Clinical Research in the Department of Neurology

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Why should we do clinical research?

- To investigate the Cause, Diagnosis and Cure of Neurological Disease.
- To use your expertise to inform appropriate study design and conduct.
- Provide an environment for clinical research that minimizes conflict of interest and maximizes patient safety.
- Because we are one of the most important advocates for our patients in the modern development of new pharmaceuticals and diagnostics.
- Because if we don’t, our “practice” of medicine will not lead to improved care for our patients.
Types of Clinical Research:

- Discovery Research

- Applied Research:
  - Pathobiology of Neurological Disease
  - Natural History of Neurological Disease
  - Diagnostic Technology
    - Biological
    - Imaging
    - Other
  - New Therapeutic Interventions
  - Clinical Study Outcomes Development and Validation
  - Long term outcomes studies
  - Comparative Effectiveness studies
  - Cost Effectiveness studies
  - Ethics, study design, analysis of clinical trials research
Overview of Current Clinical Studies in Neurology (open, about to open):

- Epilepsy 12
- Cerebrovascular 02
- Neuroimmunology 34
- Movement Disorders 35
- Neuromuscular 03
- Neuro-Opthalmology 11

Total = 97

Total Gross Grants = $19,878,455.00
Resources for Training for Clinical Research:

- **Topics:**
  - Regulatory Compliance, Subject Protection and Informed Consent, Good Clinical Practice, Study Design, Obtaining Funding for Clinical Research

- **Resources:**
  - **CCTSI KL2 (K12) Program**
  - CCTSI Courses
  - NIH-Clinical Research Training Program (CRTP), Introduction to the Principles and Practice of Clinical Research (IPPCR)
  - Web Resources:
    - [Introduction to the Principles and Practice of Clinical Research and Ethical and Regulatory Aspects of Human Subjects Research](http://www.nihtraining.com/cc/crt/indexvideo.html)
    - ANA-Translational and Clinical Research Course for Clinician-Scientists
Funding Sources for Clinical Research:

- NIH-21 Divisions (NINDS, NCI, NEI, NIA)
  - RO3- limited funding for a short period of time to support pilot or feasibility studies, collection of preliminary data, secondary analysis of existing data, small, self-contained research projects, development of new research technology, etc.
  - R34-Designed to permit early peer review of the rationale for the proposed clinical trial and support development of essential elements of a clinical trial
  - R41/R42-Intended to stimulate scientific and technological innovation through cooperative research/research and development (R/R&D) carried out between small business concerns (SBCs) and research institutions (RIs)
Funding Sources for Clinical Research 2:

- **NIH:**
  - UO1-Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies. Used when substantial programmatic involvement is anticipated between the awarding Institute and Center.

- FDA: Orphan Products Grant Program

- DOD: Congressionally Directed Medical Research Programs (CDMRP)

- Foundations

- **University of Colorado:**
  - School of Medicine Pilot Grant Program
  - CCTSI Pilot Grants

- **Pharma:** $50K vs <$250K vs $Million dollar plus
NeuroNEXT:

- 25 Centers of excellence with centralized contracting and centralized IRB.
- Structured to conduct Phase II studies with emphasis on inclusion of biomarker evaluation.
- To propose a study:
  - Complete a 2 to 4 page concept sheet.
  - This will be reviewed by:
    - NINDS Project Manager, if acceptable then
    - NeuroNEXT Steering Committee, if approved then
    - Establish Study Design Committee that you will sit on as PI
      - Which will design the study and write the grant proposal
    - Submitted to appropriate study section at NINDS
    - If funded then managed by CCC and DCC
Databases Available for Clinical Research:

- StudyManager
- REDCAP
Neurology Clinical Study’s Staff (NCSS):

- **Department Business Manager:** Kathy Illian
- **Clinical Research Grants Manager:** Open position
- **Clinical Research Manager:** Heike Newman
  - Phone 724-2211
- **IRB/Regulatory Team:** Nicole Gendelman, Dana Sarver and Karen Gronau
- **Finance and Budget Management Team:** Polly Serrano, Beverly Roush, Jennifer Locker
- **PRAs:** Haley Steinert, James Yarovoy, Mimi Burch, Chris Crumbley, Cory Griffiths, Hala Mazin, Laura Watt, Nina Wells, Nicole Gendelman, Brooke Valdez, Etta Abaca, Erika Shelton, Teresa Derian, Wendy Legg, Christy Williamson, Barbie Halliday, Jo Shattuck
What the NCSS can do to help you take an offered study from offer to ready to enroll:

1. Create and negotiate study budget
2. Create/Complete all required startup documents
3. Use standardized processes to move study and documents through IRB/HRRC/OGC
4. Ensure proper processes are followed for IRB/HRRC/OGC steps
5. Alert PRA when action is needed (e.g. PI meeting at CTO)
6. Create study in StudyManager to track visits, patients and finances
What the NCSS can do to help you take an offered study from offer to ready to enroll (cont.):

8. Upload current study documents into StudyManager to ensure regulatory compliance

9. Ensure timely invoicing and proper payments of incurred costs and startup fees

10. Ensure PRAs are properly credentialed and trained for required procedures

11. Assess options for PRA-backup plan

12. Assist PRA with creation of source document

13. Serve as liaison between all involved parties
What the NCSS can do to help you take an idea for a study from concept to final funding proposal:

– Estimate staffing needs, personnel efforts and other resource needs

– Calculate startup, maintenance, and close out costs (personnel and fees)

– Identify entities involved in the project and obtain current pricing information

– Serve as liaison between all involved parties

– Identify options to save cost (e.g. CTRC)

– Identify potential logistical issues (e.g. specimen processing, special equipment, etc.)

– Assist with creation and assembly of proposal

– Assistance with grant writing???