

Focus Group Consent Form

Introduction and Purpose:

The purpose of this research is to provide feedback on health-related materials about certain kinds of medicines called biologics. RTI International, a non-profit research organization based in North Carolina, is conducting this study on behalf of the U.S. Food and Drug Administration (FDA).

You have been invited to take part in this study because you reported taking, or caring for someone who takes, a biologic.

Procedures:

If you agree to participate, you will take part in an **online focus group discussion about biologics with about 8 other people**. 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**.

You are one of approximately 144 people from across the country participating in this study. You will not be contacted about this research after the group discussion ends.

Benefits:

There is no direct benefit to you for participating. However, you may find the discussion informative, and your responses will help the FDA better communicate with patients and caregivers about medicines.

Risk/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.

Privacy and Confidentiality:

We will keep the information that you share during the discussion secure to the extent permitted by law. The RTI study team will not disclose your full name or personal information to anyone, including FDA, and this information will not be linked to any of your responses during the discussion. Your responses will be combined with the responses of other participants in a report that will not identify you by first or last name. Only RTI and Survey Healthcare Globus will have access to your signed consent form.

Other participants will know only the first name or nickname you give in the focus group. We will ask all participants not to disclose anything that was discussed in the group. However, we cannot control what other participants say after the group is finished.

We will audio and video record the discussion to supplement our notes. Any information that can identify you will be removed from the recordings and transcripts before sending them to FDA. The recordings and other materials will be stored on password protected computers at RTI and FDA that only authorized project staff can access. RTI and FDA will retain these files for up to ten years and then delete them.

Observation:

Research team members, including FDA staff, will observe the discussion online through video streaming. You will not be able to see these observers on camera.

Right to Refuse or Withdraw:

Your participation in this study is voluntary. You can choose not to talk about any topic, and you can stop participating at any time and will still receive the honorarium.

Honorarium:

As a thank you for your time and participation, you will receive a \$75 honorarium sent to your email after the focus groups are complete and the project has concluded.

Survey Healthcare Globus uses third party providers, such as TangoCard and PayPal, to provide the honorarium. Your personal information may be transferred to these third parties so that they can prepare your honorarium on behalf of Survey Healthcare Globus. In some cases, you may be required to provide personal information directly to these third parties to receive your honorarium.

Persons to Contact:

If you have questions about the online discussion, you can call the RTI project director, Doug Rupert, toll-free at 1-800-334-8571, ext. 26495. He can be reached between 9:00 AM and 4:00 PM Eastern Time Monday to Friday.

If you have questions about scheduling, eligibility, or the honorarium, you can contact the Survey Healthcare Globus project manager, Anne Marie Bary, at (646) 616-9170 or AnneMarie.Bary@SurveyHealthcareGlobus.com.

If you have questions about your rights as a research participant or have questions, concerns, or complaints regarding the research study, you can call RTI's Office of Research Protection toll-free at 1-866-214-2043.

Your Consent:

By checking the "Yes" box below, you agree that you have read this consent form and agree to participate in the study.

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