IRB APPROVED
AS MODIFIED
Jun 24, 2020

RESEARCH SUBJECT CONSENT FORM AND HIPAA AUTHORIZATION

TITLE:	Migraine Clinical Outcome Assessment System: Understanding the Experience of People with Migraine
PROTOCOL NO.:	19192 WIRB® Protocol #20201459
SPONSOR:	Vector Psychometric Group, LLC as funded by FDA Grant the United States Food and Drug Administration #1UG3FD006795-01
INVESTIGATOR:	R.J. Wirth, PhD MiCOAS@VPGcentral.com
STUDY CONTACTS:	Maya Gerstein, DrPH, MPH mgerstein@pharmerit.com Kelly McCarrier, PhD, MPH kmccarrier@pharmerit.com 240-821-1287
STUDY-RELATED PHONE NUMBER(S):	240-821-9667 (24 hours)

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject or study participant.

This research is being funded by a grant (1UG3FD006795-01) from the United States Food and Drug Administration (FDA) to Vector Psychometric Group, LLC (VPG) and Albert Einstein College of Medicine. The current research is being conducted by Pharmerit International, a research organization that conducts studies to assess the symptoms and impacts of health conditions and their treatments on people's lives.

What should I know about this research?

- Someone will explain this research study to you. This form summarizes that explanation.
- Taking part in this research study is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.

- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions. Ask all the questions you want before you decide.
- You have the right to not answer any questions at any time.

Why is this research being done?

The purpose of this research is to gain a better understanding of people's experience with migraine. The information collected during this study will help develop and refine questionnaires that future people with migraine will complete to measure the burden of migraine and the benefits of treatment in upcoming clinical trials and other research studies.

You will be one of approximately 40 participants included in this part of this study.

How long will I be in this research?

We expect taking part in this research will last approximately 60 to 90 minutes and includes an over-the-phone, audio-recorded interview.

What happens to me if I agree to take part in this research?

First, you will review and complete the web-based informed consent process. The study will be explained to you. You can reach out to the study contacts listed at the top of this page to ask any and all questions that you have about this study. This study is entirely voluntary. Take your time before deciding whether to participate. If you agree to participate, you will be asked to complete this consent form to enroll in this study.

Your involvement will include the following procedures:

Once you have indicated your consent to participate in the study, you will be asked to answer questions about your background and health. We will ask about your gender, race or ethnicity, current health status, etc. You will also be asked to complete a short electronic form to provide us with limited contact information (such as first name or initials, telephone number/email) and preferred time of contact that the Pharmerit research team will use solely for purposes of scheduling the interview, coordinating additional interview logistics, and conducting the interview session.

You will be scheduled for a telephone interview appointment with a researcher from the Pharmerit study contacts. This schedule will be flexible to accommodate your schedule. After the interview has been scheduled, Pharmerit will contact you once, approximately 1 to 3 days before your scheduled interview, to remind you about the interview and confirm your availability.

During your interview session, you will be asked to answer questions about migraine symptoms you've experienced, the frequency and severity of these symptoms, how they have impacted your work, personal and family life as well as your experiences with treatment, medications and healthcare professionals. These questions will be open-ended initially and will then be followed by more targeted questions to help us gain a better understanding of your experience with migraine.

Your interview will be audio-recorded so the study contacts can create a transcript of the interview (a written copy of your exact words). Your transcript will be used as part of the analysis of the study results and will be combined with interviews from all of the other participants. If you do not consent to your interview being recorded and transcribed, you will not be able to participate in this study. By providing your consent to participate in this study, you are giving permission to record and transcribe your interview as described above.

Your privacy is very important to us. The transcript and questionnaire responses will not include your name or address or information that could be used to identify you. We will not use your name or identify you as an individual in any way in any reports, presentations, or publications from this study. We will store this data in secure, confidential files and will not share your data with anyone outside of our research team unless required by law. The FDA and the Institutional Review Board (IRB) will have access to the research records.

Once this study is completed, a report will be written from all 40 interviews combined, and the results may be presented at scientific or medical conferences and/or published in a scientific or medical research journal so that others can learn from this research. We will also share the report with the FDA, who is the sponsor of this study, and the general public. None of the reports or documents will have any of your identifying data or report your results alone. They will report results that are combined among participants and any quotes that are used will not include information that allows others to identify you. Study data may be made available to other researchers.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Completing a short form that includes questions about your background and your general health.
- Completing an interview session where you will be asked to answer questions about your migraine experience and how migraine may impact your daily activities (work, school, family and personal life), and your treatment experience.

Could being in this research hurt me?

There are no anticipated physical risks to participating in this study. The research involves completing a questionnaire and answering questions on the phone. There is a chance that some of the questions posed in this study may make you uncomfortable and you may become more aware of the symptoms, impacts, or other factors related to migraine. If that is the case, you may choose not to answer specific questions. You can also not answer or stop answering questions at any time.

Will it cost me money to take part in this research?

There are no costs to you for participating in this study.

Will being in this research benefit me?

You may not receive any direct health benefits from participating in this study. However, your contribution will help to provide a better understanding of your experience with migraine and migraine treatment. This should lead to the development of better ways of measuring the burden of migraine and the benefits of treatment. This research study is not designed to diagnose, treat, or prevent any disease.

Will I be paid for taking part in this research?

You will receive $125 for taking part in this research study. You will receive this payment as a gift card (e.g. VISA, MasterCard) after you complete the interview. You will be asked to sign a form confirming receipt of this payment.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in this study.

What happens to the information collected for this research?

If you indicate your consent to participate in this study, you are giving permission to:

- Collect, analyze, and share your responses to questions with designated members of the study contacts.

Additionally, if you are in this study, you are giving Pharmerit permission to:

- Conduct a one-on-one interview to gain a better understanding of your experience with migraine.
- Record and transcribe your interview.

Written reports that summarize the results of this research will be made available to the general public. Any quotes that are used in these study reports will not include information that allows others to identify you.

Any data shared won't include information that allows others to identify you

In no way are you waiving your legal rights by indicating your consent on the consent form nor does your consent release Pharmerit, the study sponsor, or any other institution involved in this study or in the review of this study from their legal and professional responsibilities to protect your identity and your personal information to the extent permitted by any applicable laws and regulations.

To protect your identity, all study related information will be stored, tracked, and analyzed using a study-specific identification number that will keep your data private. This serves to protect your identity regarding any study-related information. This identification number will be used by the Pharmerit study contacts and its representatives for the purposes of documenting information collected from the study interview. It will then be used for analysis and reporting. However, if you participate in the study, in order to confirm your eligibility, schedule, and conduct your interview, your identity will be known to the Pharmerit study contacts. The recording of your voice made during the interview will be heard by researchers at Pharmerit and those persons responsible for recording your responses and producing the written transcript.

In addition to the study contacts, the data from this study may be shared with other researchers involved in the conduct of this study (such as those grant collaborators at VPG and Albert Einstein College of Medicine) or bodies responsible for oversight of the study conduct [such as the FDA, state regulatory agencies (if applicable), and Institutional Review Boards (IRBs)]. Any data shared won't include information that allows others to identify you and will instead be aggregated, meaning information has been compiled from all study participants, to report study results. However, government authorities and IRB may access your medical records and study data for the purposes of auditing this study to ensure data integrity and protection of study participants. Not all parties who will have access to your medical information as part of this study are prohibited by federal law from further sharing it; therefore, the information once received by them, may no longer be protected by federal law.

There is a risk of loss of confidentiality when participating in a research study. Every effort will be made to protect you and your health information to the extent possible. For example, if you are participating in the study and you accidentally state your name or any other names during your recorded interview session, those names will be removed from the written transcript before it is shared with those analyzing the study data.

If you have any questions about the collection and use of your information or would like to discuss your rights regarding this information, you can ask the study contacts using the contact information listed at the top.

By completing the web-based informed consent process and indicating your desire to continue with the study, you are giving permission to use and access your data as described above.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the study contacts at the phone number(s) listed above.

This research study is being overseen by an IRB. An IRB is a group of people (scientists and non-scientists) who perform an independent review of research studies to ensure that they are ethical, fair and safe. The goal of the IRB is to protect the rights and welfare of study participants. You may talk to them at or 800-562-4789, (800) 562-4789 if:

- You have questions, concerns, or complaints that are not being answered by the study contacts.
- You are not getting answers from the study contacts.
- You cannot reach the study contacts.
- You want to talk to someone else about the research.
- You have questions about your rights as a study participant.

Can I be removed from this research without my approval?

The study contacts can remove you from this research without your approval. Possible reasons for removal include:

- If you are unable to keep your scheduled appointments
- If this study is cancelled by the sponsor, the FDA, or the IRB
- For administrative reasons

What happens if I agree to be in this research, but I change my mind later?

You may withdraw your consent to participate at any time during this study. Withdrawing at any time during this study will in no way influence the care that you are receiving from your doctor or other healthcare providers. There will be no penalty or loss of benefits to which you are otherwise entitled if you withdraw from this study.

To withdraw consent from this study, please notify the Pharmerit study contacts of your decision to withdraw consent.

If you leave or withdraw from this study prior to completion of the interview, you will receive no compensation.

If you withdraw consent from this study, no new data about you will be collected for study purposes. If you withdraw from this study none of your data will be analyzed and your data will be destroyed and left out from any analysis. If you do not complete this study but do not formally leave this study or withdraw consent, then any completed data will be used in analysis.

Agree or disagree to participate

Clicking "Yes" below indicates that you have read and understood the information provided, and that you voluntarily **agree** to participate in this research study. You will be directed to the demographic and health information form and contact information form after that.
Clicking "No" below indicates that you have read and understood the information provided, and that you **do not agree** to participate in this research study. After reading the above information, do you agree to participate in this research study?

□ **Yes, I agree** to participate in this research
□ **No, I do not agree** to participate in this research

You can print a copy of this consent document to keep for your records.