Risk Evaluation and Mitigation Strategy (REMS) Programs to Promote Appropriate Medication Use and Knowledge: Patient 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 you contacted us as someone who started taking [drug name]—a REMS program-covered drug—in the past year and is interested in taking part in the research study. We obtained your name and contact information from you.

- We are seeking to interview 160 patients 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 publicly released.

- If you chose to participate, you will receive a $50 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 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, contract the Mass General Brigham IRB at 857-282-1900.

- Your information will be kept secure to the extent required by law.

- We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. Your information will be kept secure to the extent permitted by law.