



# HCRN update



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Courtesy: Nikki Gale Photography  
(nikkigalephotography.com)

## HCRN Receives Nearly \$1MM in NIH Funding

In our last issue we reported that two NIH funding applications had been submitted by the HCRN. We are thrilled to announce that HCRN's Chairman Dr. John Kestle's "challenge grant" application was awarded NIH funding! This award will contribute greatly to HCRN research success by not only providing monetary assistance but by forging new relationships with NIH mentors. As a first step in the collaboration process HCRN's co-founder Paul Gross and John Kestle recently had a meeting with the trans NIH Hydrocephalus Working Group to further mutual understanding of funding opportunities for hydrocephalus research. As an outcome from that meeting, our NIH Program Director, Deborah Hirtz, will be joining our team of investigators at one of our upcoming bi-annual HCRN meetings and further contribute to our research progress.

We had also reported that Dr. Jay Wellons had submitted an R01 grant to NIH's National Institute of Neurologic Disorders and Stroke (NINDS) to study management of post-hemorrhagic hydrocephalus in premature babies. Although the funding decision is still pending, Dr. Wellons' grant application was given a score and sufficient comments to help him prepare for a resubmission in June 2010 if necessary. Whether or not funding is received the HCRN intends to begin implementing this study across its sites in the spring and supports Dr. Wellons in his R01 endeavors. We are hopeful for the knowledge to be gained from this new study and for its funding success!

## Ultrasound Study on Target

In spring 2009 the HCRN started recruiting patients for its study analyzing shunt insertion with intra-operative ultrasound assistance, led by Dr. Bill Whitehead of Texas Children's Hospital. We are pleased to announce that less than one year later the target number of patients has been reached! It was expected that patient enrollment would take about one year, so this study is right on schedule for a timely completion. The data collection for this study will continue throughout the next year, as the outcomes for all the enrolled patients are closely followed. We continue to move toward answering the questions examined in this study regarding the efficacy of this surgical technique and whether it might be one more tool in the fight against shunt failure. Once the study is complete Dr. Whitehead hopes to use the results as the basis for an R01 NIH Grant application. We are excited about the potential this study offers toward furthering the HCRN mission and continue to work hard as a network at ensuring its successful completion.



## HCRN Coordinators: Keeping This All Going



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We would like to take the opportunity to introduce the HCRN Clinical Site Coordinators. These are the people working "on the front line". There is a coordinator at each clinical site and the Data Coordinating Center (DCC) and clearly the Network would not exist without their hard work and commitment to the HCRN mission. Each of the Clinical Site Coordinators has been instrumental in getting their respective sites up and running in the Network and in ensuring the network's continued progress and success. The HCRN coordinators collectively bring over 43 years of research experience to the network. In addition, their varied individual educational and career experiences in business administration, grant writing, database development, epidemiology, law, education, and nursing are brought together through their cooperation and common dedication to the HCRN mission to create a highly skilled and knowledgeable research team.

The coordinator's responsibilities are diverse and some aspects of their work vary from center to center, but they all work together to achieve the same end: ensuring the highest standards of quality in all HCRN research activities. The Clinical Site Coordinators are actively involved in the preliminary phases of the research studies, assisting with refinement of study protocols and data collection forms and getting protocols through the Internal Review Board/Research Ethics Board process. Once a study is underway the coordinators are the key people involved in meeting with patients and their families to discuss their potential participation in HCRN studies, collecting and entering study data -- often in the operating room during surgery -- and maintaining accurate and confidential records of each participant. Furthermore, the coordinators ensure the highest quality of data collection and compliance has been achieved as they prepare data for analysis. The coordinators also assist with a variety of other tasks as they arise, such as gathering information needed for grant applications, serving as liaisons with their institution's grants and contracts offices, and organizing and hosting HCRN bi-annual meetings which rotate among the various clinical centers. The HCRN Site Coordinators are invaluable members of the HCRN team and their continuous hard work and ongoing enthusiasm for their research contributions continue to keep this network moving forward.

The Coordinator at the DCC works closely with the HCRN Chair, helping to keep the Network as a whole running smoothly and cohesively. She works with lead investigators to finalize and typeset their Network protocols from which she develops and maintains related documents such as manuals of operation and data dictionaries. The DCC coordinator serves as a liaison between the Site Coordinators, the DCC data management staff, and Network Investigators, recording and disseminating communication across the Network and ensuring all required documentation is accurate, up to date, and on file.

We have an outstanding team of Coordinators and the quality of their work will show in the excellence of our HCRN studies and results.



## Three Year Evaluation of Progress on HCRN Strategic Plan

In 2006, we outlined a five year strategic plan with three initiatives and several goals under each of those initiatives. At the recent HCRN meeting in Houston, we evaluated our progress with respect to these. While we are very happy with the way things are going we remain passionate about significantly improving the lives of children with hydrocephalus.

### Initiative 1: Stimulate and conduct high quality, multicenter clinical research on hydrocephalus.

Goal 1: Attract centers and clinical researchers with track records of excellence.

- We now have five centers and 11 clinical researchers actively engaged in research in the Network.

Goal 2: Launch and complete clinical studies.

- We currently have 6 active studies in several areas of hydrocephalus diagnosis and management.

Goal 3: Publish quality, field changing papers.

- Although many of the studies are still in the data collection phase, HCRN investigators have published three journal articles, given over 30 presentations and written three NIH grant applications which have all directly acknowledged the HCRN.

### Initiative 2: Create a world class, multicenter research organization.

Goal 1: Create the fiscal infrastructure.

- Funds raised from philanthropy to support study activities are managed through the Primary Children's Foundation in Salt Lake City. In addition, NIH awarded funding is being managed through the University of Utah.

Goal 2: Establish relationships with key organizations to help direct and support the studies.

- Relationships are in place with the Hydrocephalus Association (HA) and, with the recent receipt of NIH funding, with NINDS also.

Goal 3: Create appropriate governance structure.

- Much of the first year was spent developing the now established governance committees and standard operation procedures.

Goal 4: Attract 4 million dollars in support.

- Excellent progress has been made as evidenced by the 2.7 million dollars raised to date.

### Initiative 3: Create lasting relationships with key outside influencers to further our mission.

Goal 1: Collaborate and coordinate research efforts with other hydrocephalus experts.

- Presentations of HCRN research at national meetings has provided for discussions and input from other hydrocephalus experts. Also, collaboration with basic science experts has begun.

Goal 2: Improve the understanding of key government contacts and institutions concerning the importance of clinical research.

- Discussions between HA lobbyists and federal agencies have included the HCRN. Paul Gross and John Kestle recently met with the Hydrocephalus Working Group at NIH.

Goal 3: Distribute best practices to practitioners and educate them on the importance and impact of HCRN findings in their work.

- As of January 2010, surgeons from 13 centers outside of the HCRN have requested access to our protocols for their use.



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Please be sure to see them by visiting our website at:

<http://www.hcrn.org>

## To Contact the Hydrocephalus Clinical Research Network

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## To make a contribution to the HCRN

Please contact Douglas Nielsen at Primary Children's Medical Center Foundation at (801) 662-5970. All contributions are tax deductible as allowed by the IRS.