From Methods to Implementation: Real-World and Regulatory Applications of Patient Experience Data through Patient Experience Mapping & Patient Involvement

TUESDAY, 19 NOVEMBER 2024 | 10:15 - 11:15 CET

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Speakers

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Poll 1: What is your primary role in your organization?

- ☐ Patient Engagement/Advocacy
- ☐ V/HTA or HEOR
- ☐ Regulatory/Compliance
- ☐ Clinical
- ☐ Academic
- ☐ Other

Developing the Patient Experience Mapping Toolbox (PEMT)

Background

Patient Experience Data are collected by any persons; and are **intended to provide information about patients' experiences with a disease or condition**, including:

a) the 'impact (including physical and psychosocial impacts) of such disease or condition or a related therapy or clinical investigation; and
b) patient preferences with respect to treatment of the disease or condition.

- 21st Century Cures Act

The Patient Experience Mapping Toolbox is a set of resources to help researchers engage and document patients' experiences before getting a diagnosis, while getting a diagnosis, and living with a diagnosis.

Patient Experience Mapping Toolbox

- Developed by researchers at the NHC
- Disease-agnostic and pilot tested with a diverse array of patients with rare and common chronic conditions
- Customizable to study objective with a variety of conditions and demographics
- Formally reviewed for health literacy

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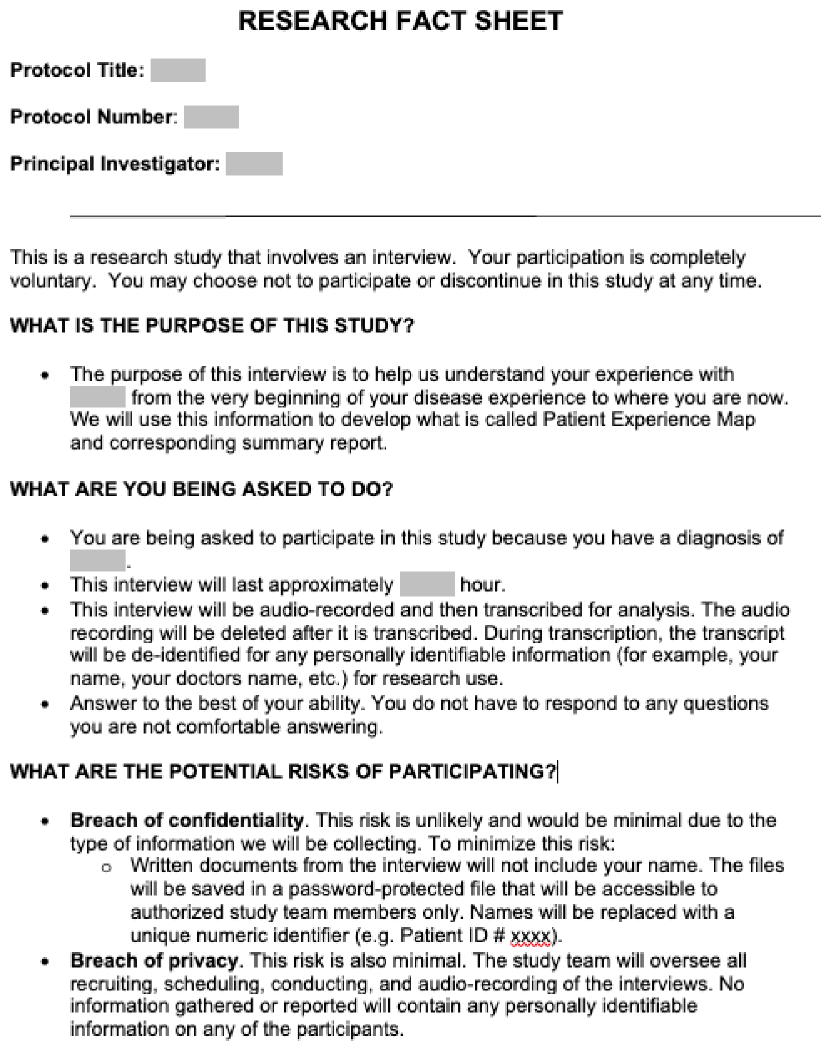
Original Consent Sheet



RESEARCH FACT SHEET

Protocol Title:

Protocol Number:

Principal Investigator:

This is a research study that involves an interview. Your participation is completely voluntary. You may choose not to participate or discontinue in this study at any time.

WHAT IS THE PURPOSE OF THIS STUDY?

- The purpose of this interview is to help us understand your experience with from the very beginning of your disease experience to where you are now. We will use this information to develop what is called Patient Experience Map and corresponding summary report.

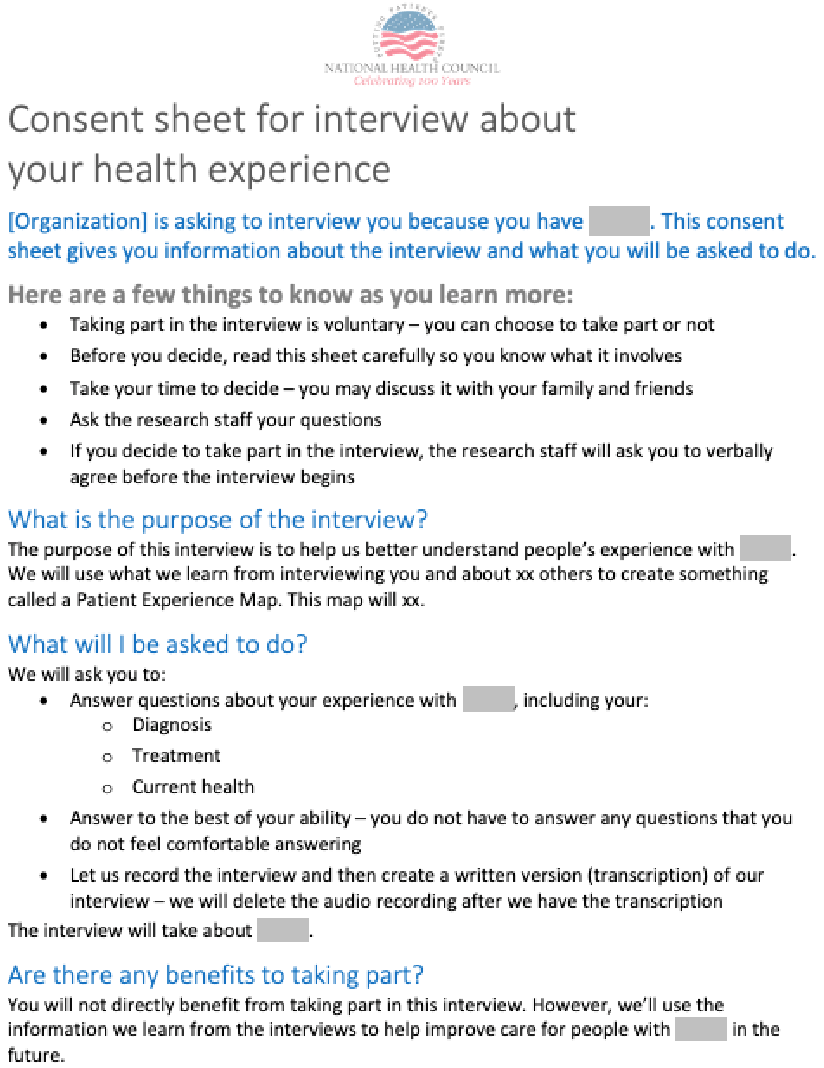
WHAT ARE YOU BEING ASKED TO DO?

- You are being asked to participate in this study because you have a diagnosis of .
- This interview will last approximately hour.
- This interview will be audio-recorded and then transcribed for analysis. The audio recording will be deleted after it is transcribed. During transcription, the transcript will be de-identified for any personally identifiable information (for example, your name, your doctors name, etc.) for research use.
- Answer to the best of your ability. You do not have to respond to any questions you are not comfortable answering.

WHAT ARE THE POTENTIAL RISKS OF PARTICIPATING?

- **Breach of confidentiality**. This risk is unlikely and would be minimal due to the type of information we will be collecting. To minimize this risk:
    - Written documents from the interview will not include your name. The files will be saved in a password-protected file that will be accessible to authorized study team members only. Names will be replaced with a unique numeric identifier (e.g. Patient ID # xxxx).
- **Breach of privacy**. This risk is also minimal. The study team will oversee all recruiting, scheduling, conducting, and audio-recording of the interviews. No information gathered or reported will contain any personally identifiable information on any of the participants.

Updated Consent Sheet



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Consent sheet for interview about your health experience

[Organization] is asking to interview you because you have . This consent sheet gives you information about the interview and what you will be asked to do.

Here are a few things to know as you learn more:

- Taking part in the interview is voluntary – you can choose to take part or not
- Before you decide, read this sheet carefully so you know what it involves
- Take your time to decide – you may discuss it with your family and friends
- Ask the research staff your questions
- If you decide to take part in the interview, the research staff will ask you to verbally agree before the interview begins

What is the purpose of the interview?

The purpose of this interview is to help us better understand people's experience with . We will use what we learn from interviewing you and about xx others to create something called a Patient Experience Map. This map will xx.

What will I be asked to do?

We will ask you to:

- Answer questions about your experience with , including your:
    - Diagnosis
    - Treatment
    - Current health
- Answer to the best of your ability – you do not have to answer any questions that you do not feel comfortable answering
- Let us record the interview and then create a written version (transcription) of our interview – we will delete the audio recording after we have the transcription

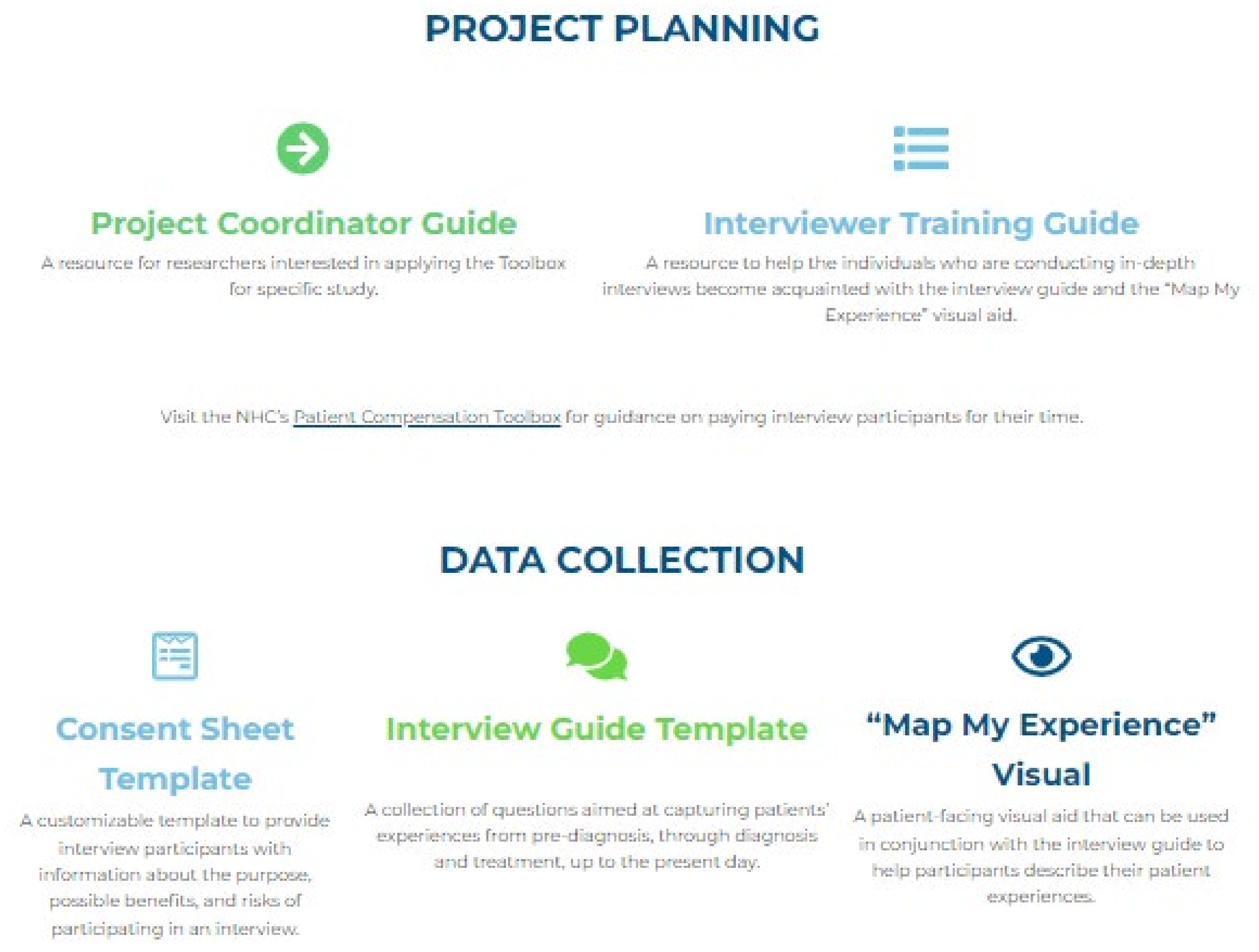
The interview will take about .

Are there any benefits to taking part?

You will not directly benefit from taking part in this interview. However, we'll use the information we learn from the interviews to help improve care for people with in the future.

https://nationalhealthcouncil.org/additional-resources/patient-experience-map/

Patient Experience Mapping Toolbox



PROJECT PLANNING

Project Coordinator Guide

A resource for researchers interested in applying the Toolbox for specific study.

Interviewer Training Guide

A resource to help the individuals who are conducting in-depth interviews become acquainted with the interview guide and the "Map My Experience" visual aid.

Visit the NHC's Patient Compensation Toolbox for guidance on paying interview participants for their time.

DATA COLLECTION

Consent Sheet Template

A customizable template to provide interview participants with information about the purpose, possible benefits, and risks of participating in an interview.

Interview Guide Template

A collection of questions aimed at capturing patients' experiences from pre-diagnosis, through diagnosis and treatment, up to the present day.

"Map My Experience" Visual

A patient-facing visual aid that can be used in conjunction with the interview guide to help participants describe their patient experiences.

https://nationalhealthcouncil.org/additional-resources/patient-experience-map/

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Map My Experience

Every patient has different experiences with their health. This map can be used as a guide to think about your own patient experience from your "starting point," through your diagnosis, to where you are now, and everywhere in between.

Life Factors

As you go along, think about how other "life factors" have played a role in your patient experience, such as:

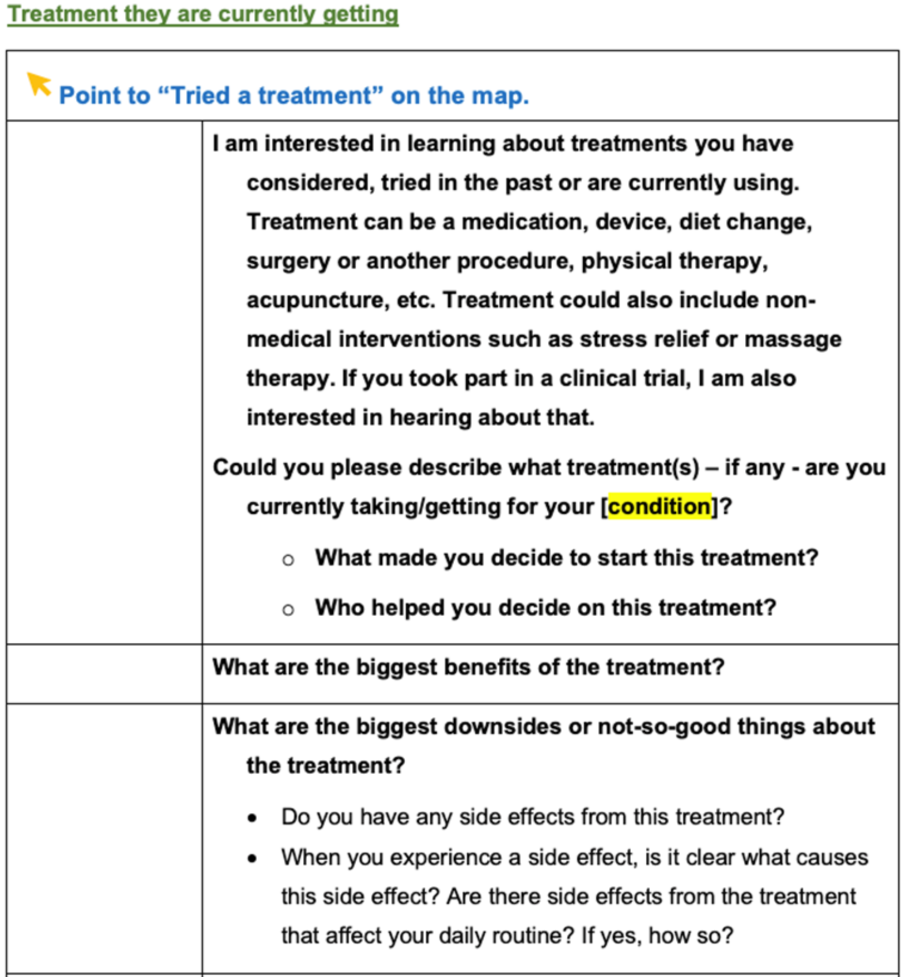
- Family and support system
- Work or student life
- Housing and transportation
- Health care
- Insurance and access to care
- Mental health & other health conditions
- Finances and other costs

Using the Patient Experience Mapping Toolbox

Patient-Facing Visual

https://nationalhealthcouncil.org/additional-resources/patient-experience-map/

Interview Guide Template



Treatment they are currently getting

Point to "Tried a treatment" on the map.	
	I am interested in learning about treatments you have considered, tried in the past or are currently using. Treatment can be a medication, device, diet change, surgery or another procedure, physical therapy, acupuncture, etc. Treatment could also include non-medical interventions such as stress relief or massage therapy. If you took part in a clinical trial, I am also interested in hearing about that. Could you please describe what treatment(s) – if any - are you currently taking/getting for your [condition]? ○ What made you decide to start this treatment? ○ Who helped you decide on this treatment?
	What are the biggest benefits of the treatment?
	What are the biggest downsides or not-so-good things about the treatment? • Do you have any side effects from this treatment? • When you experience a side effect, is it clear what causes this side effect? Are there side effects from the treatment that affect your daily routine? If yes, how so?

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Mapping Food Allergy Patient Experiences in the United States

The study sought to describe patient experiences living with and treating food allergy in the United States.

Through in-depth interviews, the NHC explored:

- Natural history of food allergy, including signs and symptoms, progression, and severity
- Impact of food allergy and its treatment on individuals and family members, including work or student life, mental health and other health conditions, finances, and other life factors/social determinants of health
- The burden of living with or managing a food allergy, such as the impact on day-to-day function and quality of life over time
- Perspectives on current and future treatments for food allergy

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Target patient population

Target food allergies
Milk
Egg
Peanut
Soy
Wheat
Tree nut
Shellfish
Fish
Sesame seeds

- Adults diagnosed with at least one of the target food allergies
- Adolescents (12-18) diagnosed with at least one of the target food allergies
- Family caregivers of young children (ages 2-11) diagnosed with at least one target food allergy

Illustrative example of results from this study:

“Signs and symptoms experienced when coming into contact with allergan”

Adult (*peanut):* “I was really upset at… I thought I was choking, but I didn’t understand why I was choking. I had no idea what was happening, to be honest with you, so that was really quite frightening.”

Caregiver of a young child *(peanut, tree nut):* “He woke up and one of his eyes was swollen, completely shut, like he could not … it was completely shut swollen, I’d never seen anything like that.”

Caregiver of an adolescent (*peanut, tree nut, shellfish, fish*): “He loved it but every time after he ate it, he would go straight to the bathroom and be in there throwing up for like, 20, 30 minutes.”

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Illustrative example of results from this study:

“Significant emotional impacts of food allergies”

Adolescent (*milk, egg, peanut, wheat, shellfish, fish*): “Honestly, but sometimes I do just sit there and realize my life would be completely different if I didn’t have any of these type of allergies. I could just be eating what I wanted to and I could try new foods without worrying that I would end up in the hospital from having an allergic reaction.”

Adolescent (*milk, peanut*): “Yeah, because there’s things that I’m not allowed to go to, or amusement parks when schools go on field trips and stuff because they could have peanuts somewhere, or something I’m allergic to, and they can’t wipe that down every five minutes after every person gets on…”

Caregiver for a young child (*milk*): “It’s not about the food itself. It's about being able to interact with people, and so much of our culture is around food. It's about a meal…”

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Poll 2: How do you see this tool being used in the future?

- ☐ Real-World Evidence/Real-World Data Studies
- ☐ Product Development
- ☐ V/HTA or HEOR
- ☐ Clinical Trials
- ☐ Quality Measurement/Safety
- ☐ Regulatory/Government