

IGKRF

International Gamma Knife Research Foundation

IGKRF Board Meeting Minutes Saturday, June 27, 2015, 5:30pm - 7:00pm Hyatt Regency

IGKRF Members Present:

L. Dade Lunsford
Lisa Baxendell (clinical research coordinator)
Jason Sheehan
John Lee
Carlos H. Carbini
Gene Barnett
Huan-Che Yang
Manmeet Ahluwalia
Veronica Chiang
Cheng-Chia Lee
Michael McDermott
Johnathan Knisely
Inga Grills
Christopher Cifarelli
David Mathieu
Jim McInerney
Hideyuki Kano

Ex Officio Members Present:

Danny Leksell
Catherine Gilmore-Lawless
Rebeca Emerick

I. Call to Order/Approval of the 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.

Encrypted flash drives with meeting documents were circulated to the members.

II. Membership Updates

Members update was noted including the following centers:

- A. West Virginia University (2014)
- B. The Valley Hospital, Ridgewood NJ (2014)
- C. NA Homolce Hospital, Czech Republic (2015)
- D. RS Unit Ruber International Hospital, Madrid, Spain (provisional)

- E. Beijing Tiantan Hospital, China (provisional)
- F. West China Hospital of Sichuan University, Chengdu, China (provisional)

Also, a current IGKRF membership spreadsheet with contract information was detailed. Members were encouraged to provide any updated contact information. Dr. McDermott provided his information to be added to the spreadsheet. Information should be sent to Ms. Baxendell.

III. Old Business

A discussion of the recently published or in press trials was held. Dr. Ahluwalia thanked his PRC committee members for the work that they have done. He also indicated that some PRC members may warrant consideration for authorship given the study design effort for certain trials. Dr. Lunsford concurred.

Dr. Ahluwalia encouraged those with new proposal to send to his PRC group for review.

Dr. Sheehan briefly discussed the author and contribute guidelines. These may need to be revised in the future. Dr. Ahluwalia noted that some journals put restrictions on the number of authors per submission. Dr. McDermott noted the importance of giving junior faculty recognition in publications.

Also retrospective trials in progress were noted. The process of study design, proposals, data collection, and data sharing was noted. Current prospective and retrospective retrospective clinical trials include those listed below. Ms. Baxendell also provided an update regarding the IRB status of various centers. Centers must maintain valid IRB approval for data sharing and participation in clinical trials. A spreadsheet of IRB status is on the flash drive. Please verify that your site is in compliance with IRB requirements.

A. Published Retrospective Trials

1. Non Functioning Pituitary Adenomas (JNS, 119(2) 446-456, 2013)
2. Parasellar & sellar meningiomas (JNS, 120(6) 1268-77, June 2014)
3. Petroclival meningiomas (J Neurooncol, 119(1) 169-76, Aug 2014)
4. Cerebellopontine angle meningiomas (Neurosurg 75(4) 398-408, Oct 2014)
5. Esthesioneuroblastoma (J Neurol Surg B Skull Base 75(6) 409-14, Dec 2014)
6. Intracranial Hemangioblastoma (JNS, 122(6) 1469-78, June 2015)
7. Posterior fossa meningioma (JNS, Epub 4/10/15)
8. Facial nerve schwannomas (JNS, Epub 5/8/15)
9. Skull base chondrosarcoma (JNS, accepted, in process)

B. Retrospective Trials being prepared for Publication

1. Craniopharyngioma Dr. Niranjan
Dr. Lunsford suggested that the Taipei group could potentially share its data for this study. Earlier in the meeting, Dr. Pan presented a large series of craniopharyngioma patients from their center.
2. AVM radiosurgery grading scale Dr. Sheehan et al
3. Facial schwannoma Dr. Sheehan
This work has been published in JNS.
4. CS hemangioma Dr. Lee
Dr. Lee encouraged members to submit more patients for this study. Gamma Knife may be the preferred treatment for these lesions even without histological confirmation per Dr. Lee's analysis of the data.

C. Retrospective Trials in Progress

1. Pineal region tumors Drs. Kano/Mathieu
Dr. Mathieu will explore options with other centers for more data accrual. Also a broadening of histologies to include more diverse pineal region histology (e.g. germinomas) was discussed.
2. Glossopharyngeal neuralgia Dr. Kano
3. Hemangiopericytoma Dr. Sheehan
This trial is still accruing patients. Please send data to Ms. Baxendell.
4. Falx/convexity meningioma edema Dr. Sheehan
The trial is closed. This work has been submitted to JNO for review.

D. Prospective clinical trials

1. 12-01: Randomized controlled study of outcomes in patients with five or more brain metastases Dr. Barani
I pads for this trial may need high speed internet through a VPN connection. UCSF is accruing patients. UPMC and UVA are ready to accrue patients in this study. Continuation of funding for

this project requires meeting certain milestones. Dr. Barani will need to provide quarterly updates about the trial.

2. 12-02: Multicenter Phase II Study of border zone SR with Bevacizumab chemotherapy in patients with recurrent or progressive glioblastoma multiforme
Dr. Niranjana
Dr. Niranjana has secured funding from Genentech. He is ready to open this trial.
3. 13-01: Radiosurgery or open surgery for epilepsy (ROSE)
Drs. Barbaro/Quigg
The ROSE trial accrual has stagnated. India and the UK may be reasonable venues for future patient accrual. This work is now being funded by Elekta. UVA is not able to accrue any additional patients for this trial.
4. 13-02: Staged stereotactic radiosurgery followed by embolization for large volume AVMs
Dr. Kano et al
This protocol will be submitted to the PRC for review. Hopefully it can be opened soon.
5. 14-01: Minocycline for ARE in brain metastasis
Dr. Niranjana
Institutional funding from UPMC was obtained to allow for opening at this site. If the preliminary results look promising, additional funding may be feasible to allow for opening at other sites. Dr. Lunsford noted there is reasonable preclinical data to support the potential therapeutic benefit of minocycline for treating ARE.
6. A Phase I trial of Afatinib for SRS brain mets for patients with HER2 positive breast cancer and EGFR positive lung cancer with 1-4 brain metastases
Dr. Ahluwalia
Industry funding has been secured, and the PRC has approved this study. Dr. Ahluwalia hopes to open the study soon. He anticipates needing accrual from 7-8 busy sites over approximately 1.5 years to achieve the target number of patients.
7. Beaumont proposal
Dr. Inga Grills
Dr. Grills will submit a proposal for a brain metastasis and neurocognitive study involving SRS. This trial will not involve randomization to WBRT and therefore may not suffer from investigator or patient bias about WBRT as other studies have. Dr. McDermott recommended that Dr. Barani help to review this protocol with Dr. Grills.

IV. Registry Initiative

Dr. Lunsford

Dr. Lunsford discussed the Elekta registry effort and integration of this under the umbrella of the IGKRF. This will require more infrastructure and oversight from personnel by the IGKRF. Also, a data governance policy will need to be created.

Ms. Gilmore-Lawless indicated that Elekta wants the IGKRF to govern the registry. Dr. Leksell agreed. Management and goals will need to be jointly defined.

Dr. Lunsford suggested that Ms. Gilmore-Lawless submit a proposal to the IGKRF regarding the registry oversight.

V. New Business

A. Next scientific meeting

Dr. John Lee

Dr. John Lee expressed interest in hosting the next IGKRF meeting in 2017. The meeting would be held in Philadelphia, PA. Dr. Lee will begin to assemble a scientific program and preliminary budget. A brief presentation by Dr. Lee was made. Dr. Lee indicated that Dr. Sean Grady is supportive of the University of Pennsylvania hosting the next IGKRF meeting. The new Perelman center would be a good venue for the meeting.

Dr. McDermott also suggested that the next meeting could be tied to the LGKS meeting. Dr. Sheehan and Dr. Barnett noted that this could decrease meeting cost for the IGKRF.

B. Funding the future

Dr. Lunsford

Dr. Lunsford noted that the IGKRF would need approximately \$200k/year to have a full time director and a separate office. Discussions for fund raising and other revenue streams was held. Dr. Leksell noted that grateful patients could be one source of funding. Dr. Sheehan and Dr. Lunsford noted the success of the FUSF by Dr. Kassell as one

potential model. Dr. Lunsford has also spoken with Ms. Emerick to gain further insight into funding possibilities for the IGKRF. Membership dues alone will not be sufficient.

Dr. McDermott and Dr. Barnett noted that there could be some synergism for the IGKRF with other organizations such as LGKS or ISRS. Dr. Barnett noted that the IGKRF meetings have been independently funded. The current meeting should break even or make a modest profit. Funding for this meeting has involved more diverse corporate partners than the prior meeting. This diverse corporate funding would be important to maintain in the future as Dr. Barnett and Dr. Sheehan noted.

Dr. Leksell noted that the IGKRF and LGKS could have sequential meetings. However, for many reasons, these two organizations should be kept separate. Dr. Leksell noted that the LGKS may soon charge for membership. Dr. Sheehan suggested that a small tax on LGKS membership could be placed for the purposes of supporting the IGKRF research efforts that benefit all in the field.

Dr. Lunsford asked Drs. McDermott, Schulder, Barnett, and Knisely to serve on a financial development committee. They expressed a willingness to serve in this capacity and explore financial models for the future of the IGKRF.

VI. Financial Report

Dr. Sheehan presented an overview of the finances for the IGKRF. The financial state of the IGKRF is solid. The current meeting is being funded through corporate support and should prove profitable. Martha Tobin and Dr. Barnett were commended for their organization of the meeting.

Dr. Lunsford and Dr. Sheehan discussed funding for the future of the IGKRF. To meet our current commitments and expand to oversee more clinical trials, the registry, and regular biennial meetings, the IGKRF will need to have additional personnel and space. Dr. Lunsford will present more details about this tomorrow in his presentation at the end of the conference.

VII. Election of New Committee Members

Dr. Lunsford noted the present composition of the board. In 2017, new members of the board should be selected. Dr. Lunsford proposed the following for the group to consider:

Dr. Kondziolka for president
Dr. Sheehan for vice president
Dr. Barnett for secretary-treasurer

More nominations would be considered. Please contact Dr. Lunsford if interested in serving in a leadership capacity. A slate will be finalized closer to 2017 and prepared for a final vote.

Additional committee chairs noted since the last meeting include the following:

Protocol review committee chair-Dr. Ahluwalia
Development committee chair-as noted above
Membership committee chair-Bruce Pollock
Biennial Meeting chair-John Lee

At 7pm, 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