

ALS-RG Monthly Conference Call Minutes-Monday, May 1st

Attendees:

- U of Kentucky: Marsha L. Sams
- Mayo/Rochester: Dr. Eric Sorenson, Sue Paxton
- U of Vermont: Dr. Rup Tandan
- Mass General: Dr. Merit Cudkowicz & Francesca Belouin
- CA Pacific: Terence Santos & Chow Saepha
- Columbia: Dr. Hiroshi Mitsumoto, Dr. Paul H. Gordon, Kate Bednarz & Mimi Leahey
- NINDS: Dr. Katrina Gwinn-Hardy
- Coriell: Dr. Judy Keen
- Database: Dr. Alex Sherman
- MDA:
- ALSA
- Genetics

1. Introduction-Dr. Hiroshi Mitsumoto
2. Dr. Judy Keen reported that enrollment was been tremendous. They have had 304 samples since January for a total for 467 samples.

3. Status report from each lead site:

Francesca Belouin/Massachusetts General

- NGA is ready
- 13 total sites, 4 dropped out
- 4 sites have IRB approval, 2 sites uncertain
- submitting samples very soon
- no executed subcontracts yet

Terence Santos/California Pacific Medical Center

- 13 total sites
- 6 sites have IRB approval
- Enrolled 25 patients and 1 control
- 2 have executed subcontracts

Dr. Eric Sorenson/Mayo Medical Center Rochester

- 12 total sites
- 8 sites have IRB approval
- Enrolled 120 (140?)patients, 111 controls from all sites

Dr. Rup Tandan: University of Vermont

- 9 total sites
- 3 sites have IRB approval
- Recently started enrolling

Marsha L. Sams/University of Kentucky

- 13 total sites, 6 drawing blood
- Recent site visit from Cindy Royds from Coriell went well.

Kate Bednarz/Columbia University Medical Center (Kaufmann)

- NGA ready
- 9 total sites
- 4 have IRB approval
- Enrolled 66 patients and 65 controls
- 1 executed subcontract

Dr. Paul H. Gordon/Columbia University Medical Center

- NGA ready
- 11 total sites
- 7 have IRB approval, 4 sites in limbo since CUMC won't guarantee money

- Enrolled 29 patients and 31 controls
 - 2 executed subcontracts
4. Difficulty in getting sites to sign subcontracts without supplying funding.
 - NGA will only award for amount of blood previously drawn, therefore will not help the sites that are in limbo join the group because they are still not secured a certain amount of money.
 - Dr. Gwinn-Hardy stated that giving sites start up money might have been a better approach to ensure enrollment.
 - Dr. Tandan reported that some sites have asked who will pay for IRB fees. (Because of NIH grants, this is not a concern for Columbia and U. of Kentucky—this may be site specific)
 - Dr. Mitsumoto suggested that the PI's personally speak with the grants office and request that the IRB fee be waived.
 5. NIH NGA-Jonathan Horsford has taken over program and is working with grants management to allocate payment.
 - The NGAs will be initiated 3 times per year but not done at council meetings since it is too overwhelming.
 6. Difficulty with controls:
 - Recommend use of flyers
 - Recruiting controls at support groups and events such as Ride for Life.
 - PI's should share strategy with subsites.
 - \$15.00 compensation (coming from \$150 sample reimbursement).
 7. NIH site regulation requirements
 - Dr. Mitsumoto clarified: sites needs per sample are:
 - i. informed consent
 - ii. CDE form
 - iii. data collection DNA (sent directly to Coriell)
 - What is needed for supervision of subsites?
 - i. Acting in good faith
 - ii. Creation of standard operating procedure.
 1. Draft created by Dr. Paul H. Gordon & Kate Bednarz of Columbia and sent to lead sites for approval.
 8. Validity of FVC and ALSFRS:
 - Any data point can be included despite date of blood draw since it won't have impact on genetic code.
 - There's no spot on the CDE for date of FVC and the ALSFRS. However, this can be recorded by individual sites.
 - It was agreed that there should be standards across lead sites. In addition, if either blood or CDE is submitted alone, there will be a 30 day window to submit remaining data.
 9. Dr. Mitsumoto reported that he has not received final approval from MDA on the grant for salary support.
 - Will notify the sites when this occurs then set up subcontracts with Columbia.
 - Suggested hiring needed staff prior to receiving funding and paying the deficit when the grant money arrives.

(MDA is waiting by a signature by one person---this is a hang-up)

10. Dr. Sherman explained how we are synchronizing data collection with Coriell in order to process payments and create status reports.
11. Longitudinal data collection:
 - Need to specify exactly what were investigating.
 - Possible meeting in Montreal to discuss proposed for June by Angela Genge.
12. Dr. Gwinn-Hardy commented that the DNA banking effort would result in an infrastructure where the whole was greater than the sum of its parts.
 - Suggested applying for additional funds from one of the mother grants to pay for the administrative work involved.
 - Supports the longitudinal reach of this effort and thought it could function as a test case for studies of other diseases.
 - Proposed a meeting with Drs. Mitsumoto and Conwit, and herself to discuss funding. Dr. Cudkowicz suggested to add Dr. Sherman for discussion. Dr. Gwinn-Hardy is leading this effort.

Date for the next meeting TBD. June 5th is a conflict for Columbia participants. We may need to change the date.

Prepared by KB and ML