INFORMED CONSENT FORM

Project Title: Incorporation of REMS into Prescriber Settings

I have been asked to take part in the Incorporation of REMS into Prescriber Settings study. This is a study being conducted by Deloitte Consulting on behalf of the Food and Drug Administration. The goal of the study is to better understand prescriber settings as they relate to prescriber practices and processes. The main focus of the study is to evaluate the impact of Risk Evaluation and Mitigation Strategies (REMS) on prescriber settings and patient access, with a specific focus on Elements to Assure Safe Use (ETASUs).

I am aware that I will be asked to share my thoughts and opinions with the research team and that the session will be audiotaped. My participation will take approximately 90 minutes. I understand that I may stop or end my participation at any time. I can also refuse to answer any question at any time for any reason. I am further aware that all my answers will remain confidential. My name will not be associated with my answers in any way. Also, my answers will be grouped with other people's answers to ensure privacy and confidentiality in my responses.

I am aware that there may be risks involved in my participation, such as that I might feel uncomfortable or awkward in providing answers to some questions. I am aware that if I am upset about something in the study, I can tell those doing the research. I am further aware that I enjoy some benefits from participating in the study, such as feeling good about sharing my thoughts and opinions, and about contributing to the understanding of prescriber settings and practices and the impacts of REMS and ETASUs.

I am aware that if I have any questions about this study, I can contact the research team: Patrick Koeppl at (240) 460-9407 at Deloitte, or Adam Kroetsch at (301) 796-3842 at the Food and Drug Administration.

Again, I am aware that I may refuse to take part at any time without worry. I have read the consent form and am aware of the risks and rewards of the project described within. I further am aware that I am not waiving any of my legal rights by signing this form. A copy of this form will be given to me upon request.

THIS PROJECT HAS BEEN REVIEWED BY THE Food and Drug Administration's INSTITUTIONAL REVIEW BOARD FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH.

_____

(Print name of participant)

_____ Date:_____

(Participant signature)

Investigator Witness:

I have fully explained the nature of the research project and its risks and benefits to the person listed above. To the best of my knowledge the person signed above understands the nature of the research and is giving informed consent to participate in all defined above.

_____ Date:_____