The University of New Mexico Health Sciences Center
Consent to Participate in Research

Oculopharyngeal Muscular Dystrophy Registry for Patients and Family Members

Purpose and General Information

You are being asked to participate in a research study that is being done by Dr. Sarah Youssof, who is the Principal Investigator, and her associates. This research is being done to establish a "registry" for individuals with oculopharyngeal muscular dystrophy (OPMD) and their family members.

A registry is a place where medical information, family history and other related information from individuals is collected and stored for medical research. Such information (without your personal identifying information) may be shared in the future with other researchers, while protecting your privacy. The purpose of the OPMD registry is to collect and store medical information from individuals with OPMD, individuals who might develop OPMD in the future, and individuals who are related by blood to someone with OPMD. The purpose of the registry is to understand more about how OPMD affects people's lives, to find out which individuals would like to be contacted for future studies on OPMD, and to establish communication between researchers and OPMD patients and families.

You are being asked to participate because you are an individual with OPMD, or who may develop OPMD in the future, or who is related by blood to someone with OPMD.

This form will explain the study to you, including the possible risks as well as the possible benefits of participating. This is so you can make an informed choice about whether or not to participate in this study. Please read this Consent Form carefully. Ask the investigator or study staff to explain any words or information that you do not clearly understand. If you are completing this form at home and have questions, you may reach us by phone, mail, email, or by making an appointment to meet in person:

Sarah Youssof, MD
MSC 10-5620
1 University of New Mexico
Albuquerque, New Mexico 87131
Phone: (505) 272-6354 Toll-Free: (855) 676-3721
Fax: (505) 272-6692
Email: opmd@salud.unm.edu
Website: http://som.unm.edu/programs/opmd

What will happen if I participate?

If you agree to be in this study, you will be asked to read and sign this Consent Form. After you sign the Consent Form, the following things will happen:

1. You will be asked to complete a questionnaire that asks about your demographic information (such as age, sex, and racial/ethnic background) and medical information. The questionnaire will take up to one and a half hours to complete.
2. You will be given a medical release form to review. If you agree to sign it, then we will have permission to contact your physicians to request medical records that are relevant to OPMD or any results of testing (including genetic testing) you have had for OPMD.

3. We will use the information from your medical records to verify the medical information you provide in the questionnaire.
4. Your information will be entered into a computer database. Once your information is entered in the computer database, we will destroy paper copies of your questionnaire and medical records.
5. The computer database is a secure database, meaning that only the research team members can see your personal identifying information in the database. This database will continue for as long as we continue the OPMD registry, which may be 10 years or longer.
6. Once a year, we will contact you to update your information and ask you about any changes in your health. This will take one hour.
7. Your identifiable information will not be shared with anyone outside the registry. Approved researchers will be allowed to see and study only the de-identified information (information that has been removed of all personal identifiers).
8. An approved researcher may search the de-identified data for individuals for their studies. If you look like a good match for a study and a researcher wants to contact you, he/she can do it only through the UNM OPMD registry. The UNM OPMD registry would then contact you but the researcher would not contact you directly.

As stated above, participation in this study will take a total of one and a half hours when you first join the study. This study entails yearly follow-ups when we will contact you to update your information. The yearly updates will take one hour.

What are the possible risks or discomforts of being in this study?
Every effort will be made to protect the information you give us. However, there is a small risk of loss of confidentiality due to unauthorized release of medical information. This may result in embarrassment, unfair treatment by others, and emotional distress. In addition, you may be inconvenienced when we contact you once a year to update your information.

How will my information be kept confidential?
Your name and other identifying information will be stored in a computer database maintained on a secure server at the University of New Mexico. Only members of the research team will have passwords that will allow them access to the personal identifying information in the computer database. No personal identifying information will be revealed to anyone other than the research team. In the event that information in the database is shared with other researchers, the information will be stripped of your personal identifying information (that is, it will be de-identified prior to sharing). Information resulting from this study will be used for research purposes and may be published; however, you will not be identified by name in any publications.

Information from your participation in this study may be reviewed by federal and state regulatory agencies, and by the UNM Human Research Review Committee (HRRC) which provides regulatory and ethical oversight of human research.

What are the benefits to being in this study?
There is no direct health benefit to you from being in this study. Your participation may give you an opportunity to participate in future studies on OPMD. In addition, you will receive a newsletter once per year about research advances in OPMD and the status of the registry.

What other choices do I have if I don't participate?
Taking part in this study is voluntary so you can choose not to participate. Your decision whether to participate in this research will not affect the medical care you receive at the University of New Mexico.

Can I stop being in the study once I begin?
Yes. You can withdraw from this study at any time without affecting your access to medical care. Simply contact the registry to inform us of your decision to withdraw. We will then remove your information from the database. Keep in mind that data already assigned to a specific study prior to your request for removal cannot be retrieved from researchers that have already used it.

HIPAA AUTHORIZATION SECTION

Authorization for Use and Disclosure of Your Protected Health Information (HIPAA)
As part of this study, we will be collecting health information about you and sharing it with others. This information is "protected" because it is identifiable or "linked" to you.

Protected Health Information (PHI)
By signing this Consent Document, you are allowing the investigators and other authorized personnel to use your protected health information for the purposes of this study. This information may include: medical history, results of physical exams, results of genetic tests, and family medical history.

In addition to researchers and staff at UNMHSC and other groups listed in this form, there is a chance that your health information may be shared (re-disclosed) outside of the research study and no longer be protected by federal privacy laws. Examples of this include disclosures for law enforcement, judicial proceeding, health oversight activities and public health measures.

Right to Withdraw Your Authorization
Your authorization for the use and disclosure of your health information for this study shall not expire unless you cancel this authorization. Your health information will be used or disclosed as long as it is needed for this study. However, you may withdraw your authorization at any time provided you notify the UNM investigators in writing. To do this, please send a HIPAA Research Withdrawal Form or letter notifying them of your withdrawal to:

Sarah Youssof, M.D.
MSC 10 5620
1 University of New Mexico
Albuquerque New Mexico 87131

Please be aware that the research team will not be required to destroy or retrieve any of your health information that has already been used or shared before your withdrawal is received.

Refusal to Sign
If you choose not to sign this consent form and authorization for the use and disclosure of your PHI, you will not be allowed to take part in the research study.

What if I have questions or complaints about this study?
If you have any questions, concerns or complaints at any time about the research study, Sarah Youssof, M.D., or her associates will be glad to answer them at 505-272-4015. If you would like to speak with someone other than the research team, you may call the Human Research Review Committee (HRRC) at (505) 272-1129. The HRRC is a group of people from UNM and the community who provide independent oversight of safety and ethical issues related to research involving human subjects.

What are my rights as a research subject?
If you have questions regarding your rights as a research subject, you may call the HRRC at (505) 272-1129 or visit the HRRC website at http://hsc.unm.edu/som/research/hrrc/.

Consent and Authorization
You are making a decision whether to participate in this study. Your signature below indicates that you read the information provided (or the information was read to you). By signing this Consent Form, you are not waiving any of your legal rights as a research subject.

I have had an opportunity to consider whether to participate in this study.

A. If I am signing this consent form in person, I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction.

B. If I am returning this consent form by mail, I am aware that I can contact the study team to ask questions. If I had any questions, I have contacted the study team. All of my questions have been answered to my satisfaction.

By signing this Consent Form, I agree to participate in this study and give permission for my health information to be used or disclosed as described in this Consent Form. I have received a copy of this Consent Form to keep.

_____	_____/_____
Name of Adult Participant (print)	Signature of Adult Participant Date

For Registry Staff Use Only

_____	_____/ _____
Name of Research Team Member	Signature of Research Team Member/Date