

OMB Control Number: 0910-0847

Expiration Date: 12/31/2022

Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Physician Surveys on Experiences with REMS Programs

Consent Form

- We are inviting you to participate in a research study, which will involve you taking a 20-minute survey. 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 you were identified as someone who has prescribed [drug name]—a REMS program-covered drug. We obtained your name and contact information from IQVIA, a health care data company.
- We are seeking to interview 200 physicians for each REMS program-covered drug as part of this research study. There are no risks associated with participation. Your returned surveys will be kept secure, with anonymized results available only to the study team. No identifiable information will publicly released and your information will be kept secure to the extent permitted by law.
- The invitation mailing included \$20 as a token of appreciation. If you chose to participate, you will receive an additional \$80 Amazon gift card as a token of appreciation.
- 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 funded by 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.