

Benefit-Risk Framework Implementation Evaluation Informed Consent for Small Group Discussion

FDA committed to continuing the implementation of the Benefit-Risk Framework into review documentation processes. The Benefit-Risk Framework is FDA's framework to assess benefits and risks of new drugs and biologics and was developed to improve the consistency and clarity of benefit-risk assessment during the premarket review process. As a part of this commitment, FDA contracted Booz Allen Hamilton (Booz Allen) to conduct an independent evaluation to assess how the Benefit-Risk Framework is being applied by reviewers across FDA.

Booz Allen is conducting discussions with patients, patient advocates, healthcare providers, and other government agencies. The purpose of this discussion is to capture insights into the Benefit-Risk Framework's clarity, understandability, and utility, as well as identify best practices and opportunities for improvement.

The time commitment for this discussion is estimated to average 90 minutes, which will include time to review the Benefit-Risk Framework (about 30 minutes) and participate in the discussion (about 60 minutes).

Your participation/nonparticipation in this discussion is completely voluntary, and you may quit, without penalty, at any time. If you feel uncomfortable answering any question during this discussion, you may choose to not answer the question. Your participation/nonparticipation, as well as your responses, will not have an effect on your eligibility for receipt of any FDA services.

Your data will be de-identified in all reporting. In instances where your identity is needed (e.g., for follow-up), this information collection fully complies with all aspects of the Privacy Act and data will be kept private to the fullest extent allowed by law.

Although there are no direct benefits to your participation in this discussion, your feedback will help us improve the implementation of the Benefit-Risk Framework into review documentation processes.

If you have any questions or concerns, please contact the Booz Allen Project Manager, Kendra Orjada, at Orjada_Kendra@bah.com.

Please check one of the options, and then sign and date below:

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

_____ I **voluntarily agree** to participate in this discussion.

I have read, understand, and had time to consider all the information above. My questions have been answered and I have no further questions.

_____ I **do not want** to participate in this discussion.

Signature

Date

Paperwork Reduction Act Statement: The public reporting burden for this information collection has been estimated to average 90 minutes per response to review this informed consent form (the time estimated to read, review, and complete). Send comments regarding this burden estimate or any other aspects of this information collection, including suggestions for reducing burden, to PRASStaff@fda.hhs.gov.