


## NORTH CAROLINA CANCER CHALLENGE 2020

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### Improving Enrollment into Cancer Clinical Trials

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## OBJECTIVES

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1. Explain the importance of the clinician to patient awareness and acceptance of clinical trial participation
2. Describe the trial recruitment process and identify strategies that are feasible for non-research clinicians to incorporate into practice
3. Identify resources for connecting patients to research education or trial opportunities
4. Distinguish possible strategies to mitigate the diversity disparity in research

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## WHY ARE PARTICIPANTS SO IMPORTANT?

- A 2015 analysis of registered trials revealed that **19% were closed or terminated early** because they could not accrue enough participants
- As many as **86% of clinical trials do not reach recruitment targets within their specified time periods**
- Data suggest that study timelines have potentially doubled beyond planned enrollment periods due to low recruitment rates
- Failures to meet recruitment goals have important scientific, financial, ethical, and public health implications
- Without participants, the best ideas could go untested

\*Huang, Grant D. et al. "Clinical trials recruitment planning: a proposed framework from the Clinical Trials Transformation Initiative". Contemporary Clinical Trials, 2018, vol 66, 74-79.



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## TRADITIONAL RECRUITMENT

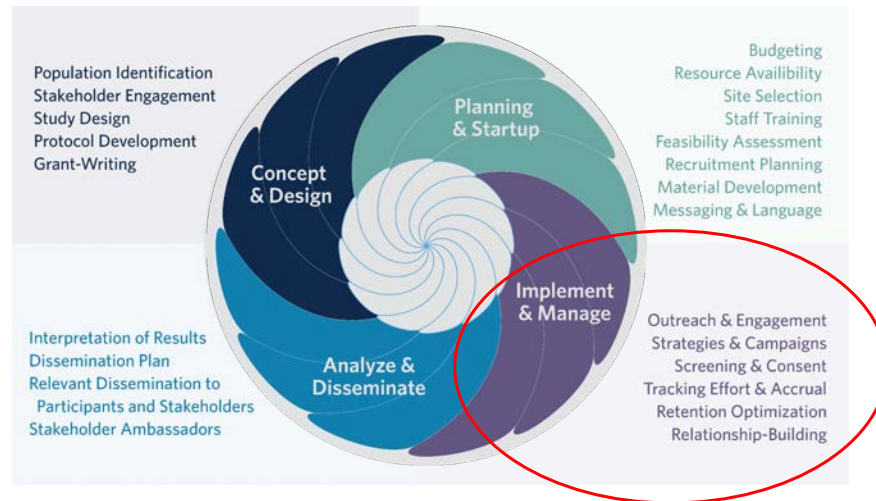
- Typically, recruitment into clinical trials and research more broadly has been driven and executed by individual research teams on a study-by-study basis
- Recruitment is primarily considered once the study has launched
- Recruitment takes many forms – both active and passive



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## EVERY DECISION CAN IMPACT RECRUITMENT SUCCESS



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## EXAMPLES OF STANDARD RECRUITMENT METHODS

- Approaching in clinic
- Provider referral
- Letters
- Cold calls
- Flyers
- Radio/TV/Newspaper Ads
- Social Media
- Technology
- Health fairs

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## WHERE IS INFORMATION COMING FROM?

- Where is this information coming from?
- History
- Friends and family
- Community
- Culture
- Media
- Health system
- Research enterprise
- Clinical staff
- Nurses and other clinical personnel
- Primary physicians
- Physician specialists
- Study coordinators/RAs
- The Principal Investigator



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## PATIENT-CENTERED RESEARCH AND ENGAGEMENT

**Engagement ladder:** based on the concept that engagement can be nurtured, supported, and cultivated

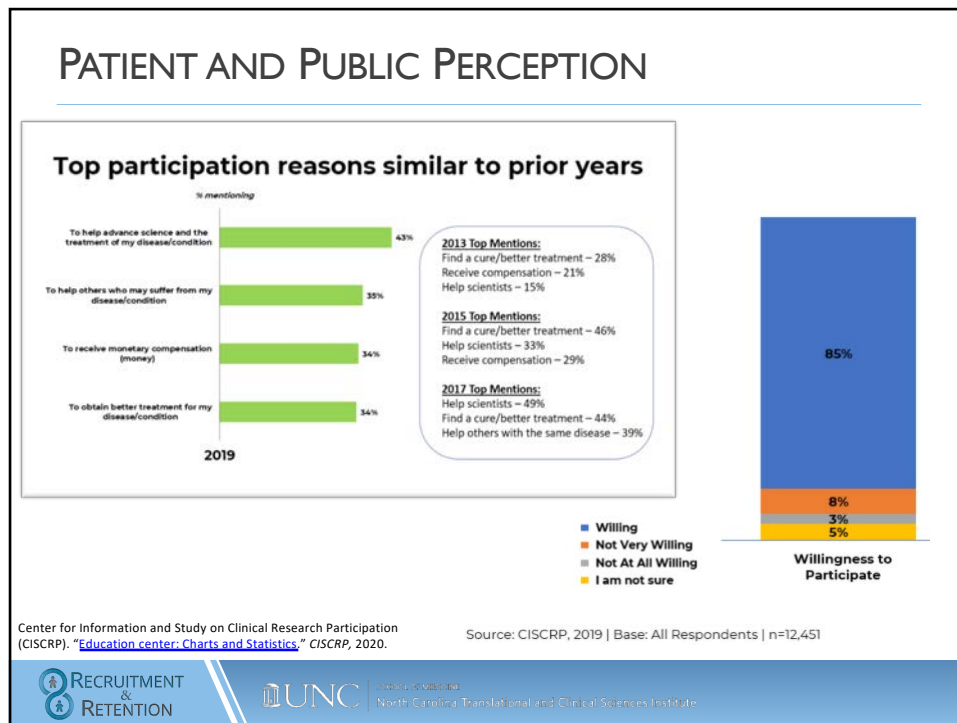


\*adapted from the PCORnet Engagement Framework, n.d.

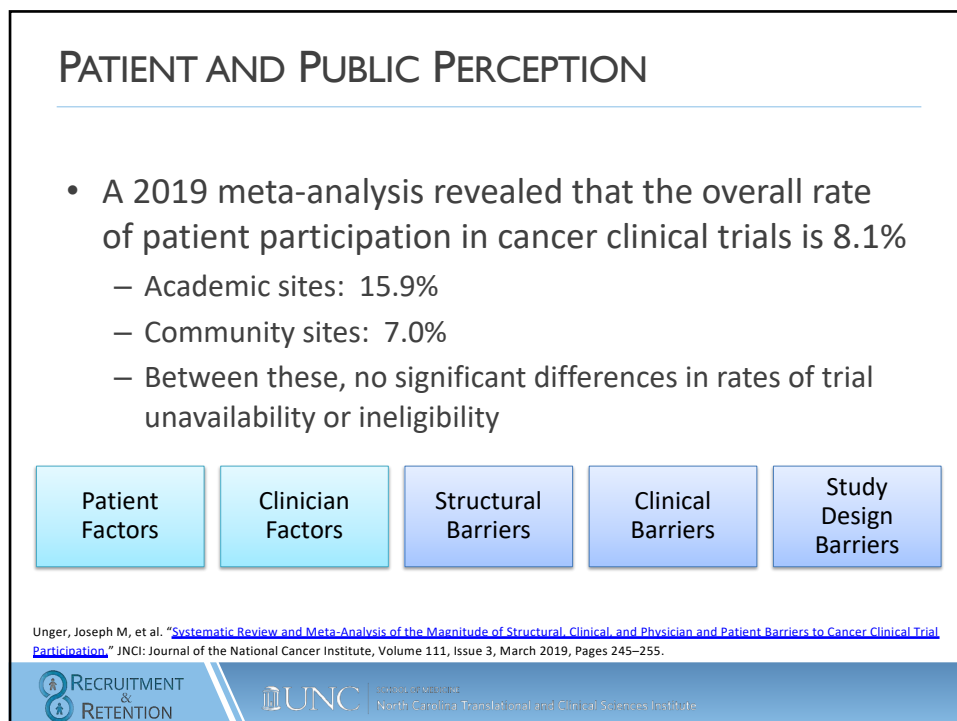


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## PERCEPTION SURVEY RESULTS

What reasons do people give for not taking part in research?

- Not aware/lack of information = 53%
- Lack of trust = 53%
- Too risky = 51%
- Adverse health outcomes = 44%
- Little or no monetary compensation = 35%
- Privacy Issues = 27%
- Too much time = 27%
- Not sure = 11%

\*Research!America survey of U.S. adults conducted in partnership with Zogby Analytics in July 2017.



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## WHERE CAN YOU MAKE AN IMPACT?



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## CLINICIAN IMPACT ON PATIENT PERCEPTIONS

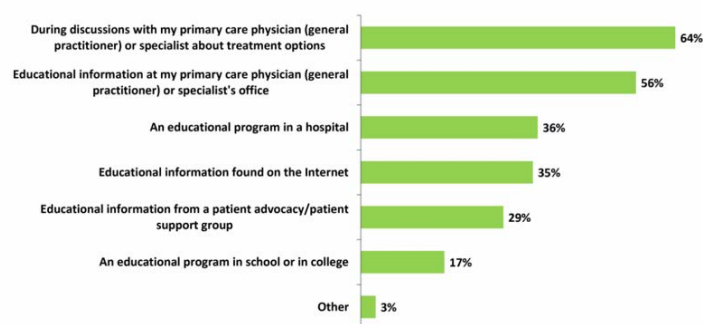
- Roles
- Timing and normalization
- Communication
- Transparency
- Meeting the patient where they are
- Lay Language and a “Shame-Free” environment
- Consider and confront your own personal opinions about research
- Resources
- Tell research teams what you need



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## Preferred Ways to Learn About Clinical Research



Source, CISC RP, All Respondents, N=12,427, 2017

Center for Information and Study on Clinical Research Participation (CISC RP). "Education center: Charts and Statistics." CISC RP, 2020.



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## THE ROLE OF THE CLINICIAN

- **The single most influential factor in enrolling patients in clinical trials is clinician influence.**
- Your role in research engagement will vary depending on your setting and patients
- The ability of your patients to engage will depend on a lot of factors
- The clinical environment, your ability to discuss research, and the resources available will all serve to either frame or reframe the patient perception of research and their possible role in it
- Empower the patient to engage and give them the tools/knowledge to drive their own choices



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## ASKING THE CLINICIAN TO MAKE THE INTRODUCTION

- Clinician introduction and referral is both the most successful and most challenging recruitment method
- Regardless of recruitment specifically, clinicians are the trusted source – a few conversations with a trusted clinician goes a long way toward helping an individual decide what is right for them
- Everyone should be approached – it's up to the patient to decide if they want to be part of research, not the clinician



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## OF NOTE IN CANCER CLINICAL TRIALS

Barriers noted specifically to participation in a cancer clinical trial:

- Fear of reduced quality of life
- Concern about receiving a placebo
- Potential side effects
- Concern that experimental drug may not be the best option
- Inconvenience of participation
- Dislike of randomization
- Difficulty with eligibility criteria
- Wanting one's own doctor to decide
- Feeling coerced
- Lost of control over treatment decisions
- Lack of encouragement or active discouragement from treating clinicians to participate
- Misinformation in that women fear **getting “no treatment”** (placebo), even though providing the best standard of care is the ethical requirement in cancer trials.
- The misconception that clinical trials are a **last-ditch effort**, and one should participate only after failing to respond to approved, conventional treatments

Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. [“Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary.”](#) Washington (DC): National Academies Press (US); 2010. 6, Clinical Trials in Cancer.

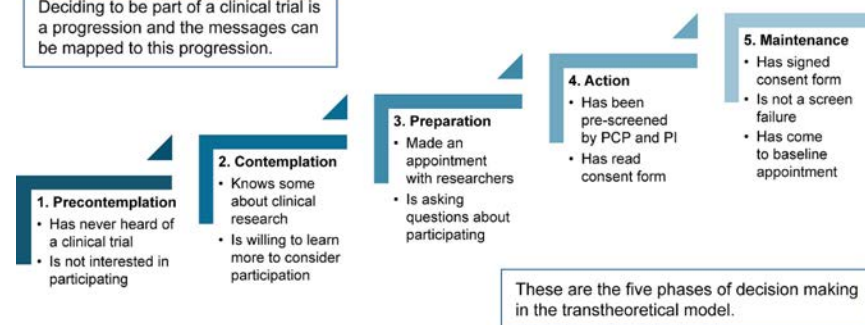


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## COMMUNICATION

Deciding to be part of a clinical trial is a progression and the messages can be mapped to this progression.



Clark, Luther T, et al. [“Increasing Diversity in Clinical Trials: Overcoming Critical Barriers”](#). Current Problems in Cardiology, Volume 44, Issue 5, 2019, Pages 148-172, ISSN 0146-2806. <https://doi.org/10.1016/j.cpcardiol.2018.11.002>.



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## WHAT DO WE MEAN BY RESEARCH?

### STUDY TYPES

- Registry
- Biospecimen
- Survey
- Lifestyle
- Community-based
- Drug
- Device
- Procedure
- Medical Outcomes
- Comparative Effectiveness

### STUDY AIMS

- Prevention
- Screening/detection
- Treatment
- Complementary approaches
- Outcomes
- Quality of Life
- Supportive Care



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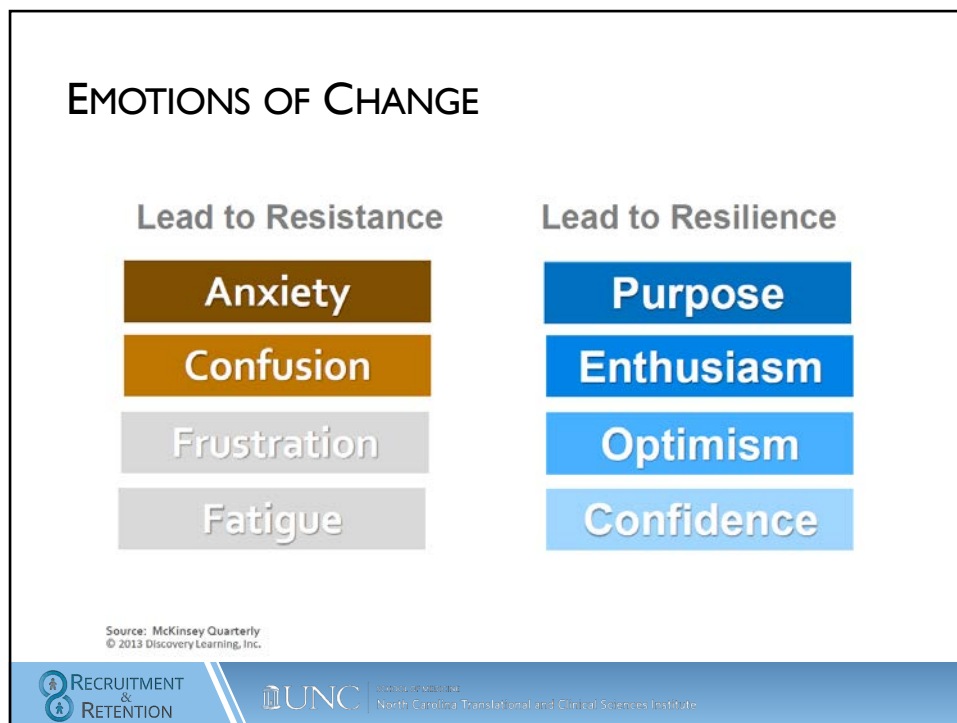
## INTRODUCING RESEARCH AS A CONCEPT

- You need to frame your message for your audience
- One, clear take-home message
- Meet the person where they are
- Provide information in manageable chunks and encourage questions
- Set aside your assumptions and consider the perspective of the audience
- Identify why you feel that research is important

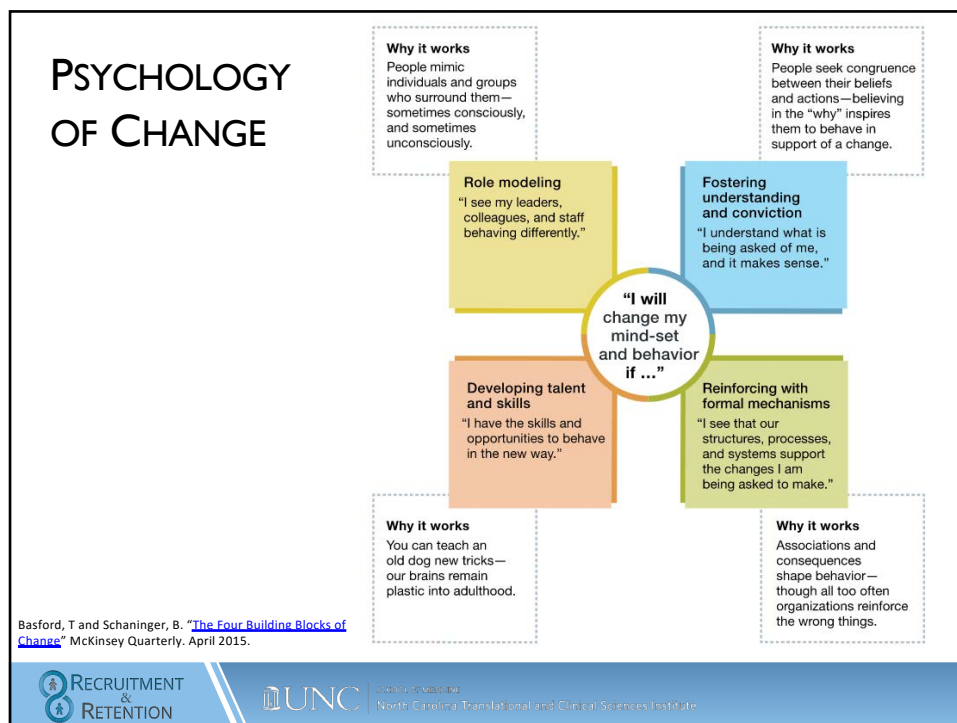


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## EXAMPLES OF PITCHES AND IMPORTANCE

- “Are you familiar with research?”
- “Have you ever done a research study before?”
- Draft some example pitches to demonstrate how easy to incorporate



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## CLINICIAN BARRIERS TO OFFERING RESEARCH

- Clinicians often decide not to ask eligible patients about trial participation due to institutional or clinic time/reimbursement constraints, treatment preference, or other reasons. This removes a key opportunity for patients to consider taking part in a trial.
- Surveys have shown that patients look to their doctors as a major source of information about clinical trials and that when eligible patients are actually offered trial participation, they say yes more than 50% of the time.



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## EXPAND ON CLINICIAN BARRIERS AND MITIGATION

- Research largely exists separately from clinical practice
- Disincentives to referrals
- Unwilling to shift care of their patients
- Time
- Study questions and protocol often designed outside context of clinical practice
- Capability of system to act on findings



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## SUMMARY OF CLINICAL STRATEGIES

- Develop strategies that are realistic within your environment
- Focus on either end of the research spectrum – help to educate and disseminate
- Create a culture that normalizes research
  - Visibility
  - Knowledge
  - Transparency
- If no time/ability to specifically recruit – begin the engagement process and provide resources



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## CONFRONTING BIASES - DIVERSITY IN RESEARCH

- It's not just about hitting a target; it's about making sure that you are gathering data on a representative sample of your intended population
- Without diverse participants, there is a real danger of missing valuable insight or developing treatment which may not impact all populations the same way
- Less than 10% of patients enrolled into clinical trials are minorities

DEMOGRAPHIC SUBGROUPS	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES	2019 Demographics
AVERAGE	72%	72%	9%	9%	18%	36%	40%	

\*FDA [Drug Trials Snapshots](#), n.d.



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## CRITICAL BARRIERS TO DIVERSE PARTICIPATION

- Mistrust
- Lack of comfort with the clinical trial process
- Lack of information about clinical trials
- Time and resource constraints associated with participation
- Lack of awareness about the existence and importance of clinical trials
- Implicit or direct bias



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## STRATEGIES TO BOOST INCLUSION/DIVERSITY

- Implicit bias/racial equity training
- Diversify research staff
- Participant navigators, patient advocates
- Participant ambassadors or peer networks
  - More important to those with chronic conditions
- Ability to include non-English speakers
- Awareness of context and perceptions
- Ability to have a transparent and honest conversation about history, lessons learned, concerns, and the many levels of engagement
- Expand involvement of community clinicians and rural communities
- Community engagement



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## FINDING A CLINICAL TRIAL (OR OTHER STUDY)

- Local Resources:
  - UNC: [Research for Me @UNC](#) or [LCCC](#)
  - Duke: [Discover Duke Research](#)
  - Wake Forest: [Be Involved](#)
- National Resources:
  - [CISCRP trial search](#): free; staff assisted
  - [ClinicalTrials.gov](#)
  - [National Cancer Institute](#)



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## OTHER BARRIERS

- Structural Barriers
  - No studies available for participant condition
  - Logistics
- Clinical Barriers
  - Narrow eligibility criteria
  - Aversion to changing/adding care provider
- Study Design Barriers
  - Question irrelevant to target population
  - Structure or compensation not well considered
  - Poorly trained staff
  - Poorly written materials



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## WHAT IS COMMUNITY ENGAGEMENT?

"the process of working collaboratively with and through groups of people affiliated by geographic proximity, special interest, or similar situations to address issues affecting the well-being of those people." (CDC, 1997, p. 9)."



CTSA Community Engagement Key Function Committee. "Principles of community engagement." (2011): 11-7782.



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## WHO IS INVOLVED IN COMMUNITY ENGAGEMENT?

**Stakeholders** are people or organizations invested in a program and/or impacted by its effect, success, or failure.

- Community members or leaders, patients, caregivers, health care providers, industry, advocacy or community-based organizations, etc.

Consider:

- Who will benefit? Who has key insights? Who are the gatekeepers? Individuals perspectives vs. group representation?



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## WHAT BENEFITS DOES ENGAGEMENT BRING?

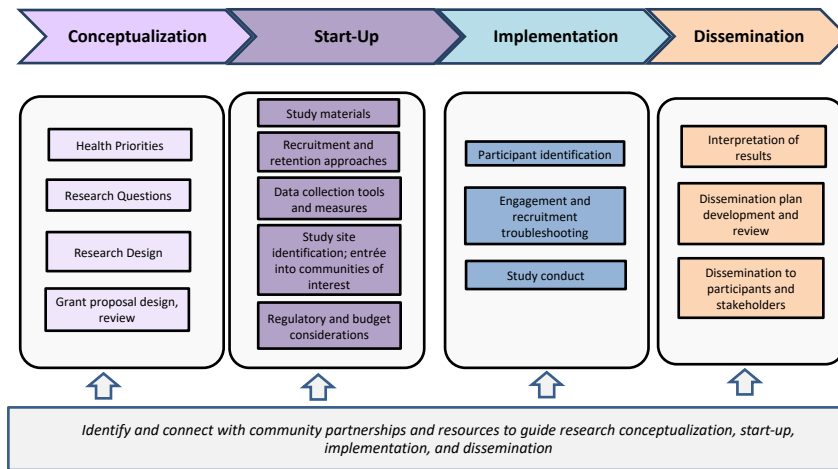
- Better understanding of community-specific issues and needs
- Community relevant research
- Utilizes community assets
- Generates new ideas and methods
- Community buy-in = sustainability
- Community satisfaction, empowerment, trust in research
- Identify potential roadblocks ahead of time
- Facilitates dissemination and translation of findings



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## HOW AND WHEN CAN YOU INCORPORATE STAKEHOLDERS INTO RESEARCH?



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## LEVELS OF COMMUNITY ENGAGEMENT

	Inform	Consult	Involve	Collaborate	Delegate	Community Driven/ led
<b>Community Participation Goal</b>	To provide the community with balanced & objective information to assist them in understanding the problem, alternatives, opportunities &/or solutions	To obtain community feedback on analysis, alternatives, and/or solutions	To work directly with community throughout the process to ensure their concerns and aspirations are consistently understood and considered	To partner with the community in each aspect of the decision including the development of alternatives & identification of the preferred solution	To place the decision-making in the hands of the community	To support the actions of community initiated, driven and/or led processes
<b>Promise to the community</b>	We will keep you informed	We will keep you informed, listen to & acknowledge concerns, aspirations, & provide feedback on how community input influenced decisions	We will work with you to ensure that your concerns & aspirations are directly reflected in the alternatives developed and provide feedback on how that input influenced decisions	We will look to you for advice & innovation in formulating solutions and incorporate your advice & recommendations into the decisions to the maximum extent possible	We will implement what you decide, or follow your lead generally on the way forward	We will provide the needed support to see your ideas succeed
<b>Examples</b>	•Fact sheets •Web sites •Open Houses	•Public comments •Focus groups •Surveys •Community meetings	•Workshops •Deliberative polling •Advisory bodies	Advisory groups •Consensus building Participatory decision making	Advisor bodies •Volunteer/ stipend •Ballots •Delegated decision	•Community supported processes •Advisory bodies •Stipend roles for community •Funding for community

Source: Adapted Community Engagement Standards for Community Health Planning Guideline, 2017



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## PRINCIPLES OF COMMUNITY ENGAGEMENT

- **Be clear about the goals** of the engagement effort
- **Become knowledgeable** about the community
- **Build trust** - go to the community, establish relationships
- **Collective self-determination** is the community's right
- **Partner with the community** to create change/improve health
- **Recognize and respect** the community's diversity
- **Identify and mobilize** the community's assets
- **Commit long-term** to community collaboration
- **Prepare to release control** to the community

Principles of Community Engagement, 2011  
[https://www.atsdr.cdc.gov/communityengagement/pdf/PCE\\_Report\\_S08\\_FINAL.pdf](https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_S08_FINAL.pdf)  
Wallerstein N, Minkler M, Carter-Edwards L, Avila M, Sanchez V, 2015.



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## WHAT CAN YOU GIVE TO YOUR STAKEHOLDERS?

- Financial compensation
- Capacity building and support
- Equal partnership
- Long term relationships, sustainable investment
- Ask them!



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## SUMMARY

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- Continuum of engagement and culture shift
- Patients are partners in the process and decision
- Communication is key
- Resources and marketing aimed at research education and awareness
- Treating people like people and research as a viable and accessible option



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## SUMMARY

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- Well-designed, patient-engaged trial design
- Reasonable inclusion/exclusion criteria
- Involvement of primary and treating clinicians
- Involvement of advocates and navigators
- Education, awareness, and accessibility



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## IMPACTS ON PARTICIPATION

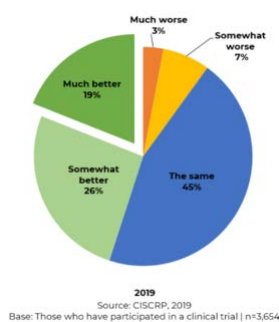
- Awareness/knowledge of research
- Perception of research
- Motivation to participate
- Accessibility of research
- Introduction to research (broadly or to a specific study)
- The study design itself and the study team



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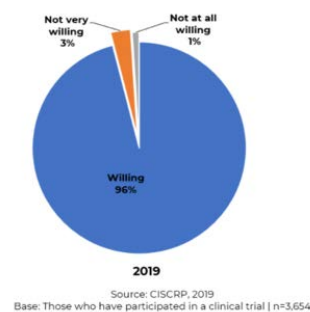
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## PARTICIPANT EXPERIENCE



**Comparing experience  
with research to  
standard of care**

97% said they would  
recommend research  
to a friend or relative



**Willing to  
participate in  
a trial again?**

Center for Information and Study on Clinical Research Participation (CISCRP). "Education center: Charts and Statistics." CISCRP, 2020.



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## QUESTIONS/DISCUSSION

Thank you!

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## REFERENCES AND FURTHER READING

- Unger, Joseph M, et al. "Systematic Review and Meta-Analysis of the Magnitude of Structural, Clinical, and Physician and Patient Barriers to Cancer Clinical Trial Participation." JNCI: Journal of the National Cancer Institute, Volume 111, Issue 3, March 2019, Pages 245–255.
- Clark, Luther T, et al. "Increasing Diversity in Clinical Trials: Overcoming Critical Barriers". Current Problems in Cardiology, Volume 44, Issue 5, 2019, Pages 148-172, ISSN 0146-2806. <https://doi.org/10.1016/j.cpcardiol.2018.11.002>.
- Fouad, Mona N, et al. "Patient Navigation as a Model to Increase Participation in African Americans in Cancer Clinical Trials". J Oncol Pract. 2016 Jun;12(6):556-63. doi: 10.1200/JOP.2015.008946. Epub 2016 May 17. PMID: 27189356; PMCID: PMC4957258.
- Regnante JM, et al. "US Cancer Centers of Excellence Strategies for Increased Inclusion of Racial and Ethnic Minorities in Clinical Trials." J Oncol Pract. 2019 Apr;15(4):e289-e299. doi: 10.1200/JOP.18.00638. Epub 2019 Mar 4. PMID: 30830833.
- Niranjani SJ, et al. "Bias and stereotyping among research and clinical professionals: Perspectives on minority recruitment for oncology clinical trials." Cancer. 2020 Jan 1;126(9):1958-1968. doi: 10.1002/cncr.32755. Epub 2020 Mar 9. PMID: 32147815.
- Carman, Kristin L, et al. "Patient and Family Engagement: A Framework for Understanding the Elements and Developing Interventions and Policies." Health Affairs. 2013 February; doi: 10.1377/hlthaff.2012.1133 HEALTH AFFAIRS 32, NO. 2 (2013): 223–231
- Huang GD, et al. "Clinical trials recruitment planning: A proposed framework from the Clinical Trials Transformation Initiative." Contemp Clin Trials. 2018 Mar;66:74-79. doi: 10.1016/j.cct.2018.01.003. Epub 2018 Jan 9. PMID: 29330082.
- Sacristán, José A, et al. "Patient involvement in clinical research: why, when, and how." Patient preference and adherence vol. 10 631-40. 27 Apr. 2016, doi:10.2147/PPA.S104259
- National Institutes of Health. "Talking to your Patient about a Clinical Trial." Health Information: NIH Clinical Trials and You. 17 Apr 2015.
- Center for Information and Study on Clinical Research Participation (CISCRP). "Education center: Charts and Statistics." CISCRP, 2020.
- Landmark: Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. "Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary." Washington (DC): National Academies Press (US); 2010. 6, Clinical Trials in Cancer.
- Landmark: Institute of Medicine (US) Forum on Drug Discovery, Development, and Translation. "Transforming Clinical Research in the United States: Challenges and Opportunities: Workshop Summary." Washington (DC): National Academies Press (US); 2010. 3, Challenges in Clinical Research.

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