

OMB Control Number: 0910-0497

Expiration Date: 10/31/2020

APPENDIX C: CONSENT FORM

Paperwork Reduction Act Statement:

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0910-0497. The time required to complete this portion of the information collection is estimated to be 120 minutes, including time for reviewing the structured reporting template + user guide and participating in a conference call with discussion questions.

Send comments regarding this burden estimate or any other aspects of this collection of information, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.

Introduction and Purpose:

We would like to invite you to participate in a focus group to discuss the usability, clarity, and efficiency of a structured protocol and reporting template for healthcare database studies. This template follows up on the work from a joint task force between the International Society for Pharmacoepidemiology (ISPE) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) on practices to improve transparency, reproducibility, and validity. This is a joint project being conducted by Brigham and Women's Hospital (BWH) and the U.S. Food and Drug Administration (FDA).

You have been invited to take part in this research study because you are a member of a key stakeholder group with experience in database studies.

Procedures:

If you agree to participate, you will be asked to review materials and join a one-time Web Conference call. The materials include the structured template and user guide. The conference call is anticipated to last 90 minutes and will involve briefly walking through the structured template and an example, then structured discussion to collect qualitative feedback on the risks, benefits, clarity, usability, and efficiency of using the template from a researcher perspective and/or your ability to evaluate the validity and relevance of evidence from a reviewer perspective.

Benefits:

This study will provide no financial benefit to you; however, what we learn from the focus groups may help improve transparency of public protocols and reporting of studies conducted with healthcare databases.

Risk/Discomforts:

We do not expect that any of the focus group questions will be sensitive or make you uncomfortable; however, you can refuse to answer any question. Your name and information will be kept secure to the extent allowed by law.

Confidentiality:

Only members of the BWH study team will have access to this signed consent form, and any information that includes your name or other personal information will be kept on a password-protected computer at the BWH study site.

Each focus group will have up to 6 members. Your name and affiliation will be shared with other members of the focus group during the introductions section of the conference call.

The input from this session will be reported back to FDA in aggregate to help revise and improve the template. All summaries will be anonymized and will not identify you by name. Your name and information will be kept secure to the extent allowed by law.

Observation:

The focus group will **not** be recorded in either audio or video form, but study staff will take notes. Only summary information from the calls will be provided to the FDA. No identifying information regarding individual responses will be shared with the FDA. The typed notes will be stored on password-protected computers at BWH for five years after the conclusion of this research project. Project staff may continue to analyze the files during this period.

Right to Refuse or Withdraw:

It is your choice to participate in this focus group. You can choose not to answer any questions, and you can stop participating at any time.

Honorarium:

If you would like to be acknowledged for your participation and confirm permission, your contribution will be recognized in a final report or paper that describes the structured reporting template, intended use cases, and the process to develop it. After the paper is drafted, we will send a short email to confirm your permission to release your name in the form of an acknowledgement of your participation. There is no monetary compensation.

Persons to Contact:

If you have questions about the research or the focus group, please contact Dr. Shirley Wang, the study Principal Investigator, at swang1@bwh.harvard.edu.

Your Consent:

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

Signature of participant _____ **Date** ___/___/___