

ALS-RG Monthly Conference Call Minutes- Wednesday July 5, 2006

Attendees:

- U of Kentucky: Dr. Edward Kasarskis
- Mayo/Rochester: Dr. Eric Sorenson, Sue Paxton
- U of Vermont: Dr. Rup Tandan, Marilee Jones,
- Mass General: Dr. Merit Cudkowidz , Francesca Belouin
- CA Pacific: Chow Saepha
- Columbia: Dr. Hiroshi Mitsumoto, Dr. Paul H. Gordon, Dr. Petra Kaufmann,
Kate Bednarz, Alex Barsdorf & Mimi Leahey
- Coriell: Cynthia Royds
- Database: Dr. Alex Sherman
- MDA: Dr. Valerie Cwik
- NIH: Dr. Katrina Gwinn-Hardy; Dr. Robin Conwitt

1. Introduction - Dr. Hiroshi Mitsumoto

2. Status report from each lead site:

Chow Saepha: California Pacific Medical Center

- 13 total sites: 7 sites have IRB approval; 2 have submitted for IRB approval; 3 are not submitting
- 4 are drawing blood
- Enrolled 100 patients and 86 controls

Dr. Eric Sorenson and Sue Paxton: Mayo Medical Center Rochester

- 4 sites not up and running
- Enrolled 220 patients, 183 controls from all sites

Dr. Edward Kasarskis: University of Kentucky

- 13 total sites: 10 IRB approval, 7 drawing blood
- 219 total samples submitted (probably a 50-50 breakdown between controls and patients)

Dr. Merit Cudkowidz and Francesca Belouin: Massachusetts General

- 3 of 9 sites currently enrolling
- 32 total samples: 16 ALS patients; 13 controls; 2 other neurology

Dr. Rup Tandan and Marilee Jones: University of Vermont

- 8 sites: 5 with IRB approval; 1 waiting to resubmit to IRB; 1 preparing to submit; 1 not submitting
- Only Vermont is enrolling: Submitted 17 samples (13 patients/4 controls)
- One subsite's IRB (Dartmouth) wanted a \$500 fee which Vermont paid

Dr. Paul H. Gordon and Kate Bednarz: Columbia University Medical Center

- 10 total sites: 8 have IRB approval and 4 executed subcontracts
- 8 sites are drawing blood
- Enrolled 78 patients and 64 controls
- 22% completed
- Subsites agreed on competitive enrollment

Dr. Petra Kaufmann: Columbia University Medical Center

- 9 total sites, 8 have IRB approval, 6 sites drawing blood, 4 executed subcontracts
- 188 patients and 277 controls
- 70% completed
- Held 26 samples until August 1 for sites that are not enrolling yet.

3. Dr. Gwinn Hardy: NINDS

- Congratulated all lead sites for sending DNA to Coriell
- Haven't reached funding limit yet
- Hoped that lead sites could work out distribution of funds and samples and encouraged sites that are having success to continue enrolling

4. Redistribution of samples:

- Dr. Kasarskis stated that by August several teams will have met 660 quota.
- Need to work out a final agreement to redistribute samples
- Dr. Gwinn-Hardy stated that if sites exceed the 660, it would not be possible to reimburse them under the current supplement program. It is acceptable for the sites redistribute among themselves.
- Dr. Mitsumoto suggested another option. That would be to consider the use of subcontracts among lead sites to redistribute funds and samples. For example, if Mayo reaches 660, a new subcontract between Columbia and Mayo (or between Univ Vermont and Mayo) would be executed, and Mayo would keep enrolling and be reimbursed by Columbia for samples collected. The slower lead sites would subcontract out to Mayo, thereby directing unused funds towards the faster enrolling center. If Mayo banked a total of 760 DNA samples, Columbia would then pay the Mayo site for the additional 100 DNA samples. If Columbia (Mino Center) is still slow at 300, they can pay Mayo for the 100 extra samples, and the Mayo Center would be reimbursed for their costs. In this way, faster enrolling centers can continue to get more DNA deposited. This is just a hypothetical scenario.
- Dr. Kasarskis urged lead sites to get agreement on this process because he feels some sites are close to reaching 660 samples.

5. Longitudinal data:

- Dr. Alex Sherman wanted all sites to be aware that they could submit longitudinal data. He felt lead sites should communicate this to subsites to increase phenotypic data.
- Columbia has entered follow-up data for 25 patients
- Cindy Royds and Kate Bednarz will work on instructions to submit longitudinal data

6. Collaboration Process Documented:

- Dr. Gwinn-Hardy suggested writing a paper that would detail the methods of DNA Repository and that this could be a model for other neurodegenerative disorders and clinical trials. This is an excellent idea.
- Dr. Mitsumoto mentioned that Dr. Kaufmann's paper summarizing the planning this DNA repository (from the Oct 2005 Chicago meeting) is supposed to be in print in the ALS journal. She will find out where the paper stands.

7. Future plans:

- There will be a database meeting in Montreal, on September 11 and 12.
- The next conference Call will be on Wednesday, September 6th at the same time, noon EST.

Prepared by KB and ML