Biostatistics Core Conference Call
Minutes 18 January 2005

On call: Laurel Beckett, Danielle Harvey, ADNI team, John Kornak, Mike Weiner.

Danielle raised the question of whether clinical data is being collected for preparatory phase; Charlie DeCarli was not aware of this need. Mike will e-mail Cliff and Ron and make sure that the sites know.

Ron reports that they e-mailed the site collection log-in and asked people to take a look, and so far only Leon has looked. We need Cliff to approve the prototype. It's currently being hosted on biostat server until a new server appears, but it can collect data already. Sarah has also e-mailed Cliff and Mike and can walk people through the site. Mike says he thinks it was not clear that this is in fact the prep phase version rather than just for execution phase. Mike will forward the email to John and Danielle so that they can check it out too.

Danielle and Laurel to post the analytic plan, which will also include what kind of summaries and

John reports that Paul has been very helpful, Gene has been quiet. Paul suggested a template frame that everyone could warp to, but no response. Some simple summaries have been proposed but being more specific is tricky until we see the results in terms of what significant results show up. Main thing to play with is Aim 4b.

Study design was sent forward for Atlanta meeting but not yet posted on web site.

Mike's main goal is to have queries and data analysis set up. What about establishing appropriate ranges for data? For example, ranges for hippocampal volume would be from 1 cc to 5 cc. We will ask Cliff to send a request to each person for ranges for each of global summaries. Ron says this needs to be part of the dictionaries for each variable. Is it possible that Cliff and the analysis sites will have different views and ranges, and, if so, which ones should be applied? Sarah says they are in touch with several sites and will elicit the information, ideally right when they go through the walk-through of site. Will run it by Cliff to get his feedback.

Mike's second goal is preparing for execution phase. What needs to be completely set up by 15 May? What will we track and what will come out? Mike guesses that Ron and his group will create a series of forms resembling those for previous studies that will track and receive all of the clinical data. Laurel, Danielle and John need to be familiar with those forms and what data they will provide. In addition, we will have MRI, PET and biomarkers. What additions will go in for these?

Mike's third point is that we will have the LONI system receiving images, and the ADNI clinical data base in San Diego, and at the moment there is no linkage between them and no plan for the nature of the linkage. Ron and Art probably need to discuss. How do you

get the images that correspond to a specific set of people? Do you have to do it as two separate operations? Ron reports that Mike Biglan has been working with Karen at LONI on this subject; Mike is charged with putting a plan together with Karen to work out the joint querying process. We should get an update shortly. More immediately, there is the question of payments for the images; we need a quality control flag to let group know what to pay for, and that is being worked out. Mike reports that LONI IRB is solved so they should be able to receive images now.

There is a steering committee meeting in Atlanta; Mike Ron will add a few power point slides to augment mine.

Action items:
Mike: Will e-mail Cliff to view and approve data collection site, also send to preparatory phase people to let them know.

Ron will augment presentation with a few power points of the site.

Laurel, Danielle and John will send summaries of proposed analyses (John focused just on the simple summaries from aim 4b).