OMB Control No. 0910-0847
Expiration Date: 12/31/2022

Attachment D

Informed Consent Form for Interviews

Introduction and Purpose:

The purpose of this research is to collect data regarding people's use of certain substances along with or as a substitute for a prescription opioid. MHA, a research firm, is conducting this study sponsored by the U.S. Food and Drug Administration (FDA).

You have been invited to take part in this research study because you told the study recruiters in the center where you are receiving treatment for substance use that you used both a prescription opioid and one of these substances.

Procedures:

If you agree to participate, you will take part in a one-time [IN-PERSON/ONLINE] interview with a professional interviewer [in your treatment facility/in your home]. The discussion will last 60 minutes. You are one of approximately 140 people from across the country being asked to participate in these interviews. Neither FDA nor MHA will contact you in the future after your participation in the interview ends.

Benefits:

This study will provide no direct benefit to you; however, what we learn from the interviews may help FDA better understand the broader context surrounding substances used along with or as a substitute for an opioid and how these substances relate to the current U.S. prescription opioid epidemic.

Risk/Discomforts:

We do not expect that any of the interview questions will make you uncomfortable; however, you can decline to answer any question.

Confidentiality:

Your identity and information will be kept secure to the extent provided by law. MHA will not disclose your full name or your personal information to FDA or anyone else, including the treatment center facility or staff. MHA will not link identifying information to any of your responses. MHA will combine the information you provide with the responses of other participants in a summary report that will not identify you by name, and this report will be provided only to the FDA. Only MHA will have access to this signed consent form. This consent form and any information that includes your name or other personal information will be kept in a locked file cabinet or on a password-protected computer that only authorized MHA project staff will be able to access or see. No names or contact information will ever be provided to the FDA.

In addition to these steps, we have obtained a Certificate of Confidentiality (COC) from the FDA to help protect your privacy. This certificate provides extra protection for you and your study information and documents. The FDA issued the COC so that we cannot be required to disclose any identifiable, sensitive information collected about you as a part of this study in a lawsuit or legal proceeding. We are also prevented from releasing your study information without your consent. This is a layer of protection over and above the already existing protections in place.

Observation:

The interview will be [AUDIO/VIDEO] recorded. It may be observed by one MHA staff member [AND ONE TECHNOLOGY ASSISTANT IF CONDUCTED ONLINE]. We will remove any information that can identify you from the transcript created from this recording, and this de-identified transcript will be shared only with the FDA research staff involved in this project. These de-identified transcripts will be stored on password-protected computers at MHA and FDA for five years after the conclusion of this research project. Project staff may continue to analyze the files during this period. We will not provide any of the [AUDIO/VIDEO] recordings to the FDA or anyone else, including the treatment center facility or staff.

Right to Refuse or Withdraw:

It is your choice to participate in this interview. You can choose not to answer some questions. You can stop participating at any time and still receive your honorarium.

Honorarium:

To thank you for your participation, you will receive a $50 Visa gift card at the conclusion of the interview.

Persons to Contact:

If you have questions about the research or the interview, contact Dr. Mark Herring, the MHA project director, at (610) 242-3987 between 9 AM and 5 PM Eastern Standard Time Monday - Friday. If you would like to speak with someone unrelated to this research; have questions about your rights as a research participant; want to report an injury from the study; or have questions, concerns, or complaints regarding the research study, please contact IntegReview IRB, 3815 S. Capital of Texas Highway, Suite 320, Austin, TX 78704; phone: 512-326-3001, ext. 225; email: sattwood@integreview.com.

Your Consent:

I have read this consent form and agree to participate in the interview. I was given a copy of this consent form.

Signature of participant_____ **Date** ___/___/___