Teaming with Participants to Improve the Validity and Rigor of Rehabilitation Research

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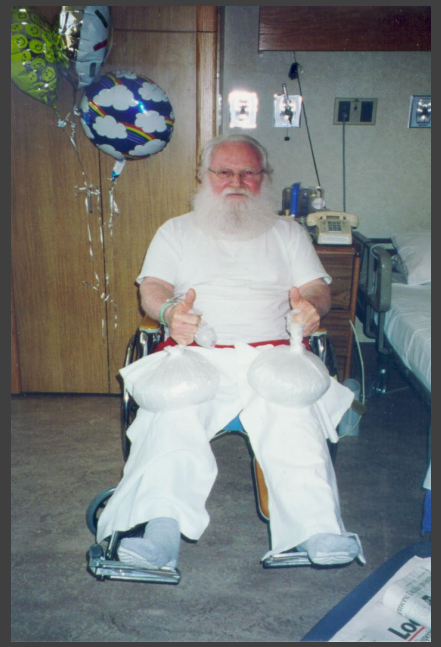
Personal Perspective



Reaching Success with Participant Input

17 years

The Current State

- Ambien (zolpidem) with male biased dosage, with dangerous side effects[1]
- Biomechanical models/NASA based on male prototypes
- Race, culture, disability, Veteran

1 https://www.fda.gov/downloads/Drugs/DrugSafety/UCM335007.pdf changed recommended dosing of Ambien to lower dose for women.

Including Participants throughout the Research Life Cycle

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- Study Design – participant centered outcomes
- Conducting Research – efficiently recruiting a diverse and appropriate population to prevent timeline extensions or underpowered studies
- Interpretation and Dissemination – the right information in the right hands more efficiently

Benefits to Including Participants

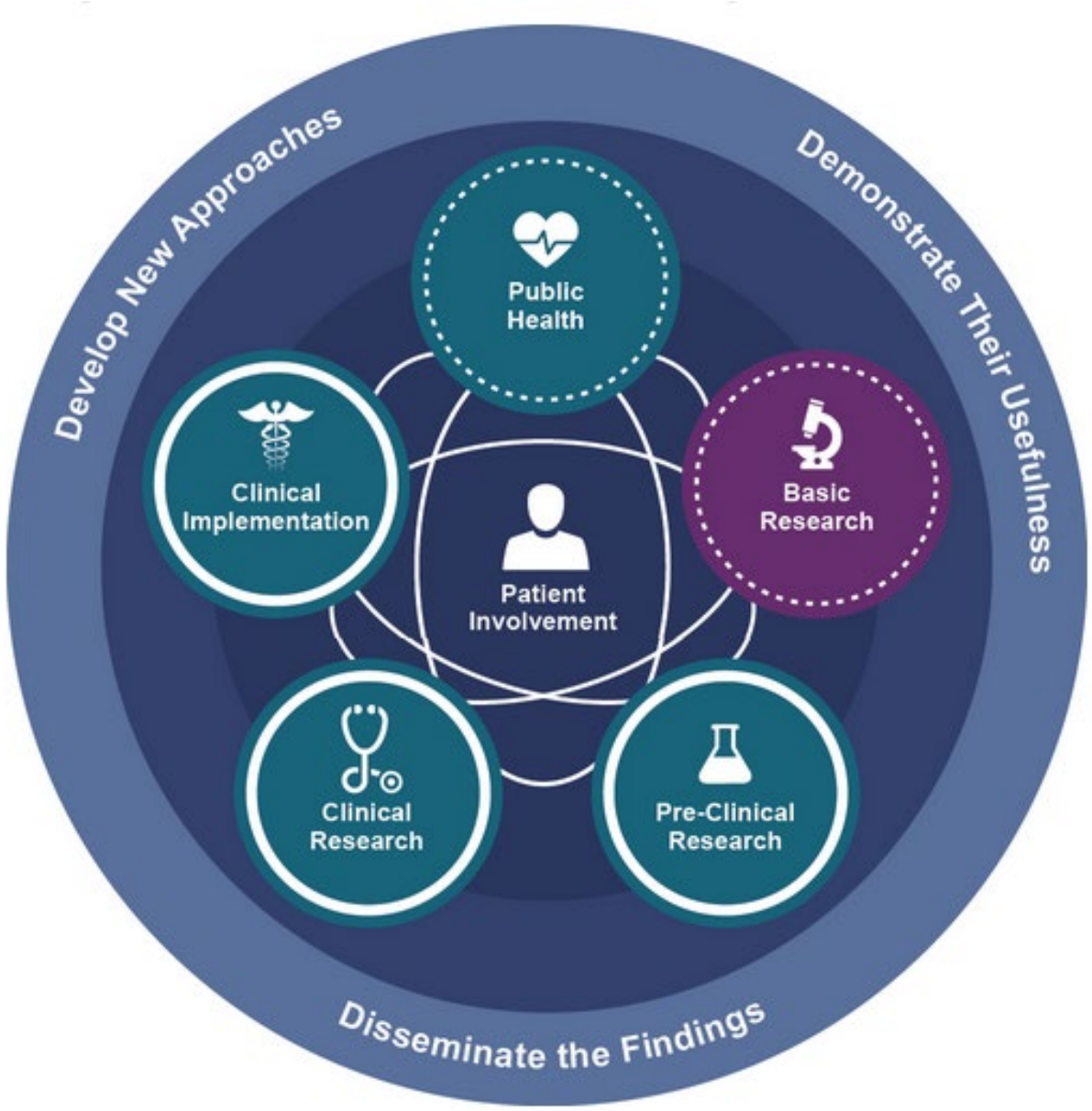
- Idea generation
- Validation of research concepts and strategy
- More competitive viewpoint for funding
- Ideal representative for research for recruitment
- Improved understanding of participants and results
- Ideal representative for your research in dissemination
- Skills outside of their conditions (engineers, doctors, etc)

FDA (Draft Guidance) Patient Engagement in the Design and Conduct of Medical Device Clinical Investigations

FDA views potential benefits as…

- Faster study/research participant recruitment, enrollment, and study completion;
- Greater study/research participant commitment, resulting in decreased loss to follow-up;
- Greater study/research participant compliance resulting in fewer protocol deviations/violations;
- Fewer protocol revisions;
- Streamlined data collection resulting in better quality data;
- More relevant data on outcomes that matter to patients

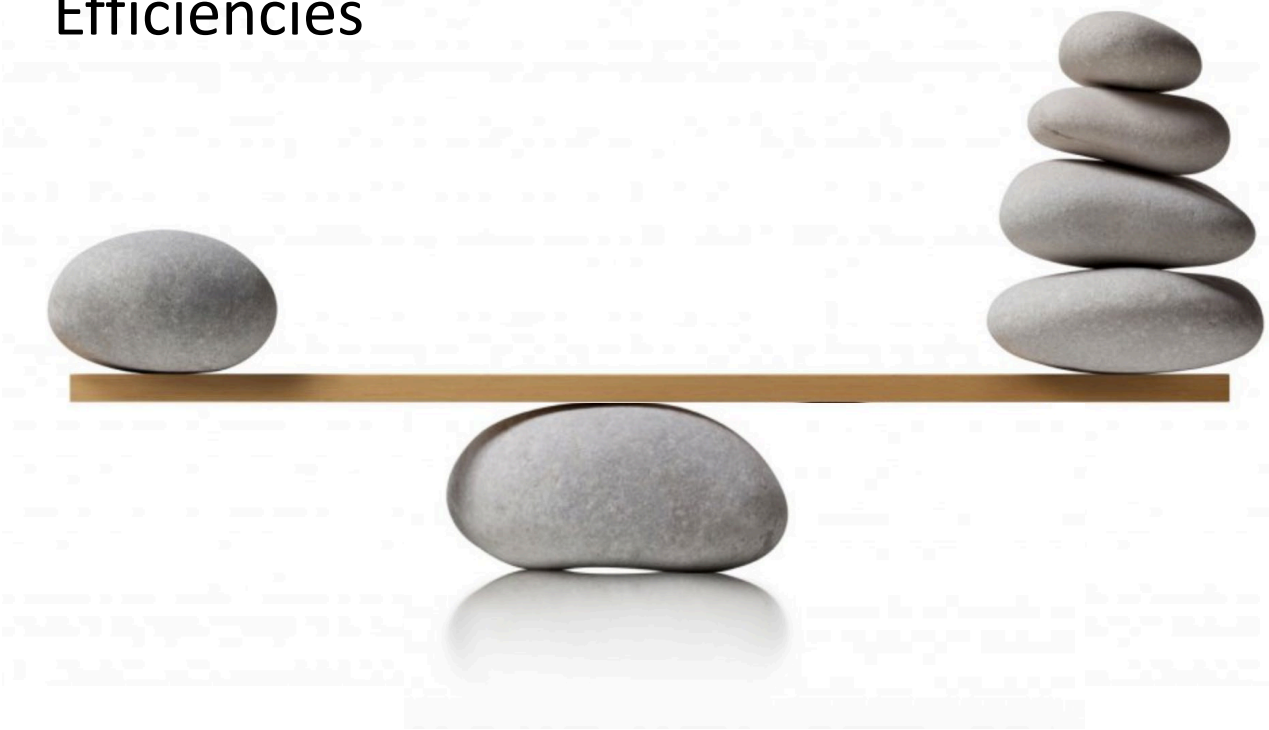
Benefits Apply to All Stages of Research



Balancing Benefits with Costs for a Stronger Outcome

Research Efficiencies

Costs and Planning



Inclusion in Study Design

Engaging Participants to Join the Team

- Academic silos are common
- Direct research towards what participants need
- Providers, patients, payers, policy makers
- If contributions are valuable, they can be treated as consultants
- Be mindful of drawing the line when consumers playing multiple roles

Good, Bad, and Ugly of Patient Engagement

Successful Engagement

- Consumer Research Consultant on Grant Writing
- Medical Device Consultant
- Consumer Peer Reviewers with CDMRP and State Research Grant Programs
- Consumer Directed Surveys Written by Consumers

Avoid Tokenism (Leads to Missed Opportunities)

- Blindly signing a letter of support for a Grant without being allowed to review grant or abstract
- Token placeholder for meetings without opportunity being duly listened to for meaningful contribution
- Scientist Leaders in Research Community Overriding Strong Consumer Opinions on “Joint Group Project”

Conducting Research: Where to Find Participants

- Patient representation organizations
- Patient online chat and community forums (e.g. WAGS, CareCure)
- Community gathering places (e.g. adaptive fitness center)
- Connecting with Clinicians in the region
- Social media
- Past or current participants

Example website – www.estand.org

E-STAND Learn More For Patients For Providers Blog Process E-STAND Team Collaborations Contact Donate

Study Mission

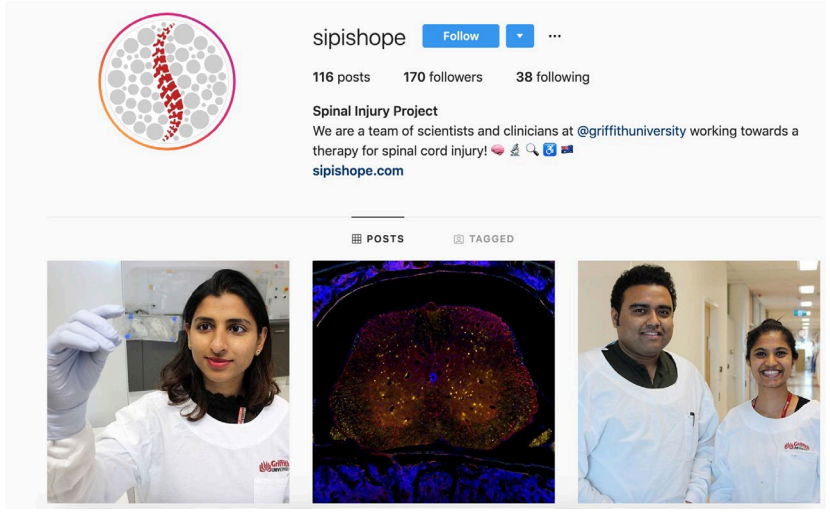
Welcome to the website for the E-STAND (Epidural Stimulation After Neurologic Damage) clinical trial in Minneapolis, MN. The goal of this trial is to test and optimize the use of epidural spinal cord stimulation to restore volitional movement in patients suffering from chronic complete motor spinal cord injury and paraplegia. We are now enrolling patients in our trial.

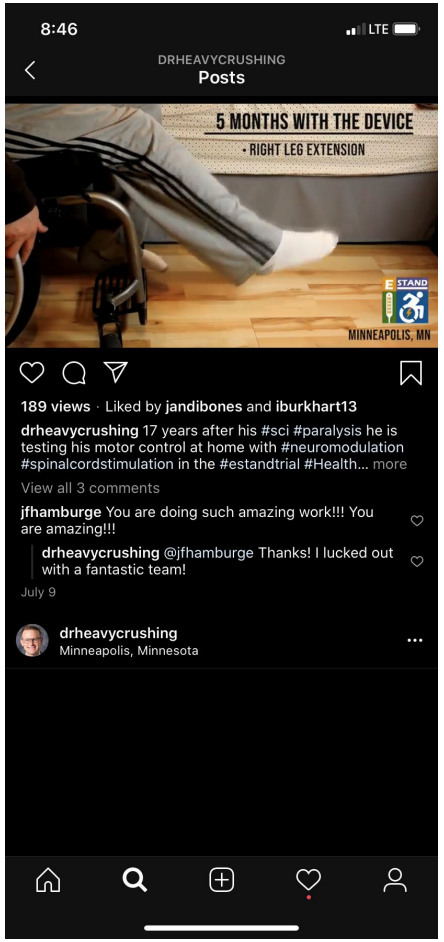
Search … SEARCH

RECENT POSTS

New Participant Enrolled!

Social Media: Instagram, Facebook, Twitter





Conducting Research: Adjusting to Participant Needs

Goal

- Provide good interactions
- Make visits easier
- Eliminate transportation barriers
- Foster affiliation with study
- Improve and adapt
- Vision or hearing impaired accessibility

Strategy examples

- Convenient, efficient, professional study visits
- Travel vouchers, free parking, car pool, maximize flexibility, schedule in advance
- Testing in patient homes; telehealth applications
- Newsletter, study updates
- Survey for actionable feedback
- Large font, visible notes on flipcharts, voice amplifier

Older Veteran Engagement Team (OVET) Example

Improve Older Veterans' Health Outcomes and Quality of Life

- OVET & Researchers/Providers Meet

- OVET provides feedback/ input on research, clinical services, outreach efforts

- Older Veterans and caregivers have a voice in creating services and supports to enhance value

Kathryn Nearing, PhD, MA, Associate Director for Education and Evaluation ,VA Eastern Colorado Health Care System GRECC

Older Veteran Engagement Team Process

- **Recruitment**
  - Diverse perspectives are essential
  - Select team members who, collectively, represent diverse Veterans, caregivers
- **Selection**
  - 20 to 30 minute interview (explores interest, military and life experiences, considerations that might facilitate participation)
- **Orientation**
  - Getting to know one another
  - Learning about the value of participation from each person's perspective
- **Monthly Meetings**
  - Review and discuss evaluations from previous meeting
  - 1 hour for discussing new topic with a guest (facilitated)
  - Review of key themes/ suggestions/ action items
- **Regular Feedback**
  - Member evaluations assess perceived responsiveness of guests
  - Presenters/guests document intentions to use OVET input
  - 6 month follow-up with presenters to determine how they used OVET input
  - All summarized and shared back with OVET

Study Design: Conducting Research

- Don’t miss the obvious questions (Powered Glove example)
- Is your questions truly **Important** and **Pertinent**?
- Figure out your target patient/consumer/participant and **Ask Them**
- Focus Groups – guided and unstructured time

Diversity

Possible Considerations

- Ethnic/racial
- Health beliefs and life priorities
- Socio-economic barriers
- Gender/Sex
- Barriers to physically accessing materials
- Health literacy and education

Fear and Mistrust

Interpretation and Dissemination of Study Findings

Participant Engagement in Interpretations, Review, Dissemination

- Why does participation end when data collection ends?
- Participant input is valuable during interpretation
- Conferences and Publications geared towards Researchers

Study Design: Funding Applications

- Tracking and rewarding investigators for inclusion of diverse consumers (grant review and funding)
- Section addressing diverse recruitment efforts in grants
- K award for individuals with disabilities
- Administrative supplements

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K01 – NINDS Faculty Development Award to Promote Diversity in Neuroscience Research

Purpose

- For support of diverse faculty scientists committed to research, in need of both advanced research training and additional experience.

K99/R00 – BRAIN Initiative Advanced Postdoctoral Career Transition Award to Promote Diversity

Purpose

- To enhance biomedical research workforce diversity by supporting a mentored research experience (K99) followed by independent research (R00) for postdoctoral fellows working in research areas supported by the BRAIN Initiative.

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- K award for individuals with disabilities
- **Administrative supplements**

Research Supplements to Promote Diversity in Health-Related Research (Admin Supp – Clinical Trial Not Allowed)

- …funds are available for administrative supplements to improve the diversity of the research workforce by recruiting and supporting **students, postdoctorates, and eligible investigators from diverse backgrounds,** including those from groups that have been shown to be **underrepresented** in health-related research. This supplement opportunity is **also available to PD(s)/PI(s) of research grants who are or become disabled and need additional support to accommodate their disability** in order to continue to work on the research project. Administrative supplements must support work within the scope of the original project.

Recommendations for Improvement

Acknowledgements

Cynthia Huang, PT, DPT

Kathryn Nearing, PhD, MA

Dr. Heather L. Gainforth, PhD

John Chernesky


You know, sometimes I think he understands every thing we say!
Danger LIVE specimen
cri

Thank you!

Questions?

Process Flow: Before, During, After Each Meeting

At least 1 month prior, guest receives Presentation Request Form and Guidelines for Engagement

At least 1 week prior, members receive Presentation Request Form + background materials, agenda

During each meeting, Review feedback from previous meeting, have discussion with guest (10:30- 11:30), summary, member evaluation

Usually within a week, prepare notes, summarize member evals, share with guest, invite to do evaluation

Two weeks before meeting, Share all materials with OVET ahead of subsequent meeting

Impact of Complexity in the Literature

- Higher levels of study design complexity associated with poorer data quality and analysis (Friedman et al. 2010; Nahm et al. 2008)
- More procedures/outcomes associated with higher incidence of unused data (Abrams et al. 2009)
- More complex study designs are associated with lower levels of clinician/physician participation and referral rates (Ross et al. 2004)
- High study volunteer drop out rates are associated with complex protocol designs (Andersen et al., 2009)