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

RESEARCH INTERVIEW GUIDE – PATIENT

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: _____

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 helping to lead 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 U.S. Food and Drug Administration's (also known as the FDA) understanding of patient and caregiver engagement and the diversity in food allergy drug 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. Icebreaker

- 1- To start off, could you please introduce yourself and tell me about your personal connection to food allergies? (*e.g. patient, Caregiver to child with food allergy, Caregiver to spouse with food allergy, Caregiver to other person with food allergy*)
Probe
Can you tell me a bit about your or the person in your care past allergy?
- 2- How do you go about knowing about food allergy?
- 3- How have you been engaged with food allergy research?
(*e.g., joining a clinical trial, joining a patient organization, reading the most recent research, etc.*)
- 4- Have you ever participated in a public food-allergy-related event or activity?
(*e.g., town hall meeting, advocacy event, etc.*)

Topic	Questions
<p>B. Experience and reasons for engaging with patient organizations</p>	<p>5- Have you ever interacted with a food allergy advocacy or research organization? <i>(e.g. informational/educational sessions or meetings, using it as a resource, joined its mailing list, participated in a research ...etc.)</i></p> <ul style="list-style-type: none"> • <u>If yes:</u> <ul style="list-style-type: none"> ✓ Do you belong to this/these organizations? ✓ If yes: How long have you been with this organization and what is your role? ✓ How did you first become involved? ✓ Please tell me more about that/these organizations or groups. ✓ What are the names? ✓ What kind of activities are you involved in with them? ✓ Are you aware if this organization works directly with the FDA or participates in FDA events? • <u>If no:</u> <ul style="list-style-type: none"> ✓ Are there any particular reasons you have not chosen to join an organization? <i>(e.g., haven't given much thought to it, requires too much time, didn't know about them, etc.)</i>
	<p>6- How about other food-allergy research? <i>not just patient-group research---maybe research done by your provider, a University or a company.</i></p>

C. Experience and reasons for engaging with the FDA

The next set of questions is about the work of the US Food and Drug Administration or FDA for short.

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 or develop drugs, its role is to review drugs for safety and efficacy.

For today, we are just going to talk about the FDA's role in medical product development until approval and how it involves patients in its work. I am going to ask you some questions about that more specifically.

Currently, there are several ways in which patients and caregivers can engage with the FDA, such as attending patient-focused drug development meetings, attending a patient listening session, and/or hosting a meeting with the FDA. Its purpose is to ensure patients' experiences, perspectives, needs, and priorities are captured and included in drug development and evaluation. Our questions are related to FDA's efforts engaging patients and caregivers to help us improve the diversity of patients and caregivers that get involved.

Topic	Questions
<p>Engagement Experience with FDA</p>	<p>7- Have you participated in any activities related to the FDA about food-allergy related treatments or for other treatments? <i>e.g. 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"> ✓ When was that? ✓ What was your experience both in general and for any specific interaction you had with the FDA? ✓ How did you feel about it? Feel free to give me specific examples from the interactions you had. ✓ What was the outcome? ✓ What was the best and worst parts of this event/interaction? ✓ Were you treated with respect? Why or why not? ✓ Did you feel heard? Why or why not? ✓ Do FDA engagement opportunities involve a wide variety of perspectives and backgrounds? ✓ What would be your advice to FDA to improve an event like that? ✓ How did you find out about this event or activity? • <u>If no:</u> <ul style="list-style-type: none"> ✓ Have you heard anything about the FDA’s efforts to engage patients and caregivers who are impacted by food allergies? ✓ Have you heard about the food allergy Patient-Focused Drug Development (PFDD) event in September? <i>If yes, where did they hear about it?</i> <p>8- Would you be interested in learning more about the FDA’s initiatives to engage patients and caregivers?</p> <ul style="list-style-type: none"> • <u>If yes:</u> <ul style="list-style-type: none"> ✓ How would you like to learn about these e.g. email social media, text messages, phone calls, newsletters...etc? ✓ What is the best way to share these efforts with you? ✓ Who can be messengers for this information that the FDA could work through. ✓ What can the FDA do to help you get involved in their work?

D. Motivation

For this next set of question, I’m interested in learning about what motivates you to be engaged in food-allergy-related activities.

Topic	Questions
<p>Motivation</p>	<p><i>For those with ORGANIZATION experience:</i></p> <ul style="list-style-type: none"> ✓ Why did you choose to participate in those specific activities (refer to Q#5 about food allergy research or advocacy organizations)?

	<ul style="list-style-type: none"> ✓ What encouraged you to join this/these patient organizations? <p><i>For those with NO ORGANIZATION experience:</i></p> <ul style="list-style-type: none"> ✓ What led you not join a patient organization or consider joining a patient organization? ✓ What may interest you to know more about these activities? ✓ What types of activities would you be more interested in learning about from patient organizations? ✓ What would motivate you to participate?
	<p><i>For those with FDA experience:</i></p> <ul style="list-style-type: none"> ✓ Why did you choose to participate in FDA activities (refer to Q#8 about FDA activities)? ✓ What encouraged you to join this/these patient organizations? <p><i>For those with NO FDA experience:</i></p> <ul style="list-style-type: none"> ✓ What led you not join a patient organization or consider joining a patient organization? ✓ What may interest you to know more about these activities? ✓ What types of activities would you be more interested in learning about from FDA? ✓ What would motivate you to participate?

E. Barriers

Topic	Questions
Barriers	<p>9- From 1 to 5, how easy or difficult is it for patients and caregivers to become engaged in FDA; especially when it comes to food-allergies?</p> <ul style="list-style-type: none"> • <u>Probe</u> <ul style="list-style-type: none"> ✓ Tell me why you think that? ✓ What do you think about logistics, time commitment, time off work, scheduling issues, childcare, travel (too far or lack of transportation), access to internet. <p>10- Are there specific groups or other types of patients that you think may have more difficulty engaging with the FDA?</p> <ul style="list-style-type: none"> • Probes: <ul style="list-style-type: none"> ✓ Who are these patients or groups? Why? <p>11- In your experience or opinion, what would make it difficult for you or a person with food allergy to engage in FDA food-allergy drug-development and approval activities? (Refer to previous examples in Q#8 if clarity is needed)</p>
	<p>12- From 1 to 5, how easy or difficult is it for you or a patient with food allergies to engage in food-allergy patient-organization activities?</p> <p>13- Are there specific groups or other types of patients that you think may have more difficulty engaging with patient-organizations?</p> <ul style="list-style-type: none"> • Probes: <ul style="list-style-type: none"> ✓ Who are these patients or groups? Why? <p>14- In your opinion, what currently makes it difficult or might make it difficult for you or others to engage in food allergy patient</p>

	organizations’ activities that involve the FDA?
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F. Satisfaction

Topic	Questions
Satisfaction	<p><i>For those with ORGANIZATION experience:</i></p> <p>15- From 1 to 5, how satisfied are you with your experience regarding food allergy research or advocacy organizations’ activities?</p> <ul style="list-style-type: none"> • Probe: <ul style="list-style-type: none"> ✓ What would make you more satisfied with these activities? ✓ How about communication e.g. dissemination/clarity, rapport with FDA staff? <p><i>For those with NO ORGANIZATION experience:</i></p> <p>16- If you were to participate in food allergy research or advocacy organization activities, what would please you?</p> <p>17- what types of things would you consider to be satisfied with the engagement or participation?</p>
	<p><i>For those with FDA experience:</i></p> <p>18- From 1 to 5, how satisfied are you with the FDA’s patient-focused efforts or other, related activities?</p> <ul style="list-style-type: none"> • Probe: <ul style="list-style-type: none"> ✓ What would make you more satisfied with these activities? ✓ How about communication e.g. dissemination/clarity, rapport with FDA staff? <p><i>For those with NO FDA experience:</i></p> <p>19- If you were to participate in FDA-related activities, what would please you?</p> <p>20- what types of things would you consider to be satisfied with the engagement or participation?</p>

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.

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