OMB Control No.: 0910-0695
Expiration Date: 3/31/2024

Appendix G

Individual Interview Consent Form

Healthcare Providers' Perceptions about Benzodiazepine and Opioid Medications
Informed Consent for Interview Participation

What is the purpose of this consent form?
This consent form is part of an informed consent process for a research study on practices, perspectives, and experiences involved in the prescribing and co-prescribing of benzodiazepines and opioids. It will provide information that will help you decide whether you want to take part in this study. Please review this document carefully, sign it, and return it.

What is this study about?
This research study is being conducted by Lake Research Partners (LRP), a research firm based in Washington, D.C., on behalf of the U.S. Food and Drug Administration (FDA). The study's goal is to help the FDA better understand healthcare providers' (HCPs') perspectives about benzodiazepines and opioids.

What will I be asked to do if I take part in the study?
If you agree to participate in this research study, you will be asked to participate in one of 30 individual virtual interviews to be conducted using a video-based platform similar to Zoom. A professional moderator will ask you a series of questions about these medications. Your participation will last about 60 minutes.

What are the benefits of participating?
This study will provide no direct benefit to you; however, what we learn will provide additional understanding that may help the FDA better communicate with healthcare providers about benzodiazepines and opioid medications, which may help you in your practice.

What are the risks or discomforts?
We do not foresee risks or discomforts associated with participating in this study. We do not expect any of the interview questions will make you uncomfortable; however, you can refuse to answer any questions. We are primarily interested in your perspectives, not in any personal information. We have processes in place to ensure that your information and responses are kept private. Every effort will be made to protect your information.

How will my personal information be kept confidential?
The research is anonymous. Your identity and information will be kept secure to the extent provided by law. The LRP study team will not disclose your full name or personal information, and this information will not be linked to any of your responses. The information you provide will be combined with the responses of other healthcare providers in a summary report that will not identify you by name. Any

information that includes your name or other personal information will be kept on a password-protected computer system that only authorized project staff have access to.

If you agree to participate, your interview will be audio and video recorded. The recording will be encrypted and the transcript will be stored securely by Lake Research Partners and the U.S. Food and Drug Administration, accessible only to authorized project staff via password-protected files on a secure network. The recording, transcript, and any written notations made by the interviewer and project team observers will be used for analysis purposes only. Recordings will be securely stored for no longer than five years and then destroyed. No recordings, transcripts, or reports will include any personally identifiable information.

What if I do not wish to take part in the study or want to withdraw?
It is your choice whether you take part in the research. You may choose not to take part or to skip any questions and you can stop participating at any time without penalty.

Will I receive an honorarium for participating?
To thank you for your participation, you will receive a [Physicians: $225; NAs or NPs: $200] Visa gift card as a token of appreciation, which will be mailed to you by the recruiter you've been in contact with about this project (Schlesinger/2020 Research) via USPS four to six weeks after you participate in the interview.

Who can I contact with questions or concerns?
If you have any questions, concerns, questions, or feedback about this project, you may contact the LRP Principal Investigator Alysia Snell at asnell@lakeresearch.com or (202) 470-4440.

If you have any questions, concerns, or complaints about your rights as a research participant or regarding this research study, you wish to speak to someone other than the research staff, or would like to report an injury from the study, you may contact the Ethical & Independent Review Services (E&I) Institutional Review Board at (800) 472-3241 or subject@eandireview.com. Please reference the following number when contacting E&I: (800) 472-3241.

Your consent:
I have read this form, and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and, if I have had them, they have been answered to my satisfaction. I voluntarily agree to participate in this study, and I give my consent to participate and be video- and audio-recorded for the purposes of the study.

Participant's Signature: _____
Participant's Full Name (Print): _____ Date: _____