

Informed Consent Form: HCP 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 healthcare professionals' opinions and experiences communicating with patients about biologic drug products (biologics). Fors Marsh Group (FMG), a research organization in Arlington, VA, is conducting this study sponsored by the US Food and Drug Administration (FDA).

Procedures:

You will take part in an online group discussion about biologics with 5 to 7 other healthcare professionals in your field. 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 issue and enable it to more effectively communicate with healthcare professionals, patients and the public about biologics.

Risks/Discomforts:

There are no known risks to participating in this study. You do not have to answer any questions that you don't want to answer. You can also stop participating in the focus group at any time. Your participation is completely voluntary.

Confidentiality:

Your identity and information will remain private to the extent permitted by law. Your personal information (name, address, phone number) 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 private. 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 to 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 will retain these files for three 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 an honorarium of \$ [AMOUNT BASED ON SPECIALTY] following the focus group. In line with the usual process, you will see this honorarium reflected in your account on the All Global Circle portal within one week of completing the focus group.

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 or loss of the honorarium.

Observation:

Some research 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 confidential.

Persons to Contact:

If you have questions or concerns about the focus group, you can contact Dr. Brian Griepentrog at FMG by email at 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 Research Involving Human Subjects Committee (RIHSC) at 301-796-9605 or RIHSC@fda.hhs.gov.

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

Your Consent:

I have read this consent form. I agree to be audio- and video-recorded. 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.

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.

Signature:

Date: 