

Dear New Institution:

Thank you for your interest in participating in the further development and validation of a temporal bone dissection simulator. Currently, approximately 30 programs have entered data into our web-database (<http://www.osc.edu/research/Biomed/survey.shtml>). Details of the specific project including PDF files of the proposal are available under the proposal link. The following is a brief outline of the research plan:

During the first year, **Phase I**, we will focus on migrating the current system to a more cost-effective portable platform. Working in collaboration with some of the collaborating institutions and possibly the Academy of Otolaryngology – Head and Neck Surgery Foundation, Inc., we will establish the criteria to certify data sets for use in the simulator.

In **Phase II**, or years 2 & 3, we will test the predictive validity of the system under a local study. In collaboration with experts at participating institutions, we will discuss and establish objective criteria for evaluating the surgical proficiency of novice otologic surgeons. These criteria will be included in the remote studies (Phase III) and will be used by an expert at a given site to evaluate performance in a traditional dissection.

In **Phase III**, or years 4 & 5, we will disseminate the system to additional sites participating in the study. We will train local representatives in the use of the system.

Through all three phases, we will continue with the acquisition and integration of multi-resolution and multi-modal data to support more complex surgical procedures. We will obtain and integrate data from the NIDCD temporal bone registry, and make recommendations for future processing and integration of registry data. We will continue to refine the level of visual and dynamic realism in the system through algorithm development.

All participating institutions will provide specific demographics on each resident subject to be involved in the trials. This will be input directly to our web-database as you did for your previous registration. Each individual subject will receive a unique ID to input data. Your institution will have to provide two (2) temporal bones to be drilled for each subject and make arrangements for storage of the bone for an indefinite period of time. Finally, the participating institution will be able to support simulation studies during which data will be collected from resident subjects using the simulator. The dissected bones will be delivered back to our institution to be blindly rated. All institutions will be invited to collaborate on the development of temporal bone data and pedagogical standards. A smaller, select number of institutions that possess requisite hardware and technical expertise (as demonstrated in the information you posted on our web-database) will be involved with early trials of the system in phase II. The larger

consortium will be involved with phase III trials. Institutions that do not have the supporting hardware and technical expertise will be provided systems on loan to conduct their site trials. Specifically, we foresee three groups of participating institutions:

- Group 1: This group will be comprised of individual institutions that have the basic hardware and local expertise to be involved in early trials. The basic hardware would include high performance graphics workstations, force feedback dexterous interfaces (Phantom 1.5 or desktop), stereo display and local technical expertise.
- Group 2: This group will include institutions that are actively pursuing simulation environments and have the wherewithal to set up a simulation laboratory on their own.
- Group 3: This group will include institutions that are interested in simulation only through the study and do not plan to obtain hardware or develop local expertise on their own. Loaner hardware and expertise will be provided for these institutions in the final phase of the study.

At this point we will need a letter of commitment that your institution will agree to the basic elements listed above and identify which group you would like to participate in. Additionally, you must agree to providing 2 cadaveric temporal bones for each subject that you enroll at your institution and be responsible to maintain the integrity of randomization, blinded data collection and care of the equipment if loaned to your institution. We are excited about this national project. It may serve as a model for further collaborative research in the development and use of new technology for training in our specialty. Thank you for your support. Further details will be forthcoming as this process moves forward. As always, if you have any specific questions, I can be reached via email at [gwiet@chi.osu.edu](mailto:gwiet@chi.osu.edu) or by phone at 614-722-6600.

Sincerely,

Gregory J. Wiet, M.D.  
Principal Investigator,  
Validation/Dissemination of a Virtual Temporal Bone Dissection Simulator  
Associate Professor  
Department of Otolaryngology and Biomedical Informatics  
The Ohio State University College of Medicine and Public Health  
Children's Hospital  
Columbus, Ohio