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ENHANCING PARTICIPATION IN CLINICAL TRIALS:

Practical Strategies for Recruitment, Engagement, and Community Partnership

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Session Objective

Acquire strategies and resources to enhance participation in clinical trials.



Agenda

- Welcome
- Poll
- Why Participation Matters & Common Barriers
- Case Study Workshops
- Practical Strategies & Available Resources
- What's next?



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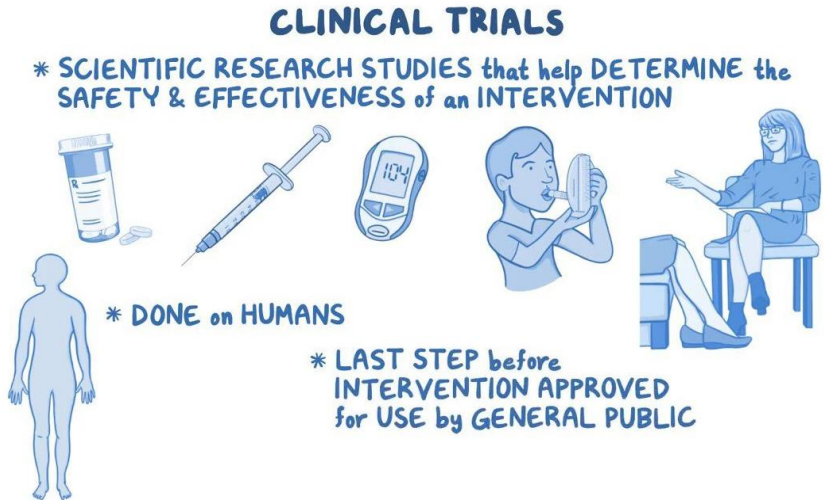
Clinical Trials Definition

NIH A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Source: NIH's Definition of a Clinical Trial | Grants & Funding



Source: Clinical trials: Video, Causes, and Symptoms | Osmosis

A medical research study with people to test how safe and how well new medical interventions work.

Medical Intervention	Example of something used in a clinical trial
Drug	COVID vaccine
Medical Device	Pacemaker, glucose monitor
Surgical Procedure	Less invasive vs open surgery
Behavioral therapy	Program to help stop smoking, learning the hula and traditional songs to reduce subjective cognitive impairment
Digital health intervention	Mobile health app for medication reminders or symptom tracking
Preventive care strategies	Health education campaign sent out via test message to see if screening rates increase for a particular health issue – for example colorectal cancer or breast cancer screenings

Diversity Includes

1 Race and ethnicity
Includes multiple racial and ethnic identities.

2 Age
Representation from children to older adults.

3 Sex and gender
Includes women, men, non-binary, and gender-diverse people.

4 Geographic location
People from urban, suburban, and rural locations across different regions.

5 Socioeconomic status
Representation across different income levels and occupations.

6 Disability status
Visible and non-visible disabilities included.

7 Language and cultural background
Includes people who speak different languages and come from a variety of cultural traditions.

8 Health conditions and comorbidities
Includes individuals with different health conditions, chronic illnesses, and comorbidities.

Why Participation Matters



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Affects Research Quality & Applicability

Improves scientific validity

People can respond differently to treatments based on biological, environmental, social, and behavioral factors.

Increases generalizability

Where study findings can reasonably be applied to broader populations

Enhances health equity

Historically, many populations have been excluded, underrepresented, or underserved in research.

Increasing Expectations



FUNDERS

Expect investigators to:

- Justify who is included and excluded
- Develop plans for inclusive enrollment
- Address barriers to participation
- Report demographic characteristics of participants



RESEARCH INSTITUTIONS

View inclusive participation as:

- An ethical responsibility
- A scientific requirement
- A component of community engagement

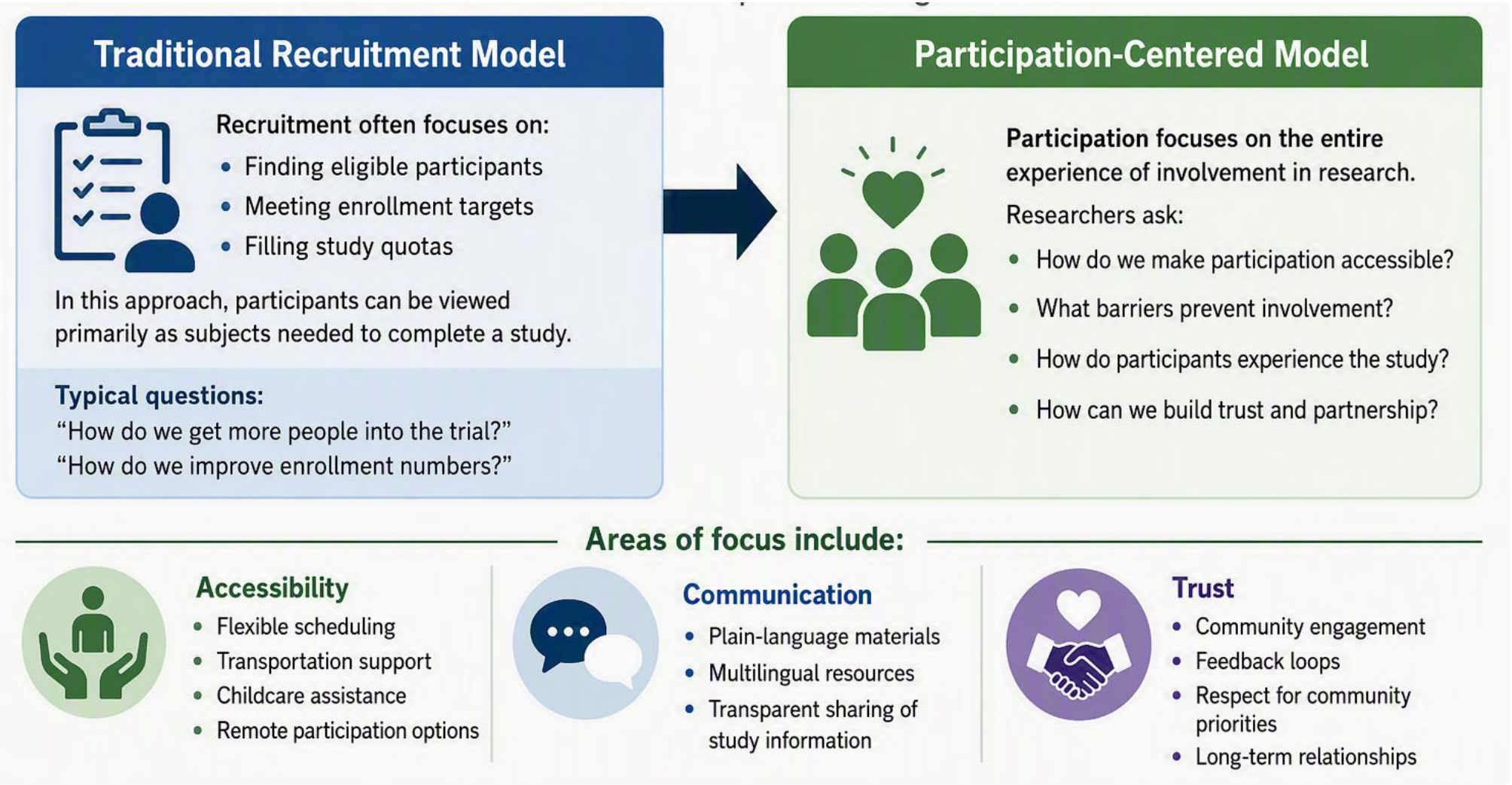


COMMUNITIES

Are asking important questions:

- "How will this research benefit us?"
- "Were community voices involved in designing the study?"
- "Why should we trust this research?"

Moving From “Recruitment” to “Participation”



Conversation is Evolving

How do we recruit enough participants?

How do we create research that people from all communities can access, trust, and meaningfully participate in?

With that, we must recognize that

Participation challenges are often not participant problems. They are system-design problems.



Case Study Workshop (25 min)



Small Group Discussion (10 min)

Let’s Share: Report Out (15 min)

Small Group Discussion (10 min)



With your group discuss the following questions:

1. What do you see as the most important barriers?
2. Who may be unintentionally excluded from participation?
3. What would be the most impactful action(s) within the study team's control that could address these barriers?
4. What resources, partnerships, or support could help?

Let’s Share: Report Out (15 min)



Top 2 for each main question:

1. What do you see as the most important barriers?
2. Who may be unintentionally excluded from participation?
3. What would be the most impactful action(s) within the study team's control that could address these barriers?
4. What resources, partnerships, or support could help?

Case Studies - Common Themes

- Participation burden
- Awareness and access
- Trust and relationships
- Communication and language

Most barriers emerge before recruitment begins.

Participation Begins During Study Design

- Who might face barriers?
- What barriers can we reduce?
- What supports will participants need?
- What resources should be built into the study?



If You’re Working with a Sponsor…

Have the conversation early.

Questions to discuss:

- Are visits realistic for participants?
- Is support for participant travel provided?
- Are translation resources available?
- Is participant compensation adequate?
- Are recruitment materials appropriate?
- What local resources will be needed?

What's Within Your Power?

Study Design & Operations

- Reduce burden where possible
- Coordinate visits
- Consider remote options

Budget & Resources

- Translation
- Transportation
- Participant compensation

Recruitment

- Referral pathways
- Community partners
- Awareness strategies

Communication

- Plain language
- Language access
- Participant-centered materials

For Your Next Study

Before recruitment begins…

1. Who might be unintentionally excluded?
2. What barriers can we reasonably reduce?
3. What resources or partnership would help?

Small changes made early can meaningfully affect participation.

Community Engagement Strategies

Relationship Building	Community Engagement Spectrum	Community Connect	Funding	Partnerships
Starts before recruitment	Opportunity for improvement & learning	Join others from UW out in community.	Bridge Funding	Community Based Research Collaboratory
Requires us to be out in community listening & learning first			ITHS	UW EDI committee, JEDI, CREATE, IHDD

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Resources to Support Inclusive Research & Clinical Trial Recruitment

Tools, funding, consultations, and data resources to advance equity, access, and community engagement

Translation & Interpreter Services
Access translation, interpretation, and communication support resources.
(UW Net ID required)

Language Access Bridge Funding
Up to $5,000 for language access and cultural advocacy needs in unfunded or underfunded studies.

Community Engagement Bridge Funding
Up to $10,000 to strengthen community engagement, cultural access, and language access in research and clinical trials.
Up to 14 projects funded.

CBRC Researcher Consultations
Community-informed guidance on study design, recruitment, engagement strategies, and equity-centered research practices.

ITHS Recruitment Support Service
Free support for study design, recruitment planning, budgets, materials, and connections to other resources.

Patient Demographics Dashboard
Data tool to align recruitment goals with the Diversity Plan using demographic, diagnostic, and interpreter data from UW Medicine.
(UW Net ID required)

Health Sciences Library Support
Expert help identifying underrepresented groups in PubMed and ClinicalTrials.gov and strengthening recruitment plans.

E-Consent & REDCap Tools
Enterprise-supported e-consent (REDCap, DocuSign) and FDA-compliant REDCap for data capture and management.
New REDCap Part 11 instance available for FDA-regulated research.

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Resources to Support Inclusive Research & Clinical Trial Recruitment

Diversity in Clinical Trials
UW Medicine Website

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What Are We Missing?

Help inform future DCTI and community engagement efforts



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Key Takeaways

Participation Begins During Study Design

Many recruitment challenges originate much earlier in the research process.

Community Engagement Is a Process, Not an Event

Relationships often need to be developed before recruitment begins.

Study Teams Have More Influence Than They Think

Even within highly structured or sponsor-driven studies, there are opportunities to reduce barriers.

Resources Already Exist

Researchers do not need to solve these challenges alone.

Small Changes Can Make a Meaningful Difference

Transportation support, language access, communication strategies, and community partnerships can significantly affect participation.

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QUESTIONS?

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