PARTICIPANT CONSENT FORM

TITLE: Qualitative Concept Elicitation to Support Development of the Migraine Clinical Outcome Assessment System (MiCOAS)

PROTOCOL NO.: MiCOAS UH3
IRB Protocol #20213555

SPONSOR: Vector Psychometric Group, LLC
Under a grant from the United States Food and Drug Administration (FDA) (#3UH3FD006795-02S1)

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Why am I being contacted?

You are being invited to take part in a research study about people who have migraine headaches. If you participate, you will be one of about 48 participants in this study.

If you choose to participate, you:

- Will be asked to answer a 10-minute online survey about your background and health.
- May be invited to participate in one interview that will last about 60-90 minutes.

The main **benefit** of this research is that your participation will help scientists develop measures of the impact migraine has on people's lives. These measures will be used to evaluate how well treatments for migraine work. But, there is no direct benefit to you for participating.

The main **risk** of the research is that you may find the interview tiring or some of the topics to be uncomfortable or bring up strong emotions.

Your participation is **voluntary**. Your alternative is to not participate. The decision to participate is up to you. You always have the right not to answer questions. You may also stop your participation at any time. If you do not want to participate or decide to stop participating, there will be no penalty or loss of benefit to which you are otherwise entitled.

More information about all these topics is provided below.

Why is this study being done?

The purpose of this study is to get a better understanding of people's experience with migraine and their views on how it affects their lives. This study focuses on how migraine affects people's ability to do the things they want to do from day to day.

How will this study help people with migraine?

The information collected during this study will be used to create questionnaires that can measure the impact of migraine on people's lives. These measures can then be used to understand whether treatments for migraine, such as medicines, are working as intended.

Who is paying for this study?

The United States Food and Drug Administration (FDA) is funding the study through grant number 3UH3FD006795-02S1.

Who is conducting this study?

Vector Psychometric Group, LLC, and Albert Einstein College of Medicine are conducting this study. In the rest of this document, Vector Psychometric Group will be called VPG.

What should I know about this research?

The study involves answering questions about yourself and your experiences. It does not involve any medical treatments and will not affect your medical care in any way.

If you have any questions about the study after you read this form, please call or email the study contact listed at the top of this form. Ask all the questions you want before you decide about participating.

Taking part in this study is voluntary. It is your decision whether to participate at all times. No matter how you choose, there will be no penalty or loss of benefits to which you are otherwise entitled.

- You can choose not to take part at all.
- You can agree to take part and later change your mind at any time.

What are you asking me to do?

We are asking you to fill out a survey about your health and background. We may also ask you to take part in an interview about your experience with migraine.

The survey will take about 10 minutes to fill out.

The interview will last about 60 to 90 minutes. The interview can take place by phone or through a computer system, like Zoom. The interview will be audio-recorded.

What do I do if I am interested in taking part in this research?

Taking part in the study requires a few steps.

1. **Consent to participate in the study**. The first step is completing this informed consent form.

   Take your time to read the form and ask any questions before giving your consent. You can reach out to the study contact listed at the top to ask any questions that you have about this study.

   If you want to participate, you should indicate your consent at the bottom of this form.

   Indicating consent to participate in the study does not waive your legal rights in any way. Your consent does not release VPG 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 required by any applicable laws and regulations.

2. **Complete enrollment in the study**. Enrolling in the study involves filling out a survey of questions about your health and your background. After you fill out the survey, you may be contacted to schedule an interview. We may not be able to interview everyone who enrolls in the study.

   The survey will ask about your health history and medications you use for migraine. It will also ask about your gender, race or ethnicity, education, and so on. We use this information to be sure that the people we interview are like all the different people who live with migraine.

   You will also be asked to provide us with contact information, such as your first name and telephone number or email address. The research team will use your

contact information only for scheduling an interview and providing payment. No one will share your contact information outside the research team.

3. **Give permission for your interview to be audio-recorded and transcribed**. Your interview will be audio-recorded so the interviewer can create a transcript of the interview. This written copy of your exact words helps the research team be accurate in describing the experiences of people living with migraine.

   The interviewer will ask you to confirm your permission to record before starting the interview.

   If you do not want to give permission for your interview to be recorded and transcribed, you will not be able to participate in this study.

4. **Complete an interview**. If you are selected for an interview, VPG will contact you to schedule an interview appointment with a researcher from the study team. The interview will be scheduled at a time that works well for you. VPG will also contact you once, about 1 to 3 days before your scheduled interview, to remind you about the interview.

   The interview will last about 60-90 minutes. During your interview, you will be asked questions about migraine symptoms you've experienced and how migraine has impacted your physical and mental function, your mood, and your work, personal, and family life. These questions will be very broad to start, such as "how has migraine affected your life?" Then the interviewer will ask more specific questions to get a better understanding of your experience with migraine. For example, the interviewer will ask questions about how migraine affects your ability to do things around the house or to think clearly.

How will you protect my privacy?

Your privacy is very important to us, and we make every effort to protect you and your health information to the furthest extent possible. But there is a risk of loss of confidentiality when you participate in a research study.

There are several things we do to protect your privacy and respect the confidentiality of information you may share with us.

- **We store information in secure locations and limit the people who can access it.** We store all our data in secure, electronic files that can only be accessed by certain members of the research team. We will never use your name or identify you as an individual in any way in any reports, presentations, or publications of this study.

- **We don't connect your name or contact information with your data**. To protect your identity, we use a study-specific identification number instead of your

name or other personal information. This number protects your identity and is used to label all information collected from you.

We keep your name and contact information separate from the interview transcript and survey responses. We only need this information to schedule your interview and provide payment, so we don't need to keep it with the study data.

- **Study staff with access to your personal data are bound by confidentiality rules**. If you participate in the study, the people who schedule or conduct your interview will know your name or personal details. The interview recording will be heard by the person who creates the transcript. These staff are bound by confidentiality rules and trained in how to maintain privacy and security of data.

- **We remove information that might help to identify you from your interview transcript**. We remove anything you or the interviewer may say during your interview that might be used to identify you. For example, you might say where you work or talk about how many children you have. When this happens, these details will be deleted from the transcript. Your transcript will then be combined with transcripts for all the other study participants for analysis.

- **We destroy audio recordings of interviews as soon as we no longer need them.** Once the final transcript is ready, the audio recording of your interview will be securely destroyed.

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 survey about your background and your health.
- Completing an interview if you are selected.

Could being in this research hurt me?

There are no anticipated physical risks to participating in this study. The study involves completing a survey 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 stop answering questions at any time.

There is a chance that you may find the interview too tiring. If that is the case, you can tell the interviewer that you are too tired to continue. You have the choice to stop your participation or to continue the interview at another 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. This research study is not designed to diagnose, treat, or prevent any disease.

However, your contribution will help researchers better understand how people experience migraine. This could lead to better ways of measuring the burden of migraine and the benefits of treatment.

Will I be paid for taking part in this research?

If you complete an interview, you will receive $125 as a thank you for your time. You will receive this payment as an electronic gift card (e.g., MasterCard) after you complete the interview.

Choosing to not answer some questions or to stop participating part way through the interview will not affect your 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?

When this study is completed, we will write a report based on what we learn from all the surveys and interviews combined. This report will be shared with the FDA, who is the sponsor of this study, and with the public. The results may also be presented at scientific conferences or published in a research journal so that others can learn from this study. None of these reports or presentations 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.

The data from this study may be shared with other researchers directly involved in the conduct of this study, such as scientists from Albert Einstein College of Medicine. Study data may also be shared with authorities responsible for oversight of the study conduct such as the FDA, state regulatory agencies (if applicable), and Institutional Review Boards (IRBs), for the purposes of auditing this study to ensure data integrity and protection of study participants. We only share the data that does not include information that could identify you and aggregated analytic results, meaning information has been compiled from all study participants. However, not all parties who will have access to your 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 possibility that identifiers might be removed from the identifiable private information, and after such removal, the information may be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

Who can answer my questions about this research?

If you have any questions, concerns, complaints, or think this research has hurt you or made you sick after participating, please call or email the study contact listed at the top of this form. You may also contact the principal investigator.

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 WCG IRB at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the study contact or principal investigator.
- You cannot reach the study contact.
- 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 research team may remove you from this research without your approval. Possible reasons for removal include:

- If you are unable to keep your scheduled interview appointment.
- If you decline to have your interview audio recorded or transcribed.
- If this study is cancelled by the sponsor, the FDA, or the IRB.

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 study contact listed at the top of this form that you want to withdraw.

If you withdraw consent prior to participating in the interview, you will receive no compensation.

If you withdraw consent, no new data about you will be collected and none of your data will be analyzed. All data you provided will be destroyed.

If you do not withdraw consent, but do not complete all parts of the study, any completed data may 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.