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UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

CONSENT FORM

Protocol Title: Patient and Caregiver Diversity in FDA Patient Engagement Activities - Interviews

Study No.: HP-00097394

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CONCISE SUMMARY
To better understand the current makeup of patients providing input regarding a specific disease or therapeutic area involving FDA-regulated products, the team will conduct in-depth interviews with patients, caregivers, and patient advocacy organization representatives with experience with food allergy to explore what patient and patient organization factors influence participation in FDA patient-engagement programs (e.g., patient-focused drug development meetings, listening sessions) and factors most associated with engagement strategies and obtaining broad patient representation and help identify opportunities to promote diverse representation in patient engagement across the different stages of therapeutic development.

PURPOSE OF STUDY

- The purpose of this research is to increase the U.S. Food and Drug Administration's (also known as the FDA) understanding of patient and caregiver engagement and the diversity of people who participate in food allergy drug development.

PROCEDURES

- The only time commitment required is the time it takes to complete this interview. There is no follow-up, or anything further required of you if you join this study. This interview will last approximately 90 minutes.

- You will be asked to share your honest opinions. There are no right or wrong answers**.** You will be addressed by first name only. We will audio and video record the conversation solely for internal use to make sure we accurately capture what was said. The recording and transcripts will not be shared outside University of Maryland for the FDA. The recording will be deleted once the project is completed.

POTENTIAL RISK/DISCOMFORTS

- The project is low risk. The potential risks with this research are no greater than risks in your normal day-to-day life.
- You may discuss personal information, such as your experiences about food allergy. There is the potential loss of confidentiality of private information within the session. We suggest you introduce yourself using only your first name and change your onscreen name to display only your first name. We will also take steps to maintain your privacy, including storing your information securely, referring to you only by your first name, removing your identity from transcripts from the interviews, and destroying the recording when the project is completed. Your name and information will be kept secure to the extent permitted by law.

POTENTAL BENEFITS TO PARTICIPANTS

- There are no direct benefits for participating in this study. However, your input provides much needed insights that will help the FDA better understand opinions of the products it regulates in order to help protect and advance public health.

ALTERNATIVES TO PARTICIPATION

- This is not a treatment study.

COSTS TO PARTICIPANTS

- It will not cost you anything to take part in this study.

PAYMENTS TO PARTICIPANTS

- You will be offered a gift card for $75 as a token of appreciation at the end of the study.

PRIVACY AND CONFIDENTIALITY

- Please know that anything you say in this interview is confidential and we will not share your name or personal information outside the project team. We will not link your name to what you say today in any of our reports.
- Your name will not be linked to any of your responses. All computer files including the study data are secured and only the research team can access them. All data will be kept secure to the fullest extent permitted by law. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

- Your participation in this study is voluntary. You do not have to take part in this research.
- You are free to withdraw at any time. If you decide to stop taking part, or if you have questions, concerns, or complaints please contact the investigator Joey Mattingly at 410-706-8068 or jmattingly@rx.umaryland.edu.