

**Minutes for the NAGKC Board Meeting**  
**Sunday, May 11, 2014, 4:00pm – 5:30pm**  
**Liberty Room 3, Sheraton New York Times Square**

**NAGKC Members Present:**

L. Dade Lunsford  
Lisa Baxendell (clinical research coordinator)  
Jason Sheehan  
Ajay Niranjana  
John Lee  
Carlos H. Carbini  
Gene Barnett  
Wade Yang  
Manmeet Ahluwalia  
Veronica Chiang  
Peter Rossi  
Dan Pieper  
Peter Y. Chen  
Igor Barani  
Penny Sneed  
Cheng-Chia Lee  
Michael McDermott  
Douglas Kondziolka  
Johnathan Knisely  
Anthony Kaufmann  
David Mathieu  
Michael Schulder  
Hideyuki Kano

**Absent Member:**

Gail Rosseau (secondary to plane delay)

**Ex Officio Members Present:**

Danny Leksell  
Catherine Gilmore-Lawless  
Jonas Garding

**Meeting Minutes:**

The meeting was called to order by Dr. L. Dade Lunsford. Introductions were made, and a sign in sheet was circulated. The minutes from the past meeting were discussed and approved.

*Membership:*

Members update was noted including the center from Taiwan. This addition makes the NAGKC an international one. Other centers have also recently joined or are in the process of joining the NAGCK. These include Emory Healthcare/St. Joseph's Hospital (2013), William. Beaumont Hospital (2013), North Shore-LIJ Health System (2013), Taipei Veterans General (2014), University Hospitals: Seidman Cancer Center, Penn State Hershey Medical Center, and Washington Hospital.

#### *Clinical Trials:*

A discussion of the recently published or in press trials was held. Also retrospective trials in progress were noted. The process of study design, proposals, data collection, and data sharing was noted. Current retrospective clinical trials include craniopharyngioma, AVM grading, pineal region tumors, cavernous sinus hemangioma, glossopharyngeal neuralgia, hemangiopericytomas, and facial schwannomas. Ms. Baxendall will circulate spreadsheets to the members centers regarding these trials.

Dr. Pieper from the Beaumont group proposed a retrospective study would evaluate the predictive value of tumor volume in patients with brain metastases. Their recent paper in the Journal of Neurosurgery was summarized. This study showed that a total metastatic tumor volume of less than 2 cc was significantly linked to overall survival. They proposed a study that looks a tumor volume as a predictor of survival and to analyze it by tumor type. Dr. Barnett noted that this would not offer class 1 evidence. Mr. Carbini noted that a U.S. study would be of value. Dr. Kondziolka noted that a different study would be to look at leptomeningeal disease as a function of patients treated with GKRS alone. Dr. Ahluwalia noted the need to take into account tumor histology and molecular/receptor subtype in such a brain metastasis study. Dr. Barani mentioned the importance of looking at treatment dose and its relationship to local control, tumor histology, and toxicity. A proposal will be devised and circulated to the group.

Dr. Barani detailed his prospective trial of brain metastases. Approximately 20 patients have been accrued at UCSF thus far. Yale has recently had its site visit. Other site visits are imminent. However, IRB and contract issues have delayed the study. Dr. Barani has requested a no-cost extension. Dr. Kaufman noted that study accrual may be difficult and raised the issue of the value of an observational database for the group. Dr. Lunsford underscored the importance of neurocognitive outcomes and the level 1 evidence that this study would provide for patients, clinicians, and payers.

Dr. Niranjana updated the group on a study for glioblastoma using GKRS and Avastin. It took 2 years to get approval institutionally. Approval has now been received from UPMC. The target accrual is 40 patients. Dr. Niranjana will draft a multicenter protocol to broaden the patient accrual at other member centers. The study protocol is on the flash drive that has been circulated. Dr. Kondziolka noted the importance of involving a biostatistician in the study design. Avastin is covered by Genentech.

The ROSE trial contract is working its way through the administrative process at UVA. The study will hopefully accrue a smaller number of patients. Patients could be accrued through other countries including England and India. Dr. Kondziolka suggested that members could work with their local neurologists to try to treat patients with epilepsy who are not good candidates for other procedures. He notes the solid basic science and pilot study data for this indication that are already in the literature. This may or may not require IRB approval if it were done in the context a single center study.

Dr. Lunsford outlined the concept of an AVM study that looks at studying the effects of embolization in patients treated with radiosurgery. A proposal has been sent to Mr. Jonas Garding at Elekta who is reviewing it for funding consideration. Also, Dr. Niranjana has proposed a study of minocycline to reduce the risk of ARE's for brain metastases. The drug would be given after prior failure of steroids being tapered in the setting of patients with documented ARE's. Dr. Niranjana will send out the proposal to members. Funding from Elekta is still under consideration. The new fiscal year for Elekta has just begun, and funding opportunities for this study

should be promising. Dr. Ahluwalia indicated that there is interest in the use of concurrent minocycline and radiation for glioblastoma patients.

Dr. Ahulwalia described the study of Afatinib for HER2 positive breast CA and EGFR positive lung CA patients. The study is a phase 1 trial for selected metastasis patients, but if safety was demonstrated, hopefully it would lead to a phase 2 trial through the NAGKC. Dr. Barani noted that the hypothesis is control of microscopic disease in the brain and also to help with systemic therapy from the Afatinib. Dr. Ahulwalia agreed and noted that SRS should provide the control of macroscopic disease. Four to six centers would be needed for the phase 1/2 trial.

#### *Administrative Matters:*

Ms. Baxendell indicated that UPMC has renewed its status as the coordinating center for the NAGKC. The flash drive contains the membership contacts list. Please provide Ms. Baxendell with any updates. Also kindly send information about IRB renewal for member sites to Ms. Baxendell.

Dr. Lunsford indicated the bylaws require each member center to contribute at least 10 patients per year to ongoing studies. Dr. Kondziolka noted that this requirement could potentially be lowered. Dr. McDermott noted that IRB approval can sometimes be challenging for data accrual and trial participation.

Dr. Lunsford reviewed the composition of the board. Dr. McDermott noted that Dr. Barani can take his place on the board for the representative for UCSF. A motion was made to approve the substitution of Dr. Barani for Dr. McDermott. The remainder of the board was reappointed for another term. The composition of the board was approved unanimously by the members in attendance. Dr. Kondziolka noted that a few names on the list were reversed. This will be corrected by Ms. Baxendall.

The NAGKC still has its separate website. This remains open, and members are encouraged to visit the website and provide relevant content. A newsletter also is put together by a member of the staff at UPMC.

The NAGKC is a 501-3(C) registered through the state of Pennsylvania. We are functioning as a foundation as opposed to a public charity. The NAGKC maintains D&O insurance.

#### *Financial Summary:*

Dr. Sheehan presented the financial update for the NAGKC. Invoices for annual membership dues have been recently sent. Kindly submit payment in the near future. Please contact Dr. Sheehan if you have not received your invoice. The financial state of the NAGKC is a sound one. The financial report is summarized in an Excel spreadsheet on the flash drive. Contact Dr. Sheehan with any questions.

Dr. Kondziolka noted that the group should consider adding indirect charges particularly to clinical trials.

Dr. Kano receives some support for his biostatistics help to the NAGKC. This is reflected in the group's budget for the current fiscal year. This support may not be able to be given as a grant secondary to institutional regulations at UPMC. Other options for provided this support are being explored.

#### *Future Scientific Conference:*

Drs. Lunsford and Kondziolka also noted that the NAGKC should support another meeting in 2015 and 2016. Dr. Lunsford encouraged interested parties to submit a proposal for hosting the next NAGKC scientific meeting. Drs. John Lee from University of Pennsylvania and Gene Barnett from Cleveland Clinic will consider hosting an education meeting of the consortium in that time frame.

At 5:30pm, a motion for adjournment was made by Dr. Lunsford and accepted by the group. With that, the meeting was concluded.

Respectfully submitted by:  
Jason Sheehan