



NETT=WORKINGS

NEUROLOGICAL EMERGENCIES TREATMENT TRIALS (NETT) NETWORK

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NETT STEERING COMMITTEE CONFERENCE CALL INFORMATION

The next NETT Steering Committee conference call will be held on August 22nd at 12:00 p.m. EDT. Please send items for the agenda to Lori Avers at: lavers@umich.edu by August 17, 2007.

Dial-in number: (888) 242-1836
 Access code: 4905767

MARK YOUR CALENDARS
NETT INVESTIGATOR GET-TOGETHER
FOR THOSE AT THE ACEP MEETING
OCTOBER 9, 2007
SEATTLE, WASHINGTON
12:00 P.M. PDT
LOCATION AND DETAILS TO FOLLOW

NETT CLINICAL TRIAL PROPOSAL PROCESS



Do you have an idea for a grant proposal that you would like to see as a trial conducted in the NETT? We are here to help.

Per the NETT SOP grant submissions, a summary of the submission must be provided to the NETT Executive Committee six (6) months prior to submission date. For more information please review the Process for Solicitation and Review of Clinical Trials and Grant Writing Timeline SOPs on the NETT website at: http://nett.umich.edu/nett/operating_procedures

Visit the NETT web site at
nett.umich.edu

Pleased to meet you...

DANIEL H. LOWENSTEIN, M.D.

Co-Investigator
NETT Clinical Coordinating Center



Dr. Daniel H. Lowenstein is Professor and Vice Chairman in the Department of Neurology at the University of California, San Francisco (UCSF), Director of the UCSF Epilepsy Center, and Director of Physician-Scientist and Education Training Programs for the UCSF School of Medicine. He was also a recent president of the American Epilepsy Society.

Dr. Lowenstein received his B.A. degree in Mathematics from the University of Colorado in 1973, an M.S. degree in Man-Environment Relations from The Pennsylvania State University in 1978, and an M.D. degree from Harvard Medical School in 1983. Following an internship in Pediatrics at UCSF in 1983-84, he completed his residency in Neurology at UCSF from 1984-87, serving as Chief Resident in the final year. He then did a two-year fellowship in Stanley Prusiner's Laboratory, investigating the sequence homology of the PrP gene in various rodent species. He went on to become a faculty member in the Department of Neurology at UCSF, established the UCSF Epilepsy Research Laboratory, and was the Robert B. and Ellinor Aird Professor of Neurology from 1998-2000. He then joined Harvard Medical School (HMS) as the Dean for Medical Education for two and a half years, overseeing a re-organization of curricular governance, the creation of a new educational technology program, the establishment of the HMS Academy (a novel structure for the support of the school's education mission), and the initial planning for a major revision of the curriculum. In 2003, for family reasons, he moved back to UCSF in his current position.

Dr. Lowenstein is a clinician-scientist who studies both basic science and clinical aspects of epilepsy. The main efforts of his research group are focused on the various forms of cellular reorganization that are observed in humans with temporal lobe epilepsy, and the parallels between reorganization in the adult nervous system and normal developmental processes. Important findings by his team have included the discovery that seizure activity in an adult model of temporal lobe epilepsy causes a marked increase in the birth of hippocampal neurons, and the recognition that numerous molecules responsible for normal development are also expressed in this same brain region in the adult. These studies bear not only on the neurobiology of epilepsy, but also on the broader issue of neurodevelopment and the capacity for regeneration in the adult nervous system after injury.

Dr. Lowenstein's main clinical research to date has been on the management and treatment of patients with status epilepticus, i.e., unusually prolonged seizures. He has been the Principal Investigator of a prospective, multi-centered, NIH-sponsored clinical trial looking at the potential benefits of active treatment of patients in status epilepticus in the pre-hospital setting.

This five-year study, completed in 1999, helped define the optimal therapy for these patients nationally.

Most recently, Dr. Lowenstein has turned his focus on approaches designed to advance our understanding of the complex genetics that are thought to underlie a substantial portion of the idiopathic epilepsies, and he is a leader of a national effort (The Epilepsy Phenome/Genome Project) designed to make new discoveries in this area.

Dr. Lowenstein's efforts in epilepsy research were recognized by the American Epilepsy Society's 2001 Basic Research Award, an honor given each year to the foremost basic science investigator whose research "contributes importantly to understanding and conquering epilepsy." Dr. Lowenstein has also been actively involved in defining scientific policy at the national level, and recently completed a four year term as a member of the Advisory Council of the National Institute of Neurological Disorders and Stroke.

In addition to his research interests, Dr. Lowenstein is an avid and highly-regarded teacher, and he has had an active role at UCSF concerning issues related to cultural diversity and civil rights. In recognition of his leadership at UCSF in these areas, as well as his long-standing advocacy for students, staff and faculty of all backgrounds, he received the 1998 Black Student Health Association's Faculty Award, the 1998 UCSF Dr. Martin Luther King, Jr. Award, and the 2006 Holly Smith Award for Exceptional Service to the UCSF School of Medicine.

Dr. Lowenstein has received every major award related to medical student education granted both locally at UCSF and nationally. He received multiple awards from the first and second year classes at UCSF, including those for "A Major Contribution to Teaching," "Outstanding Lecture," "Outstanding Lecture Series," and "An Outstanding Role Model." Other major awards include the 1992 UCSF Academic Senate Distinction in Teaching Award, the 1993 and 1998 UCSF Kaiser Award for Excellence in Teaching, the UCSF Class of 1995 John V. Carbone Award for Excellence in Teaching, and Faculty Teaching Awards in 1994 and 1996. Dr. Lowenstein has given the keynote address for graduating students at commencement ceremonies at UCSF in 1994, 1996, 1997 and 2000. In 1996, the UCSF students awarded him the American Medical Student Association (AMSA) Golden Apple Award for Excellence in Teaching. He went on to receive the AMSA 1997 National Golden Apple for Teaching Excellence Award, which is given to one medical school teacher in the country each year. In addition, the American Neurological Association (ANA) named him the first recipient of the ANA Distinguished Teacher Award in 1997, and in 1998 he was granted the Alpha Omega Alpha Robert J. Glaser Distinguished Teacher Award by the American Association of Medical Colleges.

ALIAS

REGULATORY
ROUND UP

COLLECTION AND SUBMISSION OF ALIAS DOCUMENTS

Are you on the starting line for the ALIAS trial? Don't let your engine stall from not having the required regulatory documents

in place. Before you begin, make sure that you have uploaded your 1572s, Human Subjects Protection Certificates, CVs, and relevant IRB approvals to the NETT C-tools site in your site-specific "For CCC Review" folder. The CCC will then verify and catalogue your documents. Once all are in you will receive the green flag from the CCC site management staff. Please email your study staff contact information to NETT-contact@umich.edu to expedite the process of collecting these documents.

Please remember that the WebDCU system cannot accept documents with a file size greater than 1MB.

To assist us with identifying the documents provided, please use the following naming conventions: Site Name/Document Name/Person or Spoke Name/Document Expiration Date if known.

For example: `WSU_CLIA_Harper_exp_10JUN2009`

Each document must be uploaded to its own place in the database, so merged documents (e.g., a single PDF file that includes two CVs) cannot be accepted.

Document Updates

We will update you on the progress of regulatory document collection on a weekly basis via email and in later editions of *NETT-Workings*.

Keep those documents coming!



DON'T SUBMIT THAT INFORMED CONSENT DOCUMENT

Remember to have Dr. Tamariz at the University of Miami check your informed consent document before submitting it to your IRB. If you have not already done so, please send your ICD to Dr. Tamariz at dtamariz@med.miami.edu.

Should your IRB have comments or questions, please forward them to Dr. Tamariz via email or contact by phone at **(305) 968-0766**. He will be able to provide some ready answers or suggestions based on his experience with this project. This should streamline the review process for you and add consistency to the project.

Thank you to everyone for all of your efforts to get the ALIAS project under way.

TECH TALK REDUCING .PDF FILE SIZE



Is the size of your regulatory document .pdf file greater than 1 MB? If so, you'll need the program Adobe Acrobat Professional, which will let you create, streamline, and otherwise modify the many PDFs that form the life-blood of this all-electronic research regulatory system. You can use the "optimize scanned PDF" feature to turn huge scanned PDFs into much smaller files.

Check out the "extract pages" feature to separate multiple documents scanned into a single PDF. Say you have two CVs in one PDF. Use this feature to split the CVs into two separate PDF files before uploading them to the network site. If you need assistance or have other questions about regulatory document file size please contact the NETT CCC at: NETT-contact@umich.edu.

RAMPART

The NETT's first Exception from Informed Consent (EFIC) trial is soon to begin. The first few months are anticipated to be full of activity. It will be essential for RAMPART sites to prepare for a flurry of activity and a very busy Fall 2007.

Early milestones include:

- * Determining RAMPART study sites
- * Developing Letters of Introduction and survey instruments to collect information from participating IRBs
- * Assessing Study Site Community characteristics
- * Identifying and hiring EMS coordinator
- * Cultivating and implementing Public Disclosure (PD) and Community Consultation (CC) plans
- * Identifying relevant EMS agencies, agency characteristics, and beginning EMS EFIC research education and training.

In preparation for the first quarter, we at the NETT CCC are developing surveys and training modules to get the first wave moving. Look forward to hearing from Ms. Deneil Kolk, NETT Human Subjects Protection Coordinator, as RAMPART gears up for a busy 2008.

NETT IN THE NEWS

The *Annals of Neurology* spotlighted the NETT in the December 2006 issue of the journal. The journal's *NerveCenter* features events, people, and issue in academic neurology. The article can be found on our NETT website:

http://www.nett.umich.edu/nett/links_and_downloads



Are you and the NETT in the news in your community? Please let us know and we will feature the article in the next issue of *NETT-Workings*.

ADMIN MINUTE

The Over-Arching Agreement

The over-arching agreement is a generic subcontract that allows flexibility when adding trials within a network such as the NETT. Once the agreement is in place, trials can be added with short amendments that include budget information, which may be quicker and less burdensome than routing a brand new contract. The agreement also allows the site distributing protocol funds to use one subcontract which can decrease the F&A burden on protocol funds incurred when issuing individual contracts.

The generic nature of the agreement can raise a few eyebrows. The biggest challenge can be asking a Sponsored Projects Office to accept and sign a document without a budget. On the positive side, institutions are seeing this type of agreement more, and are actually requesting this format.

An amendment for ALIAS will be issued to all the sites as soon as the agreements are in place. The central pharmacy for the trial will ship study drug to your site after the Miami/UM contract is executed even if you have not executed the contract at your site; therefore you may be able to begin enrolling if your institution allows you to begin and you have all the required trial elements satisfied with the NETT CCC.



NINDS Funding Opportunities:
http://www.ninds.nih.gov/funding/funding_announcements/funding_opps.htm

**Have a question?
Email us at:
NETT-contact@umich.edu**

Do you know someone you would like to contact but don't have his or her contact information? Visit the roster on the NETT website at: http://www.nett.umich.edu/nett/about_us for specific contact information.