information about them from their medical records could be released. Possible problems related to the release of information include trouble getting insurance or getting a job. We will try to make sure that this does not happen by taking measures to protect your information.
- 2. Unanticipated medical information: It is possible (although not likely) that we will find information about your health that you did not expect. If this information is important to your health care, we will give you and your doctor the information.

If you are accepted into the UDN you will be asked to sign another consent form that goes over the risks of the entire study.

Your decision to participate in this study will not affect your current health care.

# What are the benefits of applying to the UDN?

Applying to the UDN may not benefit you directly. You may receive a diagnosis if you are accepted into the UDN.

### What are my other options?

You do not have to participate in this study if you do not want to.

# What if I change my mind?

You may stop participating at any time. If you choose, you may request to have your information destroyed.	
☐ I have read and understand this section.	

#### Confidentiality

#### Who else will know that I am in this study?

Only people at the UDN medical and research centers will know that you applied to the UDN and will have your contact information. All of the information that you share with the UDN during the application process will be kept confidential and private.

I have read and understand this section.	

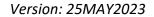
#### **Payment**



will I receive payment for being in this study?
You will not receive payment for taking part in this study.
☐ I have read and understand this section.
Other Pertinent Information
1. <b>Confidentiality.</b> When results of a research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the UDN will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, if asked the UDN will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance. The Federal Privacy Act protects the confidentiality of your UDN medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.
2. <b>Policy Regarding Research-Related Injuries.</b> In general, no long-term medical care or financial compensation for research-related injuries will be provided by the UDN medical and research centers or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.
3. <b>Payments.</b> In general, patients are not paid for taking part in research studies at the UDN medical and research centers.
4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the UDI Coordinating Center through the website, by email, or by phone. Email address: UDN@hms.harvard.edu Phone: 1-844-RINGUDN (1-844-746-4836)
5. <b>Future Contact.</b> In the future, we may re-contact UDN applicants to ask if they are interested in participating in activities like surveys and interviews.
6. <b>Consent Document.</b> Please keep a copy of this document in case you want to read it again.
☐ I have read and understand this section.

☐ I would like to be contacted in the future even if I am not accepted into the UDN.

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Applicant Contact Information
Applicant or parent/guardian email address:
Email address belongs to (e.g. applicant, mother, father):
Applicant first name:
Applicant last name:
Applicant street address:
Applicant apt/suite/floor (optional):
Applicant city, state, zip code:
Applicant country:
Applicant phone number:
Primary language:
Parent/guardian name (if applicable):
Applicant Information
Date of birth:
Sex Assigned at Birth (select one):
If none of these, what sex was assigned at birth?
Gender Identity (select one):
<ul> <li>☐ Man/Boy</li> <li>☐ Transgender man/Trans man</li> <li>☐ Additional identity</li> <li>☐ Woman/Girl</li> <li>☐ Transgender woman/Trans woman</li> <li>☐ Prefer not to say</li> </ul>
If additional identity, what is the applicant's current gender identity?

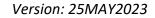
Race (please select all that apply):



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<ul><li>☐ American Indian or Alaska Native</li><li>☐ Asian</li><li>☐ Black or African American</li></ul>	] Native Hawaiian or Other Pacific Islander ] White ] Other
If other, please explain:	
Ethnicity (please select one of the following):	
☐ Not Hispanic or Latino ☐ Hispanic or Latino	☐ Unknown/Not Reported Ethnicity
Category of Applicant's Primary Symptoms	
Many patients with undiagnosed conditions have categories. However, it would be helpful for us to the applicant's primary symptoms. If possible, plealist shown below that BEST describes the application or not answering it correctly will not be	know the category that BEST describes ase select the symptom category from the nt's primary symptoms. Not answering
Allergies and disorders of the immune system Cardiology and vascular conditions (heart, arte Dentistry and craniofacial (bones of head and Dermatology (skin diseases and disorders) Endocrinology (disorder of the endocrine gland Gastroenterology (disorder of the stomach and Gynecology and reproductive medicine (disord Hematology (blood diseases and disorders) Infectious diseases Musculoskeletal and orthopedics (structural ar and joints) Nephrology (kidney diseases and disorders) Neurology (disorders of the nervous system, in Oncology (tumors and cancer) Ophthalmology (eye disorders and diseases) Other (please explain: Psychiatry Pulmonology (lung disorders and diseases) Rheumatology (immune disorders of the joints Toxicology and environmental medicine (disordexposure) Urology	ds and hormones) d intestines) der of the reproductive system)  Ind functional disorders of muscles, bones, including brain and spinal cord)  Ind muscles, and ligaments) Index related to toxin or environmental
When approximately were the applicant's sym about the month, take your best guess	ptoms tirst noticed? If you are not sure

Does the applicant have any relatives with the same or similar symptoms?





☐ Yes	☐ No	Unknown	
is related t		this family member's symptoms and how ant. If there is more than one relative with icate this.	
undiagnos	ed condition	nything in the environment you think may n? Examples could be hazards at work of ssive drugs, poisoning, habits, hobbies, e	r around the home,
☐ Yes ☐	□ No		
If yes, plea	ase describe	·-	
mother or Examples drugs, pois during the	father's live could be ha soning, hab pregnancy	Iren who are applying: were there any ex s that might have resulted in the child's o zards at work or around the home, an un its, hobbies, etc. Were there any exposur that might have resulted in the child's cu r chronic exposures during infancy, child	current condition? usual diet, excessive res the mother had rrent condition? Were
life?			
☐ Yes ☐	☐ No		
If yes, plea	ase describe		
Is the appl	icant curren	tly involved in any other clinical trials?	
☐ Yes [	☐ No		





Has the applicant previously been seen by health care providers at one of the following UDN clinical sites? Select all that apply.

☐ Baylor College of Medicine in Houston, TX	
Brigham and Women's Hospital, Boston Children's Hospital and the Massachus	etts
General Hospital in Boston, MA	
Children's Hospital of Philadelphia and University of Pennsylvania in Philadelphi	ia, PA
Duke Medical Center in Durham, NC	
Stanford Medical Center in Palo Alto, CA	
UCLA Medical Center in Los Angeles, CA	
Undiagnosed Diseases Program (UDP) at the National Institutes of Health (NIH)	) in
Bethesda, MD	
University of Miami in Miami, FL	
<ul><li>☐ University of Utah in Salt Lake City, UT</li><li>☐ University of Washington and Seattle Children's Hospital in Seattle, WA</li></ul>	
☐ University of Washington and Seattle Children's Hospital in Seattle, WA	
☐ Washington University in St. Louis, MO	
Please note: if the applicant participated in the NIH UDP prior to 9/15/2015, please	email
NIHUDN@nih.gov BEFORE submitting this application.	
Applications are assigned to the UDN clinical sites based on site resources a	
location. If you would prefer to have your application reviewed by a specific s	
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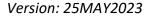
Please explain why you want to be assigned to this site.



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Does the applicant have any travel linapply.	nitations we should know about? Select all that
□None	
☐ Bed bound	☐ Partially ambulatory
Permanently hospitalized	Continuous intravenous infusion
☐ Ventilator dependent	☐ Other
If other, please describe.	
	<del></del>
To your knowledge, have other family or NIH UDP?	members of the applicant applied to the UDN
☐ Yes ☐ No ☐ Unknown	
	embers of the applicant applied to the NIH UDP N@nih.gov BEFORE submitting this application.
How did you hear about the UDN?	
<b>Health Care Provider Contact Informa</b>	tion
Please provide contact information for that about this application.	ne health care provider who should receive updates
Health care provider email address: _	

Health care provider first name:

Health care provider last name: \_\_\_\_\_





Health care provider street address:
Health care provider apt/suite/floor (optional):
Health care provider city, state, zip code:
Health care provider country:
Health care provider phone number:
Health care provider fax number:

#### **Attachments**

# Required attachment

**Study recommendation letter:** Please attach a study recommendation letter from one of the applicant's licensed health care providers. The letter should be on letterhead and signed by the health care provider. Please contact the UDN Coordinating Center (email: UDN@hms.harvard.edu, phone: 1-844-RINGUDN (1-844-746-4836)) to request an example study recommendation letter.

# Optional attachments

**Narrative summary:** Applicants are welcome to provide a 1-page (500 words maximum) summary of the undiagnosed condition from their perspective. This narrative summary may be helpful for the UDN team to learn more about the applicant's experience with the undiagnosed condition. If you would like to provide a narrative summary, please attach it to this application.

**Photo:** Sometimes photos help us better understand the symptoms the applicant is experiencing. If you would like to provide a photo of the applicant, please attach it to this application. Up to 5 photos may be attached.