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The study we are conducting is on behalf of the U.S. Food and Drug Administration (FDA).

RESEARCH INTERVIEW GUIDE – ORGANIZATION

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

Study No.: HP-00097394

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Study Sponsor: U.S. Food and Drug Administration (FDA)

Date/Time: _____

Interviewee (ID #): _____

Organization Name: _____

Interviewer: _____

Introduction

Hello, my name is.... Thank you for taking the time to meet with me (us). I will let my colleague introduce him/herself (if anyone else on the research team is going to assist). I am conducting this interview for the University of Maryland. This interview will take about 90 minutes to complete.

Because this is part of a research project, there are some specific things I need to be sure I let you know. This interview is being conducted by research team members from the University of Maryland, Baltimore. This interview is completely voluntary, and you may ask questions at any time throughout our discussion. This interview is used to increase the US Food and Drug Administration’s (also known as the FDA) understanding of the diversity of patients and caregivers impacted by food allergies and how they engage with food allergy therapy development.

[Informed consent] If you had a chance to review the consent form and agree to participate, we can move right into the interview. If not, we can go over the consent form together. I am happy to answer any question you might have.

[Begin recording]: Before we get officially started, I need to ask: Do I have your permission to record the interview? The recording will be for note taking and transcription purposes only so that I can be sure I have been accurate in taking down your answers. Interviews will be audio and video recorded and professionally transcribed. Neither the recordings nor the transcripts will be shared or used for any other purposes. 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. Only members of the research team will have access to this information Please say, "yes," if you agree to allow the interview to be recorded. Wait for person to say, "yes."

Thank you. Today is [Date], my name is [Interviewer] and I'm interviewing [Interviewee] representing the [Name of Organization] for the food-allergy engagement study.

Next, I also need to ask: Do you agree to participate in this interview? Please say "yes" if you agree. Wait for the person to say, "yes."

Thank you. Wonderful, so let's begin:

A. General engagement

Let's talk a bit about the work your organization does on food allergy to engage patients.

1- Can you please tell me a bit more about your organization: the populations you serve? mission? vision?

Probe:

- ✓ Tell me more about one experience in which you and your organization participated in a public food-allergy-related activity (*e.g., town hall meeting, advocacy event, fund raising, ...etc.*)?

B. Engagement with the FDA

The next set of questions is about the work of the US Food and Drug Administration, also called the FDA for short, and that is what I will call it to make it easier. The FDA has many responsibilities. The FDA is the Federal government agency that aims to promote public health and safety by checking the safety of food, drugs, vaccines, and medical devices. The FDA doesn't conduct clinical trials but it conducts medical product reviews.

2- Are you familiar with the FDA and its work?

Follow-up: The FDA has many responsibilities. For today, we are just going to talk about the FDA's role in engaging patients in its work. I am going to ask you some questions about this more specifically.

There are several ways that people can engage with the FDA and share their experiences, such as attending a workshop, participating in patient listening sessions, hosting a meeting with the FDA, etc. The purpose of these is to ensure patients' experiences,

perspectives, needs, and priorities are captured and included in the drug review process .
Our questions are related to FDA's work and this particular initiative.

<p>Engaging with FDA</p>	<p>3- Are you aware of the FDA patient engagement activities?</p> <p>4- Specifically, are you familiar with FDA activities in food allergy?</p> <ul style="list-style-type: none"> • <u>If yes</u>, can you elaborate on these activities? <p>5- Have YOU interacted with the FDA in the past ? <i>This could include: meeting with FDA staff on an issue; speaking at an FDA meeting; making public remarks at an FDA meeting; submitting comments to an FDA docket, etc...</i></p> <ul style="list-style-type: none"> • <u>If yes:</u> <ul style="list-style-type: none"> ✓ Can you tell me more about your different experiences with the FDA? ✓ Did you feel that your engagement was meaningful in impacting FDA decisions? How so or in what way? ✓ <i>If engaged in food allergy drug development:</i> Did you feel you were involved in early/middle/final steps of drug development? • <u>If no:</u> <ul style="list-style-type: none"> ✓ Why? <p>6- Based on your experience working with the patient community, how do you feel about patients sharing their experiences with the FDA?</p> <ul style="list-style-type: none"> • <u>Probes</u> <ul style="list-style-type: none"> ✓ Is it worthwhile? Do you feel like you're all making an impact? Why? <ul style="list-style-type: none"> ○ <u>If not worthwhile:</u> What would make it worthwhile? How could it make a difference? What suggestions do you have? <p>7- Has YOUR ORGANIZATION been involved in working directly with the FDA in any way? <i>This could include: meeting with FDA staff on an issue; speaking at an FDA meeting; making public remarks at an FDA meeting; submitting comments to an FDA docket, etc...</i></p> <ul style="list-style-type: none"> • <u>If yes:</u> <ul style="list-style-type: none"> ✓ Was this in-person or virtual? ✓ What attracted you and made you interested in engaging with the FDA? ✓ How do you prioritize FDA activities at your organization? ✓ Can you please tell me what happened in this workshop (or other activity)? ✓ Did you feel that your organization's input was valued? Why? ✓ From 1 to 5, can you rate your experience? Why? ✓ What would be your advice to FDA on an event like this? • <u>If no</u> <ul style="list-style-type: none"> ✓ Has your organization considered getting more involved in FDA-related patient-focused activities? ✓ What have you considered as the positives? What are the negatives? ✓ Are there any other activities you are looking at?
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	<p>8- Does your organization have the resources to contribute to the FDA to help inform their decision-making?</p> <p>9- Do you have direct access to FDA activities or you use intermediate sources like a middle-man for small-size organization to help the connect with FDA e.g. coalitions?</p> <p>10- Is there anything else you'd like to add about engaging/interacting with the FDA?</p>
<p>Barriers for Patients</p>	<p>11- What do you do to engage your patient communities?</p> <ul style="list-style-type: none"> • Can you elaborate more on your strategies, activities, and programs? <p>12- How do you reach out to patients? Find them? Recruit them? (In general)</p> <p>13- Do you think the folks you are engaging reflect the true population of food allergy?</p> <p>14- Do different groups respond differently to engagement activities?</p> <p>15- Do you see variation when engaging diverse population groups in drug development?</p> <ul style="list-style-type: none"> • <u>If yes</u>, why is that? What can we do to overcome that? <p>16- Are there certain demographic groups within the population <i>e.g. racial, gender, age, occupation like school educators</i>, that you think are not as engaged in the development of new therapies for food allergies (<i>e.g., participating in advocacy activities, providing their input on research or participating in research</i>)?</p> <ul style="list-style-type: none"> • <u>Probes:</u> <ul style="list-style-type: none"> ✓ Who are these subpopulations? ✓ Have you tried to engage them? ✓ What worked well / didn't work well?
<p>Barriers for organizations</p>	<p>17- From 1 to 5, can you rate how easy or difficult is it for patient organizations like yours to engage in FDA food-allergy activities?</p> <ul style="list-style-type: none"> • <u>Probes:</u> <ul style="list-style-type: none"> ✓ Why? What makes it easy/difficult? ✓ What would make it easier? <p>18- What barriers may get in the way when it comes to engaging in FDA food-allergy activities?</p> <ul style="list-style-type: none"> • <u>Probe:</u> <ul style="list-style-type: none"> ✓ Are these barriers/difficulties related to your organization type or size, or the engagement processes?
<p>Satisfaction</p>	<p><i>For organizations with FDA engagement experience:</i></p> <p>19- From 1 to 5, can you rate how satisfied are you with the FDA's patient-focused work or other, related activities? <i>e.g. attending public meetings, workshops, patient listening sessions, docket comments.</i></p> <ul style="list-style-type: none"> • <u>Probe:</u> <ul style="list-style-type: none"> ✓ Why? <p>20- What would make your organization more satisfied with these activities?</p> <p>21- Do you think the food allergy patient community trust the FDA activities?</p> <ul style="list-style-type: none"> • <u>Probe:</u>

	<ul style="list-style-type: none">✓ Why?✓ How the FDA can build/improve this trust? <p><i>For organizations with NO FDA engagement experience:</i></p> <p>22- What would your organization need to get engaged with the FDA activities?</p> <p>23- How would you like to get information about FDA engagement activities?</p>
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Wrap-up and closing

We have reached the end of the interview.

Is there anything you'd like to add? Is there anything you would like to ask me?

If you think of anything else you would like to share with us about food allergy patient and caregiver engagement, please feel free to contact the principal investigator, Joey Mattingly via email: jmattingly@rx.umaryland.edu; or phone: 410-706-8068

Thank you for your time and sharing your experiences with us.