Participating in FTD Clinical Trials

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Appreciation

For all our patients and families

Who shared their research experiences with us

Experiences with FTD Clinical Trials

- *FTD: A Basis for Clinical Trials*
  - Knopman, Mayo Minnesota (2004-2008)
  - Developed methods for clinical trials
- *Comparing Namenda to Placebo*
  - Boxer, UCSF and Forest Pharm (2008-2012)
  - Namenda not helpful in bvFTD or SD
- *TauRx0237: Safety and Efficacy*
  - TauRx Therapeutics International (2013)

Evaluating Research Projects: *Is this a good study for "us"?*

EDUCATE

Obtain information through process of informed consent

EMPOWER

Consider *your* unique situation

- Rewards and challenges
- Wishes of patients *and* families

Informed Consent

- Provides information about study
- Details potential risks and benefits
- Describes research procedures
- States research is voluntary
- Includes consent of study partner
- Encourages discussion with others

Capacity to Consent
Who signs the consent form?

- Assess FTD participant's understanding
- Evaluate decision-making ability
- Obtain surrogate consent as necessary
  - *Agent in advanced health care directive*
  - *Spouse*
  - *Domestic partner*
  - *Adult son or daughter*
  - *Custodial parent*
  - *Adult brother or sister*
  - *Other relative*

Study Introduction

Why is this study being done?

- Support future research
- Better understand FTD
- Discover if drug is safe and useful for FTD

How is a drug study designed?

- Placebo-controlled: receive study drug or placebo
- Randomized: assigned by chance
- Double-blind: for research team, patient & families
- Continuation study?

Screening:
Do "we" match the study requirements?

- Establish type and stage of FTD
- Exclude other medical conditions
  - Prevent masking effectiveness of drug
  - Protect from side effects
- Assess ability to complete procedures
- Evaluate study partner readiness
  - Monitor drug intake and side effects
  - Keep study appointments

Description of Procedures
Is the study right for you?

- Cognitive testing
  - Anxiety, boredom, fatigue, inability to sit still
- Brain scans
  - Noise, enclosed space
- Blood tests
  - Concern about needles
- Transportation issues
  - Traffic, comfort with automobile trips
- Time commitment

Study Risks or Discomforts

- *From study drug*
  - ✓ Likely, less likely, rare but serious
  - ✓ Reproductive risks; contraception required
- *Randomization:* drug not helpful vs. more side effects
- *Placebo:* worsening of condition
- *Identification of elder abuse*: report to authorities
- *Psychological:* feelings of sadness about disease
- *Confidentiality:* identifiable personal information

Are there benefits if you participate?

- Possible benefits to study participants
  - Improvement in FTD symptoms
  - But symptoms could get worse
- Possible benefits to others or society
  - Help researchers learn more about FTD
  - Help future FTD patients

What are your choices if you decide not to participate in the drug study?

- Receive no experimental treatment now
- Receive standard treatment for FTD
  - Currently no available medicines to slow disease
  - Medicines and strategies to control behavior
- Take part in another study when available

So, is the study right for "us"? Educate and Empower

- Consider *your* situation and challenges
  - Respect wishes of patient and family member
  - Consider risk, effort, emotional response
- Balance with potential rewards
  - Improve symptoms
  - Help others
  - Relationship with FTD research team
- There are multiple ways to further research!
  - We are ALL working together
  - Support AFTD effort to emphasize our numbers to pharmaceutical companies