



## Paper Application Process

Please return your completed application and study recommendation letter by mail or fax to:

Undiagnosed Diseases Network  
Attn: Paul Mazur  
Department of Biomedical Informatics  
Harvard Medical School  
10 Shattuck Street  
Boston, MA 02115  
Fax: (617) 432-5105

Alternatively to apply online go to: <http://undiagnosed.hms.harvard.edu/apply>

If you have any questions, please contact:

**1-844-746-4836 (1-844-Ring-UDN)**

**Email: [UDN@hms.harvard.edu](mailto:UDN@hms.harvard.edu)**

**Are you the applicant or legal guardian of the applicant?** Yes

No- Please review the information on this page with the applicant or his/her legal guardian. By agreeing to the fields on this page, you are confirming that the applicant or his/her legal guardian agrees to the information.

Name: \_\_\_\_\_

Relation to applicant: \_\_\_\_\_

**Directions**

Please read the following consent form carefully. The consent form applies to the person applying to the Undiagnosed Diseases Network and “you (your child)” refers to the applicant.

**Introduction**

We invite you to take part in a research study supported by the National Institutes of Health (NIH).

First, we want you to know that:

- Taking part in this research is entirely voluntary.
- You (your child) may choose to not take part, or you (your child) may withdraw from the study at any time. In either case, you (your child) will not lose any benefits to which you (your child) are otherwise entitled.
- You (your child) may receive no benefit from taking part. The research may give us knowledge that may help in the future.

Second, some people have personal, religious, or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your (your child’s) doctors or research team before you agree to the study.

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 physician or other health professional.

 I have read and understand this section.

## About the Study

### ***Why is this study being done?***

The purpose of this study is to diagnose people with unnamed conditions and improve our ability to care for people with rare and undiagnosed diseases.

The Undiagnosed Diseases Network (UDN) is a group of medical and research centers across the United States.

### ***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 (your child's) physician. Once you complete your (your child's) application, your (your child's) application will be given to one of the UDN medical centers. The medical center will contact you and ask you to send all of your (your child's) medical records. This may take you a couple of hours or many hours to collect and send your (your child's) records to the medical center. Medical information, including photographs, about you (your child) will be shared with healthcare 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 their doctor, medical records that describe their (their child's) 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 (your child) apply and provide this information but are not accepted into the UDN, we will keep this information. Keeping your (your child's) 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 (your child), like your (your child's) name or birth date. If you are (your child is) accepted into the UDN you (your child) will be asked to sign a consent form for the entire study.

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

If you are (your child is) accepted into the UDN, you may need to spend several more hours obtaining additional medical records and speaking with the medical center staff to plan the visit. You (your child) would 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. This visit would last about a week. During the visit, you (your child) would be looked at by multiple doctors. We would ask you questions about your (your child's) health and the health of

your family. After the visit, you would likely talk to people at the medical center regularly about updates of the testing.

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 (your child's) 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 (your child's) information.
2. *Unanticipated medical information:* It is possible (although not likely) that we will find information about your (your child's) health that you did not expect. If this information is important to your health care, we will give you and your (your child's) doctor the information.

If you are (your child is) 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 (your child's) current healthcare.

#### ***What are the benefits of applying to the UDN?***

Applying to the UDN may not benefit you (your child) directly. You (your child) may receive a diagnosis if you are (your child is) accepted into the UDN.

#### ***What are my other options?***

You do not (your child does not) have to participate in this study if you do not (your child does not) want to.

#### ***What if I change my mind?***

You (your child) 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 Coordinating Center and the UDN medical centers will know that you (your child) 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 (your child) will not receive payment for taking part in this study. We would cover travel expenses and meals during the visit if you are (your child is) accepted into the UDN.

I have read and understand this section.

### Other Pertinent Information

1. **Confidentiality.** When results of an NIH 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 NIH will not release any information about your (your child's) 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 (your child's) medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you (your child) 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. **Policy Regarding Research-Related Injuries.** In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.
3. **Payments.** In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.
4. **Problems or Questions.** If you have any problems or questions about this study, or about your (your child's) rights as a research participant, or about any research-related injury, contact the UDN Coordinating Center through the website, by email, or by phone.  
Email address: UDN@hms.harvard.edu  
Phone: Toll-Free (US Only)- 1-844-RINGUDN (746-4836), Outside US- 617-432-2344
5. **Future contact.** In the future, we may re-contact UDN applicants to ask if they are interested in participating in activities like surveys and interviews.
6. **Consent Document.** 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.

## Identification

Patient or Parent/Guardian Email Address: \_\_\_\_\_

Email address belongs to (ex. patient, mother, father, etc.): \_\_\_\_\_

Patient's First Name: \_\_\_\_\_

Patient's Last Name: \_\_\_\_\_

Patient's Address (Street, Apt/Suite/Floor, City, State, Zip Code):  
\_\_\_\_\_

Patient's Phone Number: \_\_\_\_\_

Parent/Guardian Name (If Applicable): \_\_\_\_\_

## Patient Information

Date of Birth: \_\_\_\_\_

Gender:     Male     Female     Other

If other, what sex was assigned at birth? \_\_\_\_\_

If other, what is the applicant's current gender identity? \_\_\_\_\_

Race (please select all that apply):

American Indian or Alaska Native

Asian

Black or African American

Native Hawaiian or Other Pacific  
Islander

White

Other

If other, please explain: \_\_\_\_\_

**Ethnicity (please select one of the following):**

- Not Hispanic or Latino  Unknown/Not Reported Ethnicity  
 Hispanic or Latino

**Category of Applicants Primary Symptoms**

*NOTE: Many patients with undiagnosed conditions have symptoms that fall into multiple categories. However, it would be helpful for us to know the category that BEST describes the applicant's primary symptoms.*

*If possible, please select the symptom category from the list shown below that BEST describes the applicant's primary symptoms. Not answering this question or not answering it correctly will not impact the status of the application.*

- Allergies and Disorders of the Immune System  
 Cardiology and vascular conditions (heart, artery, vein, and lymph disorders)  
 Dentistry and craniofacial (bones of head and face)  
 Dermatology (skin diseases and disorders)  
 Endocrinology (disorder of the endocrine glands and hormones)  
 Gastroenterology (disorder of the stomach and intestines)  
 Gynecology and reproductive medicine  
 Hematology (blood diseases and disorders)  
 Infectious diseases  
 Musculoskeletal and orthopedics (structural and functional disorders of muscles, bones, and joints)  
 Nephrology (kidney diseases and disorders)  
 Neurology (disorders of the nervous system, including brain and spinal cord)  
 Oncology (tumors and cancer)  
 Ophthalmology (eye disorders and diseases)  
 Other

Please explain: \_\_\_\_\_

- Psychiatry  
 Pulmonology (lung disorders and diseases)  
 Rheumatology (immune disorders of the joints, muscles, and ligaments)  
 Toxicology and Environmental Medicine  
 Urology

**When approximately were the applicant's symptoms first noticed? If you are not sure about the month, take your best guess.** \_\_\_\_\_

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

Yes       No       Unknown

**If yes, please describe this family member's symptoms and how he/she is related to the applicant. If there is more than one relative with the same or similar symptoms, please indicate this.**

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**Is there exposure to anything in the environment you think may have caused this undiagnosed illness? Examples could be hazards at work or around the home, an unusual diet, excessive drugs, poisoning, habits, hobbies, etc.**

Yes       No

**If yes, please describe:** \_\_\_\_\_

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**For undiagnosed children who are applying: were there any exposures during the mother or father's lives that might have resulted in the child's current illness? Examples could be hazards at work or around the home, an unusual diet, excessive drugs, poisoning, habits, hobbies, etc. Were there any exposures the mother had during the pregnancy that might have resulted in the child's current illness? Or, any accidental or chronic exposures during infancy, childhood, or young adult life?**

Yes       No

**If yes, please describe:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**Is the applicant currently involved in any other clinical trials?**

Yes       No

**Has the applicant previously been seen at NIH or one of the following UDN clinical sites? Select all that apply.**

- UCLA Medical Center in Los Angeles, CA
- Undiagnosed Diseases Program (UDP) at the National Institutes of Health (NIH) in Bethesda, MD
- Baylor College of Medicine in Houston, TX
- Vanderbilt Medical Center in Nashville, TN
- Brigham and Women's Hospital, Boston Children's Hospital or the Massachusetts General Hospital in Boston, MA
- Duke Medical Center in Durham, NC
- Stanford Medical Center in Palo Alto, CA

**Applicants will generally be referred to the closest UDN site if space is available. May we assign you to the closest site?**

Yes       No

**If no, please explain why you do not want to be assigned to the closest clinical site.** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**If you would prefer to be seen at a specific clinical site, please select that site.**

- UCLA Medical Center in Los Angeles, CA
- Undiagnosed Diseases Program (UDP) at the National Institutes of Health (NIH) in Bethesda, MD
- Baylor College of Medicine in Houston, TX
- Vanderbilt Medical Center in Nashville, TN
- Brigham and Women’s Hospital, Boston Children’s Hospital or the Massachusetts General Hospital in Boston, MA
- Duke Medical Center in Durham, NC
- Stanford Medical Center in Palo Alto, CA

**Does the applicant have any travel limitations we should know about?**

- |   |  |
|---|--|
| <input type="checkbox"/> None                     | <input type="checkbox"/> Wheelchair dependent            |
| <input type="checkbox"/> Bed bound                | <input type="checkbox"/> Partially ambulatory            |
| <input type="checkbox"/> Permanently hospitalized | <input type="checkbox"/> Continuous intravenous infusion |
| <input type="checkbox"/> Ventilator dependent     | <input type="checkbox"/> Other                           |

**To your knowledge, have other family members of the applicant applied to the UDN or UDP?**

- Yes       No       Unknown

**Does the applicant speak English?**

- Yes       No

**If no, what is the applicant’s preferred language?** \_\_\_\_\_

**How did you hear about the UDN?**

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### Health Care Provider Information

Health Care Provider's Email Address: \_\_\_\_\_

Health Care Provider's First Name: \_\_\_\_\_

Health Care Provider's Last Name: \_\_\_\_\_

Health Care Provider's Address (Street, Apt/Suite/Floor, City, State, Zip Code):  
\_\_\_\_\_

Health Care Provider's Phone Number: \_\_\_\_\_

Health Care Provider's Fax Number: \_\_\_\_\_

### Study Recommendation Letter

**Please attach a summary letter from your referring licensed healthcare provider. The letter should be on letterhead and signed by the healthcare provider. Please contact the UDN Coordinating Center (email: [UDN@hms.harvard.edu](mailto:UDN@hms.harvard.edu), phone: 1-844-RINGUDN (1-844-746-4836)) if you need an example study recommendation letter so your licensed healthcare provider will know what information we need to begin the application review process.**