

ALSRG Meeting
Dublin, December 7, 2005.
(Meeting was supported by ALSA)

The investigators thanked NINDS, ALSA and MDA for their support of the meeting and the ALSRG DNA Banking initiative. Summarizing the scope of this initiative, its goal is to bank DNA from ALS patients and controls. A supplementary award of up to \$100,000 per currently NIH-funded study (up to \$ 600,000 for all 6 studies) can be given by NINDS. This amount will allow for the collection of 2000 control and 2000 ALS patient samples. Each sample will be reimbursed at \$ 150 per sample. The task for the sites are kept simple and consist in identifying patients and controls, completing a brief data collection form and performing venipuncture in order to obtain a blood sample to be send to the Coriell Institute in New Jersey along with the data elements.

The NINDS reimburses the six currently NIH funded US ALS principal investigators who forward the per sample fee in total to the site that has submitted a sample to Coriell. Reimbursement per principal investigator and their sites will occur once 25 control and patient samples have been submitted.

The IRB protocol template has been forwarded to the sites and the feedback has been positive so far. No information that would allow identifying a participant will go to Coriell. However, the ALSRG is considering a parallel effort of collecting longitudinal data on patients who participated in the initial DNA Banking initiative. In that case the identifying link between additional information collected and the sample will remain at the site locally and not be transmitted to Coriell or others.

Some sites can likely begin as soon as IRB approval is in place, other institutions will require that the sub-contractual agreements are in place. The total reimbursement of \$ 600,000 will not be available indefinitely, but only until funds have been used up at the NINDS. It is therefore in the group's interest to collect the samples in a timely fashion. Dr. Gwinn-Hardy congratulated the group to their coordinated and response to the supplementary award. She emphasized that the \$ 600,000 are not earmarked for ALS and therefore underscores the need to move forward as soon as possible in order to capture this amount for ALS. She also pointed out that individual investigators can in addition to this effort individually submit samples to Coriell without being reimbursed. The samples individually submitted outside of the supplement award fall under the contractual agreements between NINDS and Coriell in terms of data and specimen processing, but will not interfere with the \$ 600,000 obtainable under the supplemental award.

The NINDS gives \$100,000 per principal investigator in direct cost only. There is no indirect cost given to the lead investigative sites. The lead sites pass on the total amount of \$ 150 available per sample fully to the consortium sites. Should indirect cost be required by the consortium site's institution, this would have to come out of the total of \$150 available.

Dr. Cwik (MDA) expressed the MDA's support of the ALSRG in this important initiative. Dr. Brujin (ALSA) had previously stated her organization's interest and support for this project.

The ALS DNA Banking initiative includes a web-based system (ALSBank.org). This system has two purposes: 1) It will serve as a platform for the collection of additional data and biomaterial, and 2) it will facilitate administrative tasks and data workflow for the current ALS DNA Banking initiative. Summarizing the data flow, the consortium sites collect and submit data to Coriell. Coriell will verify, initiate queries and enter data into their database. Data entered into the Coriell database will be available to the consortium site users. Data clarifications from the consortium sites can be either submitted on paper or via the Coriell website. The ALS DNA bank (ALSRG) managers will have access to the ALSRG submitted working data for administrative and tracking purposes only. This will allow them to notify the lead site when a sample has been submitted (including subject ID, tracking number and shipment date). The "critical" number of submissions will trigger payment. Payment reports will be generated with site IDs and payment due dates. This will be an advantage over the Coriell database itself because in that database only information by Coriell ID number is available, not by site. Sites can enter additional information, for example the information included in the "long form" into the ALS DNA Bank. The ALSDNA bank will also have a portal where all templates necessary for consortia sites will be ready for download.

The group will have to decide early on about access to the system and to additional "long form" data collected. Conflicts of interests need to be anticipated and dealt with appropriately. The access of lead investigators to data refers to the data collection phase only and serves tracking and administrative purposes. Once data and specimen have been collected, all will have equal access, but will have to pay for the information and specimen. The current initiative is not hypothesis driven research, but rather the creation of a public resource. Investigators around the world, not restricted to this group, will have access to data and specimen. All the information that will be passed on to investigators requesting samples from Coriell will be entirely de-identified. Investigators requesting samples will therefore likely not need full IRB approval. As the ALSRG generates hypotheses that require the collection of additional data guidelines need to be developed as to who holds the linking key between samples and newly collected data and how access to this key can be controlled in an ethical manner acceptable to the regulatory agencies.

The issue of duplicate collection of DNA and data from the same individual was raised. There are two steps to avoiding duplication: Firstly, investigators collecting specimen should ask patients and controls specifically if they have submitted specimen to any other DNA bank. Secondly, Coriell will analyze all samples using a set of six micro-satellite markers that would be expected to identify duplicate submissions.

The current ALS DNA Banking effort is the first step. We need to now build the next layer of database that would probably include some information in addition to the minimum dataset such as information on disease progression, site of onset etc. An ALS Databank task force has been constituted and includes participants suggested by the chairman and additional ALSRG members who expressed their interest to serve on this taskforce. The taskforce will meet in the Connaught Room (Burlington Hotel) on December 9 at 7pm to discuss possible ways to move forward.

In addition to the scientific mission, the ALSRG has other missions including an educational mission. A mentoring program had been discussed that might include mentoring within the ALSRG as well as mentoring of additional researchers outside of the group. Dr. Rudnicki had sent out a letter asking for those willing to mentor or those seeking a mentor in ALS. She encouraged ALSRG members to respond. To obtain more responses, it might be important to publicize the goal of the program and to provide a more formal written description about what kind of opportunity this is for the candidate. Funding for the educational exchanges would enhance this educational program, but may be hard to come by.

Dr. Mitsumoto has explored for the group the possibility of becoming a non for-profit organization. This will require a change of bylaws.

The draft of an ALSRG publication policy was distributed to the group. One concern is the requirement to circulate manuscripts to the ALSRG membership. One might want to specify the timeframe for commentary, for example to a maximum of 1-2 months. Also, the modifications should be at the discretion of the lead author who ultimately decides if and how the manuscript is modified. Additional feedback to the publication policy is invited via email. Once the publication procedures have been modified in response to the comments, then the publication guidelines could be ratified by the ALSRG along with the revised bylaws.

The website is up for viewing at www.ALSRG.org. The website has been updated according to the suggestions made at the Chicago Meeting. ALSRG members are encouraged to link their own websites to the ALSRG website to increase awareness and visits to the website.