




Engagement across the Phases of Research: PCORI Engagement Rubric

KIDNEY RESEARCH CONNECT TRAINING WEBINAR




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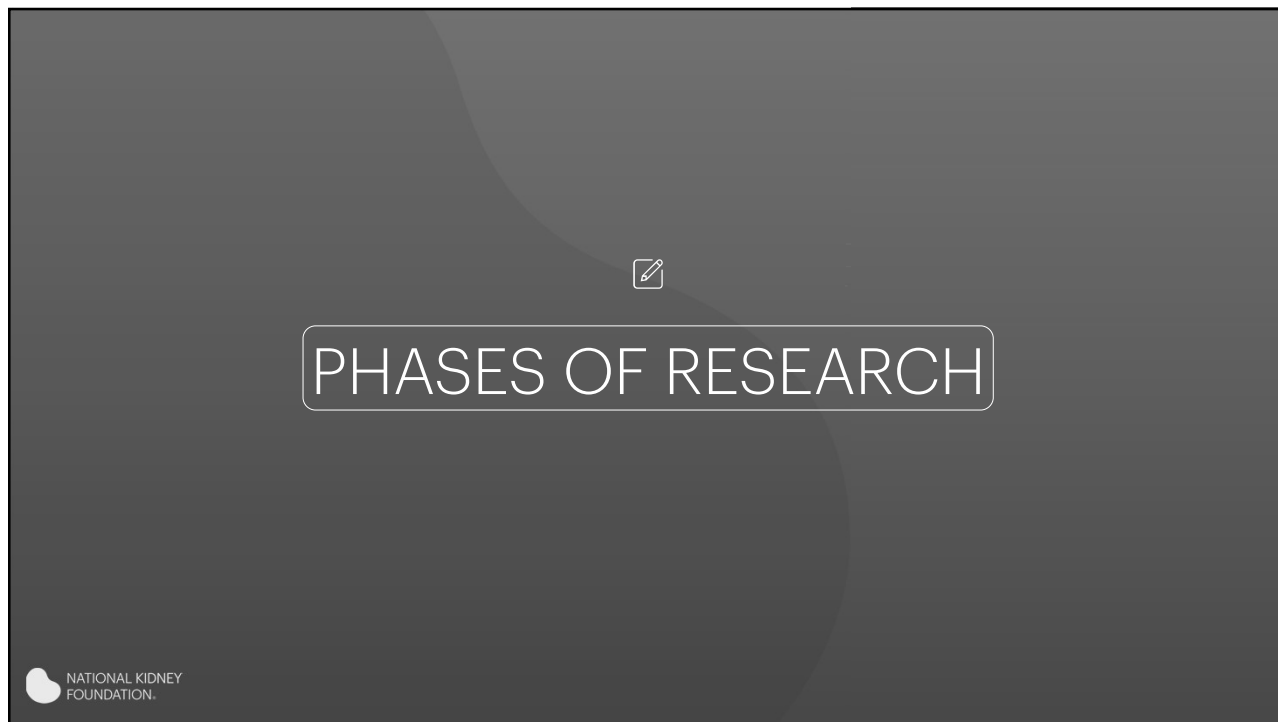


Overview

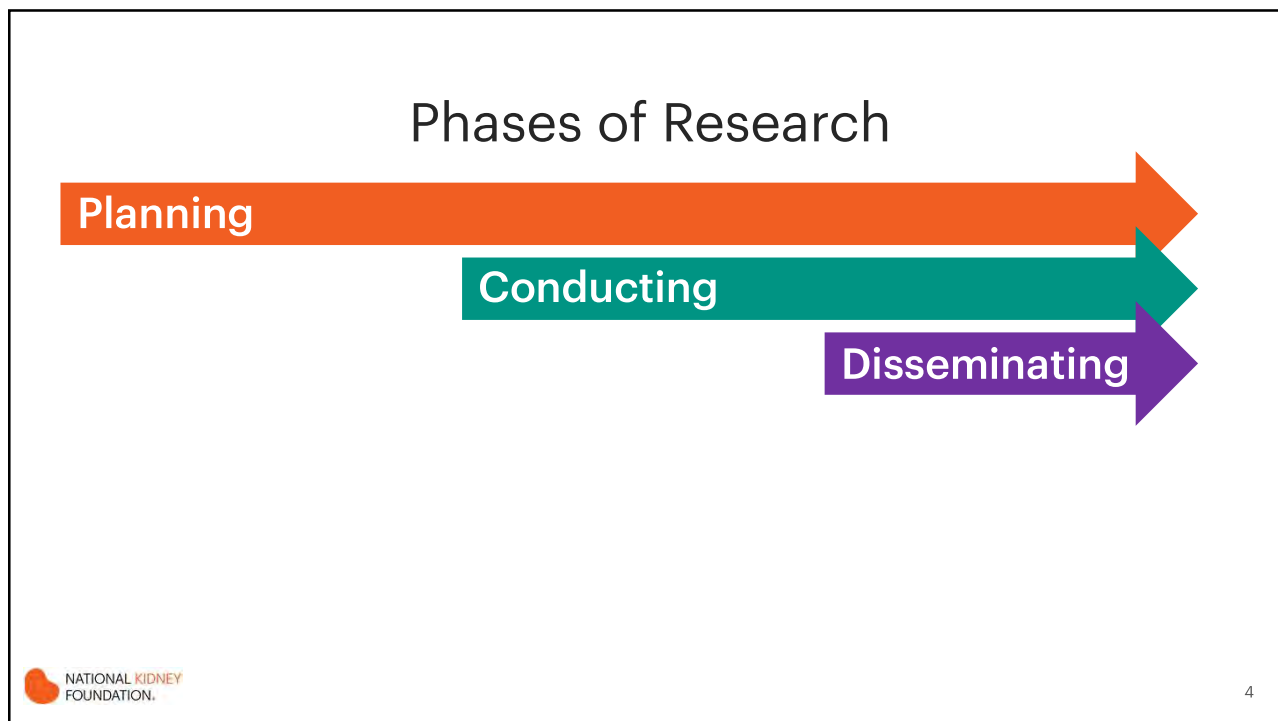
- Phases of research: planning, conducting, disseminating
- PCORI engagement rubric
- Opportunities for patient/family/ care partner involvement
- Challenges to (and potential solutions for) meaningful involvement



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Planning Research

Planning

- Identify problem(s)
- Come up with research question(s)
- Pick a research design
 - Chart reviews?
 - Interviews?
 - Clinical trial?
- Develop a plan (**written plan = protocol**)
 - Where will it be?
 - How will patients be recruited?
 - What data will be collected?
 - How will data be analyzed?
- Find research funding
- Get approval from research oversight group (**Institutional Review Board = IRB**)



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Conducting Research

Planning

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Conducting

Disseminating

Conducting

- Train study and/or clinic staff on protocol
- Explain study to potential participants and answer questions
- Obtain **informed consent** from patients who want to participate
- Start study
- Analyze study data and interpret findings
- This phase can be short (**days**) or long (**years**)
 - May need to re-train clinic staff
 - May need to update study participants

Disseminating Research

Planning

- Identify problem(s)
- Come up with research question(s)
- Pick a research design
 - Chart reviews?
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Disseminating

- Share results with the community
 - Manuscripts published in journals
 - Presentations at conferences
 - Websites, social media
- Provide follow-up to participants and people who helped with the study
- Identify areas for future research and potential collaborators, funders

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PCORI RUBRIC



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Research Has Many Stakeholders

STAKEHOLDER: SOMEONE WHO HAS AN INTEREST OR CONCERN IN THE ISSUE

- Patients, family members, care partners
- Medical providers and personnel
- Researchers
- Hospitals and health systems
- Payers (ex. insurance companies)
- Industry (ex. drug and medical device manufacturers)
- Policy-makers



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PCORI Engagement Rubric (Statement)

The PCORI engagement rubric...

- Explains when and how engagement can occur throughout the phases of research
- Defines the PCORI engagement principles
- Includes guidance about potential engagement activities during research and supporting examples



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PCORI Stakeholder Engagement Principles



Reciprocal Relationships

- Including patients and other stakeholders as key personnel
- Roles and decision making are defined collaboratively



Co-learning

- Researchers help patients and other stakeholders understand their process
- Team learning about patient-centeredness



Partnerships

- Fair compensation and reasonable requests for time
- Commitment to diversity and cultural competence



Transparency – Honesty – Trust

- Inclusive decision-making
- Information is readily shared

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OPPORTUNITIES FOR INVOLVEMENT

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Opportunities for Involvement: Planning

Planning

- Identify issues that are important to patients
- Come up with research question(s) and relevant outcomes
- Help design the study to reduce disruption and/or hardship on study participants
- Recommend other patients or stakeholders

Conducting

Disseminating

who might be important to involve in the project



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Opportunities for Involvement: Planning

EXAMPLES: PROJECT IDEAS



Funding Announcement:
Small-Scale Pilots to
Implement Principles of
Patient-Centered
Measurement

American Institutes for Research



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Opportunities for Involvement: Planning

EXAMPLES: PATIENT-PRIORITIZED STUDY OUTCOMES



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Opportunities for Involvement: Conducting

Planning

- Identify issues that are important to patients
- Come up with research question(s) and relevant outcomes
- Help design the study to reduce disruption and/or hardship on study participants
- Recommend other patients or stakeholders who might be important to involve in the project

Conducting

- Draft or revise study materials
- Participate in study recruitment
- Participate in data collection and analysis
- Participate in the evaluation of patient (and other stakeholder) engagement
- Serve as a patient representative on a study monitoring panel (**Data Safety Monitoring Board**)

Disseminating

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Opportunities for Involvement: Conducting

EXAMPLES: STUDY FLIER + INFORMED CONSENT INFO



Research Interviews about Goals and Dialysis Care Plans

Study Staff


Jenny Flythe,
Lead Researcher


Derek Forfang,
Lead Researcher


Adeline Dorough,
Study Coordinator

What is the purpose of this study?

- We are trying to understand how to better match hemodialysis care with your personal goals.
- This is part 1 of a 3-part study. This part is only an interview.

What would I do in this study?
If you choose to participate, you would take part in a 45-60 minute interview.

What would we talk about in the interview?

- We will talk about your personal goals and your experience with dialysis care plans.
- We also want to hear your thoughts on how to personalize your dialysis treatment plans.



What if I start the interview but decide that I want to stop?
You can stop at any time. Participation in the study is voluntary.

What are some possible benefits to being in this study?

- Discussing your dialysis experience in a supportive environment.
- Helping future dialysis patients.

Would I receive anything for participating?
You will receive \$30 for interview participation.

When would I know the results of the study?

- We will give an update on what we are learning in about 3 months.
- We expect all 3 parts of the study to be done by the end of 2019.
- We will share the final results with you if you are interested.

What will study staff do with the information I share?
Our conversation is private. Your answers will help our team figure out how to better match patient goals with dialysis treatment plans.

What if I have more questions in the future?
Contact Adeline Dorough, Study Coordinator.
Email: dorough@med.unc.edu | Phone: (919) 445-2898



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Opportunities for Involvement: Conducting

EXAMPLES: CLINICAL TRIAL - SOCIAL MEDIA POST



National Kidney Foundation 14h

Are you interested in participating in a clinical trial for patients with Alport syndrome? See if you qualify by visiting <https://www.alportstudy.com>.

For questions about the study or to learn about enrollment, email contact-US@sanofi.com.

Do you have Alport Syndrome?

See if you qualify for this clinical trial.

HERA



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Opportunities for Involvement: Disseminating

Planning

- Identify issues that are important to patients
- Come up with **research question(s)** and relevant outcomes
- Help design the study to reduce disruption and/or hardship on study participants
- Recommend other patients or stakeholders who might be important to involve in the project

Conducting

- **Draft or revise study materials**
- Participate in **study recruitment**
- Participate in data collection and analysis
- Participate in the evaluation of patient (and other stakeholder) engagement
- Serve as a patient representative on a study monitoring panel (**Data Safety Monitoring Board**)

Disseminating

- Identify partner organizations to help share the information
- Participate in dissemination efforts (manuscripts, presentations)
- Share on social media
- Help reach patients who might not use the internet much
- Identify areas for future research



Opportunities for Involvement: Disseminating

EXAMPLES: PATIENT VOICE - SOCIAL MEDIA POST



National Kidney Foundation @nkf · Now

Patient voice is so critical, especially when it comes to topics as important as this one. NKF advocate and patient Monica Fox @Monicafox99 talks about "Barriers to Kidney Transplantation in Racial/Ethnic Minorities" in this @CJASN article. Read NOW.

Barriers to Kidney Transplantation in Racial/Ethnic Minorities
Culture and the conditions in which one is born, grows, lives, works, and ages affect many areas of life, including health and health care. In this ...
cjasn.asnjournals.org

Online Toolkit

DIALYSIS RESEARCH

10 Tips For Researchers Conducting Studies in Dialysis Settings

Understand the dialysis environment

Build trust and gain insight

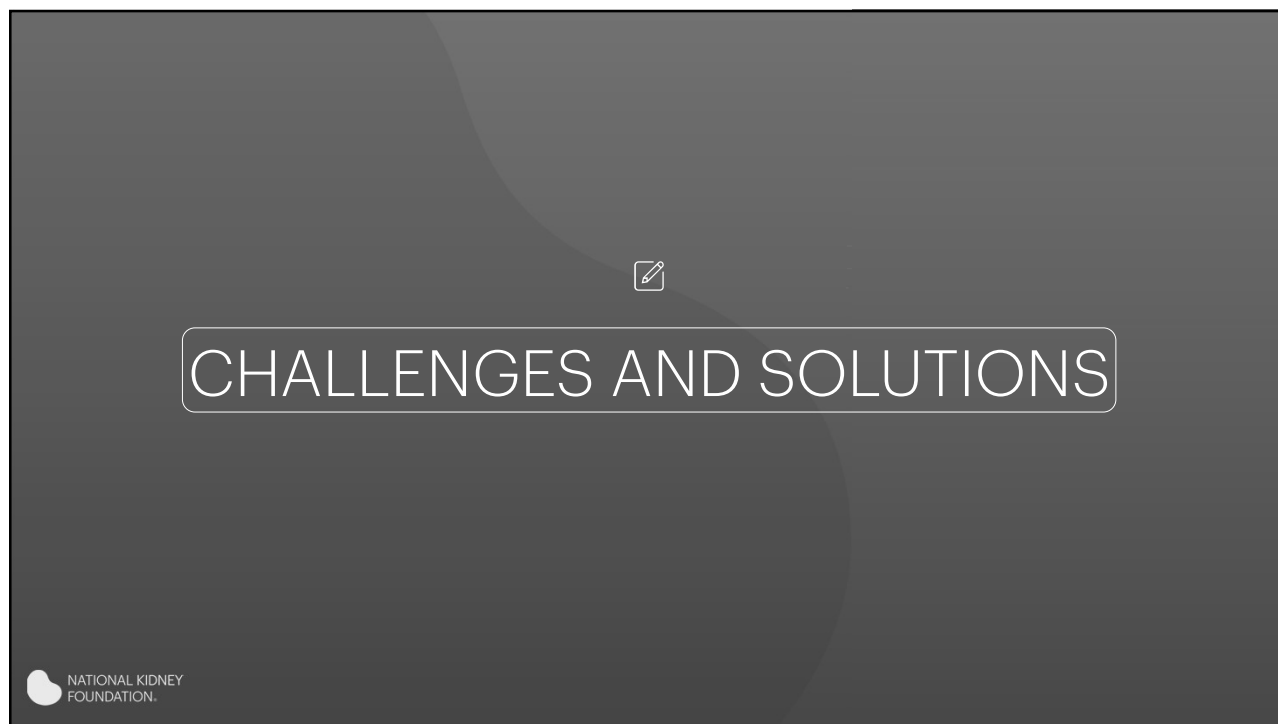
Provide ongoing research education and training

Communicate and Follow-up

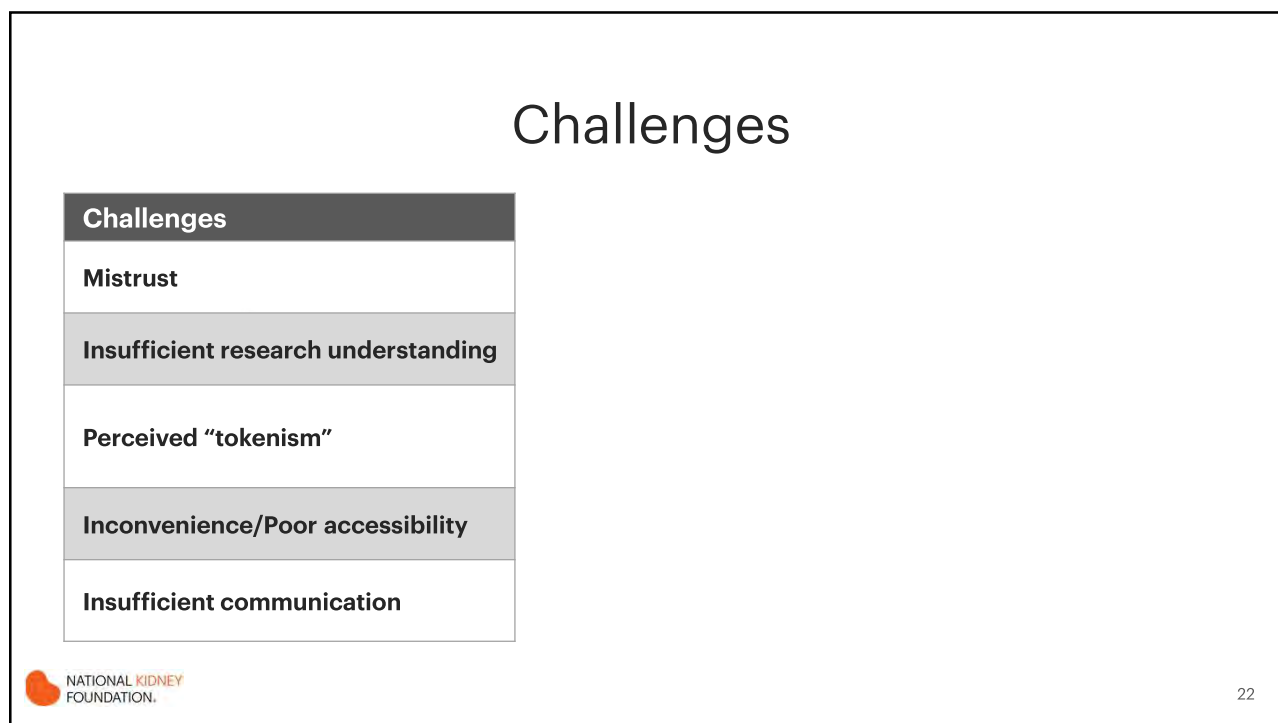
What's Inside?

- What is Research? 2
- What Are the Types of Research? 6
- What Do You Need to Know? 7
- What Are Your Research Aims? 8
- Why Participate? 10
- What Questions Might You Ask? 11





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Challenges: In Their Own Words

Do I want to go out of my way to help [the researchers]? Have they made a connection with me, so that I want to help them? **Trust**

Don't use those big words ... break it down to a human level. Come down to a level that I understand. **Plain Language**

I mean, it's a no-brainer, you would try to do [research] while we're in the center. **Convenience**

Communication is the biggest word in dialysis. That's with the research assistants. That's with your techs. That's with your doctors. That's with your nurses. Communicate. Get on the person's education level. Just communicate. **Communication/Follow-up**

Are you doing [research] for yourself or are you doing it for humanity? **Plain Language**



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Potential Solutions

Challenges	Potential Solution
Mistrust	<ul style="list-style-type: none"> • Build trust through transparency • Engage trusted intermediaries
Insufficient research understanding	<ul style="list-style-type: none"> • Provide appropriate education • Frequent check-ins to verify understanding
Perceived "tokenism"	<ul style="list-style-type: none"> • Respect individual stakeholder expertise • Incorporate input throughout research process – including the very start
Inconvenience/Poor accessibility	<ul style="list-style-type: none"> • "Bring it to them" – reduce burden of involvement • Offer different ways to get involved
Insufficient communication	<ul style="list-style-type: none"> • Establish and adhere to a co-developed communication plan • Follow-up, check understanding, follow-up...



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Summary

- The three phases of research are planning, conducting, and disseminating.
- There are many opportunities to engage patients/family members/care partners in each of these phases.
- Effective patient engagement rests on commitment to shared values and objectives, trust, transparency, respect for individual perspectives, among other factors.
- ***Engagement of patients/family members/care partners is possible and makes research more meaningful and impactful.***

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