

OMB Control Number: 0910-0847

Expiration Date: 12/31/2022

Methodological Approaches to Evaluate the Impact of Risk Evaluation and Mitigation Strategy (REMS) Programs: Physician Interviews on Experiences with REMS Programs

Consent Form

- We are inviting you to participate in a research study, which will involve you sitting for an approximately hour-long interview. Your participation is voluntary, and you may stop at any time.
- The purpose of the research study is to understand the benefits and burdens of risk evaluation and mitigation strategy (REMS) programs, which the Food and Drug Administration (FDA) requires manufacturers of certain medications to implement.
- We are asking you to participate because we think you might have prescribed [drug name] —a REMS program-covered drug—in the past year, which we will confirm prior to the interview. We obtained your name and contact information through a search of specialists who treat the indication of [drug name] or from you directly in the event you responded to our recruitment message forwarded by a professional group.
- We are seeking to interview 60 physicians as part of this research study. There are no risks associated with participation. Recorded interviews will be kept secure, available only to the study team, and transcriptions of those interviews will be stripped of identifiers. No identifiable information will be publicly released.
- Your information will be kept secure to the extent required by law.
- If you chose to participate, you will receive a \$100 Amazon gift card as a token of appreciation for your participation.
- The principal investigator for this study is Ameet Sarpatwari, PhD, JD. Please contact him at asarpatwari@bwh.harvard.edu should you have any questions.
- The research study is being conducted on behalf of the FDA.
- If you would like to speak to someone not involved in this research study about your rights as a research subject or any concerns or complaints you may have about the research, contact the Mass General Brigham IRB at 857-282-1900.