Research: Why You Should Be Involved!

Presented By The Emory DREAMS TEAM

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Our Talk Road Map

- The Clinical Research Process
- Health Literacy & Participating in Research
- Ethics in Research
- Advocacy in Research: Why, Who & What
The Clinical Research Process
A little quiz….

Match the Definition to the Correct Research Term

1. Randomized trial
   a. The participant is not told which arm of the trial he is on
   b. One group of participants is given an experimental drug, while another group is given either a standard treatment for the disease or an inactive treatment.

2. Controlled trial
   c. Participants are assigned by chance to one of two or more treatment arms of a clinical trial
   d. An inactive pill, liquid, or powder that has no treatment value.

3. Placebo

4. Blind

Courtesy of the Parkinson’s Disease Foundation
What is Clinical Research?

- Research performed to gain insight about human behavior or body function

- It can involve
  - A particular person
  - Groups of people
  - Human behavior or tissues

NIH: https://www.nichd.nih.gov/health/clinicalresearch/Pages/index.aspx
Why is Clinical Research Important?

- Provides scientific foundation (evidence) for clinical practice
- Provides an ethical framework for considering new treatment strategies
- Reduces bias in healthcare
- Increases trust in medical science
Clinical Trials

- Phase I: Safety or feasibility
- Phase II: Check for efficacy
- Phase III: Confirm efficacy
- Phase IV: Post-market evaluation
Clinical Trials

New Drug Clinical Trials

Downward Trend: Only 16 out of every 100 drugs that enter Phase 1 will make it to FDA approval.

Phase 1
Checking for Safety
- 20-100 volunteers
- First state of testing in humans

Phase 2
Checking for Efficacy
- 100 - 500 patients
- How well does the drug work?

Phase 3
Confirm results
- 1,000 – 5,000 patients
- Drug MUST be safe
- Comparison with current 'gold standard' treatment

FDA Review / Phase 4 trials
- Safety surveillance in ‘Real-life’ patients
Find out more and find studies:

- ClinicalTrials.gov
- ResearchMatch.org
- Fox Trial Finder
- Find Clinical Studies at Emory: ClinicalTrials.Emory.edu
Patient-Centered Outcomes

- Subjective symptoms and objective measures don’t always correlate — but which are most important?
- Maintain relevance for persons living with disease
- Include patients in the process of research

Examples of patient-centered outcomes
  - Health-related quality of life
  - Symptom scales
  - Survival
  - Function
  - Factors informing health decisions
Health Literacy & Participating In Research
What is Health Literacy?

“The degree to which individuals can obtain, process, and understand the basic health information and services they need to make appropriate health decisions”

(Selden, Zorn, Ratzan, & Parker, 2000)
Health Literacy Challenges

- People need information they can understand and use to make informed decisions to promote and protect their health.

- The majority of adults have trouble using everyday health information available in our health care facilities, retail outlets, media, and communities.
When Reading Your Prescription Label, Do you Feel Like You're Reading Another Language?

WHMC PHARMACY
LACKLAND AFB TX 78236
292-7000
3 800-469-7170
RXWM1234567
J SMITH
PATIENT, JOHN Q
9999
TYLENOL (ACETAMINOPHEN) 325MG
REF LEFT: 2 OF 3
(01 JAN 05)
TAKE ONE TABLET BY MOUTH TWICE A DAY AS DIRECTED
KEEP OUT OF REACH OF CHILDREN
Health Literacy and Research

- Health literacy challenges can negatively affect research:
  - Can affect understanding of what is required to participate in study
  - Often reduces research participation, particularly by minorities
  - Reduces ability to trust findings and assume that they apply to the general population
Questions to Ask Before Joining a Study

- What is the main purpose of the study?
- What will I be asked to do during the study?
- How will I benefit from participating in this study?
- What are the possible risks?
- How will the results be shared?

http://buildingtrustumd.org/unit/informed-decision-making/knowledge-is-power
Questions to Ask Before Joining a Study (continued)

- How will my personal information be kept confidential?
- How long is the study going to last?
- Are there reimbursements or incentives?
- Who is funding the study?
- What are the researcher and institutional credentials?
Ethics In Research
What is ethics?

- Definitions:
  - Rules of conduct recognized with respect to a class of human actions or a particular group, culture, etc. e.g., medical ethics
  - Philosophy dealing with values relating to human conduct, with respect to the rightness and wrongness of certain actions and to the goodness and badness of the motives and ends of such actions

- How do you define ethics?
- How can we make sure that research is ethical?
Abuse of Research Ethics

Well known abuses in the 20\textsuperscript{th} century:

- Nazi experiments
- Tuskegee Study of Untreated Syphilis (1932-1972)
- Stanford prison experiment (1971) (http://www.prisonexp.org/rebellion)

Prompted development of required review procedures for human subject studies
1974 – National Research Act

- Established federal regulations for research with human subjects
- Required Institutional Review Boards (IRBs)
- Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- 1979 Commission issues the Belmont Report: Ethical Guidelines for the Protection of Human Subjects
To conduct human research we must:

- Minimize harms and risks
- Maximize benefits
- Respect human dignity, privacy, autonomy
- Take precautions with vulnerable populations
- Strive to distribute benefits and burdens of research fairly

Recruitment Factors

- Potential for coercion
  - Financial incentives
  - Benefit of social contact
  - Participants’ trust of authority figures

- Participants must know they can withdraw from study at any time because research participation is completely voluntary
What is Informed Consent?

- Not just signing a form! Participant must understand:
  - Nature of the study and procedures
  - Risks and benefits

Teach-back method should be used —
- “Let me tell you in my own words what I understood”

- Continued invitation to ask questions throughout the study
Getting Others Involved: How To Advocate Effectively For Research Participation
Why research advocacy matters

- Many believe that research answers: “Does this treatment work?”

- Research actually asks: “Does this treatment work on these particular study subjects?”

- Treatments don’t work identically on every group... so every group needs to be included in clinical trials
Who can be an advocate?

Anyone:

- Who cares about a cause or group
- Who would be trusted by this group
- Who wants to minimize suffering
- Who is concerned about health equity
- Who believes in scientific research
What does an advocate do?

Helps researchers:
- Think about the importance of including their group in research
- Ask the right questions
- Recruit the right participants

Helps peers:
- Think about the importance of participating in research
- Ask the right questions
- Agree to participate in the right studies
What could an advocate do?

- Join associations and organizations for causes that you care about
- Develop the study concept:
  - Discuss with researchers what is important to the community
  - Assist in writing and reviewing grants
- Prepare the study protocol:
  - Provide input on study design, barriers to recruitment
  - Help finalize eligibility criteria
  - Assist in creating the informed consent
What could an advocate do?

- **Implement study:**
  - Assist with study recruitment
  - Serve as a peer advocate during informed consent

- **Monitor the study:**
  - Join a Data Safety Monitoring Board
  - Sit on an IRB

- **Analyze data and Interpret results:**
  - Provide feedback on how the community will view the study results
What could an advocate do?

- Disseminate study information:
  - Write newsletter articles or blog about results
  - Co-present results at a conference or support group
  - Work with research team to ensure that study participants get feedback from the study
What could an advocate do?

- **FDA review and approval:**
  - Apply to be a consumer representative to an FDA advisory committee
  - Attend FDA hearings and give comments

- **Post-approval studies:**
  - Advocate with physicians for continued tracking of drugs, devices, therapies
What interests you?

- What issues in research are important?
- What healthcare areas need improvement?
- What peer groups could I educate about research?
- How can I get involved as an advocate and educator?
- Tell us what YOU would like to do
Thank you!

- Please contact any member of the DREAMS Team on how you can get involved in research!
- Advocate for yourself and your peers; recruit others into research!

Thank you to the Parkinson’s Disease Foundation, National Parkinson Foundation and the Patient-Centered Outcomes Research Institute for generous support, which made the DREAMS Team possible.
Check out the Patient-Centered Outcomes Research Institute website:
- PCORI.org — you can get involved by suggesting a research question, becoming a reviewer, or joining an advisory panel
- ClinicalTrials.gov
- ResearchMatch.org
- Fox Trial Finder
WHAT IS PATIENT ENGAGEMENT IN RESEARCH?

**Develop Concept and Secure Funding**
- Assist with grant writing
- Review grants with the Patient Centered Outcome Research Institute (PCORI)

**Prepare Protocol and Create Procedure**
- Help finalize eligibility criteria
- Help make informed consent form

**Implement and Monitor**
- Join a Data Safety Monitoring Board
- Help revise study as needed

**Analyze Data and Interpret Results**
- Help recruit participants
- Serve as a peer advocate

**Share Results**
- Provide feedback on how older adult community views the study

**FDA Review and Approval**
- Provide input on study design. What might prevent someone like me from participating?

**Post Approval Studies**
- Advocate continued tracking of drugs
- Work with researchers on patient centered outcomes

*Adapted from Parkinson's Disease Foundation materials for Emory's DREAMS project*