INFORMED CONSENT FORM

Assessment of physician applicants' experiences with FDA's Expanded Access and Compassionate Use programs

The purpose of this research study is to obtain feedback from physician applicants who have experience with FDA's Expanded Access and Compassionate Use (EA/CU) programs in order to gather information about their real-world experiences. This feedback is critical to understanding the impact of FDA's internal processes and practices and will aid in identifying what is working well and which areas are ripe for improvement.

This survey is expected to take up to 20 minutes, during which you will be asked to answer a series of questions about your experiences with FDA's EA/CU programs. We do not believe there are any risks or discomforts associated with your participation; however, you can refuse to answer any question or stop participating at any time. Your response to this survey is voluntary.

You will receive $50 for participating in this survey. In addition, FDA's EA/CU programs represent a "last chance" for patients who have no other reasonable medical options; improvements to the program that increase use is a benefit to those patients.

Staff at an independent third party research firm and the FDA will see the information that you provide. The results of this survey will be shared with FDA.

Your participation/non-participation is completely voluntary and your responses will not have an effect on your eligibility for receipt of any FDA services. All respondent identification and information are confidential and will be anonymous unless otherwise indicated. In instances where respondent identity is needed (e.g., for follow-up of non-respondents), this information collection fully complies with all aspects of the Privacy Act and your identity and information will remain private to the extent permitted by law.

Aggregate results may be made public. Individual answers may also be made public (e.g., example responses).

If you have questions about your rights as a participant or are dissatisfied with any aspect of the survey, or have questions about the research, you may contact Kate Chavez at Kate.Chavez@fda.hhs.gov or 973 549-6967.

Consent1. If you have read the previous screens and agree to participate, please click the Yes button. If not, click the No button.

1-Yes, I agree to participate.
2-No, I do not agree to participate.
[SP, IF CONSENT1=NO, FORCE TO ANSWER]

Consent2 if they don't click yes. Are you sure you don't want to participate? Your opinions are important. Please select the Yes button to continue this survey. Select the No button to exit.

1-Yes, I agree to participate.
2-No, I do not agree to participate.

[PROGRAMMING INSTRUCTION: IF CONSENT2=NO, TERMINATE THE SURVEY]