

## *Consent Form: Patient Focus Groups*

### **Introduction and Purpose:**

Thank you for agreeing to participate in this research study. The purpose of the study is to learn more about consumers' understanding of and experiences with biologic medicines (biologics). Fors Marsh Group (FMG), a research organization in Arlington, VA, is conducting this study sponsored by the U.S. Food and Drug Administration (FDA).

### **Procedures:**

If you agree to participate, you will take part in an online group discussion (up to ten people) about biologics with up to nine other consumers. The focus group will be conducted online using a video and audio platform, so you will be able to see and talk with the moderator and other people in the group. The discussion will last about 90 minutes.

### **Benefits:**

There is no direct benefit to you for participating. However, what we learn from the focus groups will help the FDA better understand this topic and enable the agency to more effectively communicate with patients, health care professionals, and the public about biologics.

### **Risks/Discomforts:**

There are no known risks to participating in this study. We will be asking you to discuss some medicines you currently take or have recently taken for a diagnosed medical condition. You do not have to answer any question that you do not want to answer. You can also stop participating in the focus group at any time. Your participation is completely voluntary.

### **Confidentiality:**

FMG will keep the information you share in this focus group secure to the extent permitted by law. Your personal information (name, address, phone number, etc.) will not be linked to any of your responses. The information you provide will be combined with the responses of other participants in a summary report that will not identify you by name. Because we are using an online platform, we cannot guarantee that what is said in the group will remain secure. However, we will ask the other participants not to disclose anything that was discussed in the group, and we will take every precaution to protect your privacy. We will audio and video record the discussion to supplement our notes and ensure your comments are accurately captured. Recordings and transcripts will not include full names or any other personally identifiable information, and they will be stored on password-protected computers at FDA and FMG that only project staff can access. FMG and FDA will retain these files for up to five years and then delete them. You will not be contacted in the future about this study after your participation in this group ends.

**Honorarium:**

In appreciation for your time and participation, you will receive \$75 after completing participation in the focus group. You will receive this payment as a check or through PayPal from FieldGoals.

**Right to Refuse or Withdraw:**

Your participation in this study is voluntary. You can choose not to talk about any topic, and you can withdraw from the group for any reason at any time without penalty.

**Observation:**

Some team members from FMG and FDA will observe the focus group discussion through video streaming. They will not record your name and will keep all of your comments secure.

**Persons to Contact:**

If you have questions or concerns about the focus group, you can contact Dr. Shane Mannis at FMG by email at [pi@forsmarshgroup.com](mailto:pi@forsmarshgroup.com) or by phone at 571-858-3757. If you have questions about your rights as a study participant, concerns about how you are treated in the study, or want to report an injury from the study, contact the FDA's Institutional Review Board (IRB) at 301-796-9605 or [HSPPMS@fda.hhs.gov](mailto:HSPPMS@fda.hhs.gov).

We advise that you keep a copy of this consent form for future reference. If you would like to do so, please print a copy now.

**Your Consent:**

I have read this consent form. I had a chance to ask questions, and my questions were answered. I was given the opportunity to print or save a copy of this consent form. I agree to participate in the study. I agree to be audio and video recorded as part of this study.

By clicking "yes" below, you are consenting to participate. If you click on "no" below, you are not consenting to participate.

I have read and understand the information provided above, and the study's purpose and procedures are clear to me.

- Yes, I agree to participate in this study.
- No, I do not wish to participate in this study.

Please indicate your preferred method of honorarium payment.

Check

PayPal

Signature:

Date: