## SAFETY IN HUNTINGTON'S DISEASE CLINICAL TRIALS Huntington Society of America Meeting, June 5, 2009 Phoenix, Arizona JOHN N. CAVINESS, M.D.

## **Key Points:**

- NEW TREATMENTS FOR HD MUST BE PROVED IN CLINICAL TRIALS TO BE <u>SAFE</u>
- BE ACTIVE, NOT PASSIVE, WHEN PARTICIPATING IN CLINICAL TRIALS
- EDUCATION AND COMMUNICATION ARE THE BEST TOOLS FOR SAFETY
- KNOW WHAT EFFECTS OF THE STUDY DRUG TO LOOK FOR
- NOTIFY STUDY COORDINATOR WITH <u>ANY POSSIBLE</u> <u>SIGNIFICANT MEDICAL EFFECT OF THE STUDY</u> <u>DRUG ON YOU, MILD OR SEVERE!!</u>
- There are multiple groups that provide safety oversight in a clinical treatment trial
  - -Investigators, Study Sponsor/Funding group
  - -Institutional Review Board, Data Safety Monitoring Board