

## **Biosimilars Study Focus Groups**

### *Consent Form – Nurse Practitioners / Physician Assistants*

#### **Introduction and Purpose:**

Thank you for agreeing to participate in a research study about biological drugs. The purpose of the study is to learn more about what healthcare providers know about biological drugs and how they prescribe them.

RTI International, a non-profit research organization in North Carolina, is conducting the study. We will be conducting focus groups in Dallas, TX, and Chapel Hill, NC. You are one of approximately 80 people being asked to participate in this study.

You are eligible to participate in this study because you are a nurse practitioner or physician assistant who reported prescribing biological drugs recently.

#### **Procedures:**

If you agree to participate, you will take part in a **group discussion (6-8 people)** about biological drug decisions. The discussion will last about **90 minutes**.

#### **Benefits:**

There is no direct benefit to you for participating. However, you may find the discussion informative and may learn more about biological drugs.

#### **Risks:**

There are no known risks to participating in this study. While the questions we ask are not meant to be sensitive, there is always a chance that you may feel uncomfortable with some of the questions. You do not have to answer any question that you don't want to answer.

#### **Confidentiality:**

We will try to keep the information you share in this focus group confidential. The study team will not disclose your name or any of your comments, and your personal information (name, address, phone number) will not be linked to any of your responses. We also will ask the other participants not to disclose anything that was discussed in the group. However, we cannot control what other participants say after the group is finished.

With your permission, we will audio and video record the discussion to supplement our notes. Recordings will not include full names and will be stored on password protected computers that only project staff can access. All hardcopy forms will be kept in a locked file cabinet that only project staff can access.

Your answers will not be used against you for employment and/or legal retaliation. You will not be reprimanded for your comments, and your direct supervisor will not have access to your responses, the live streaming, or the audio/video recordings at any point in the study. The purpose of the recording is to ensure the study team accurately captures your comments.

**Observation:**

Several research team members will be observing the discussion online through video streaming. They will not record your name and will keep all of your comments confidential.

**Reimbursement:**

In appreciation for your time and travel, we will reimburse you **\$225** at the end of 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.

**Persons to Contact:**

If you have questions about the study, you can call the project director, Mr. Doug Rupert, at 1-800-334-8571, ext. 26495 (toll free). He can be reached between 8:00 AM and 4:00 PM Eastern Time Monday to Friday.

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

**Your Consent:**

I have read this consent form. I had a chance to ask questions, and my questions were answered. I was given a copy of this consent form. I agree to participate in the study.

\_\_\_\_\_  
**Signature of Participant**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Signature of Person Obtaining Consent**

\_\_\_\_\_  
**Date**