

BUDGET JUSTIFICATION

Justification of Direct Costs for First Year

A.1. Tuncali, Kemal, Principal Investigator, 1.2 calendar months

Dr. Tuncali is the Director of the Genitourinary Radiology Service and Assistant Director of the Cross Sectional Interventional Radiology Section at Brigham and Women's Hospital, and Instructor of Radiology at Harvard Medical School. He routinely performs thermal ablation of both liver and kidney at the hospital and is actively involved in research collaborations to advance the procedure's state of the art. He has performed the procedure under both CT and MR guidance and has prior experience with intraoperative navigation systems and the transition of technological advances into the operating room.

During the first year of the proposed research Dr. Tuncali will be responsible for providing a clinical perspective for the hardware modifications required in Specific Aim #1 and during the work-flow and software design in Specific Aim #2. He will also perform the phantom trials once the navigation system and software have been integrated, as specified in Specific Aim #2. He will also coordinate the technical research performed between the Brigham and Women's Hospital and the subcontractor Actiview Ltd.

A.2. Hata, Nobuhiko, Investigator, 3.0 calendar months.

Dr. Hata is an Associate Professor of Radiology at the Brigham and Women's Hospital, Harvard Medical School, Boston, and Technical Director of the Image-Guided Therapy program. He recently founded and became the director of Surgical Robotics and Navigation Laboratory. To date, he has developed pre- and intra-operative medical image registration methods for surgical navigation, as well as software systems for image guided therapies (see his Biographical Sketch). Of particular note, Dr. Hata is the first developer of the 3D Slicer program, which he originally developed to guide brain surgery in 1997. The 3D Slicer program is associated with Specific Aim #2.

During the first year of the proposed research, Dr. Hata will be responsible for designing and developing the navigation software 3D Slicer which will integrate information from both the CT scanner and the navigation device, as presented in Specific Aim #2. Dr. Hata will also organize the necessary phantom studies as described in the same specific aim. In this capacity he will supervise a postdoctoral fellow (see B.1. Elhawary below).

B.1. Elhawary, Haytham, Postdoctoral Research Fellow, 9.6 calendar months.

Dr. Elhawary is a research fellow at the Surgical Planning Laboratory at Brigham and Women's Hospital and a postdoctoral research fellow at the Harvard Medical School. He previously developed a robotic device capable of performing biopsy of the prostate under real-time MR image guidance in a closed bore scanner, where he acquired experience in both the hardware and software components of image guided therapy systems, and authored 9 journal publications. He is skilled and experienced in 3D Slicer software development, ranging from information visualization using VTK and ITK, modeling and data analysis, to open-source and cross-platform software development.

During the first year of the proposed research he will work closely with Dr. Hata to develop the 3D Slicer navigation module along with the software communication protocols required to exchange information with the navigation system and the CT scanner as described in Specific Aim #2. He will prepare and provide the technical support for the performance of the phantom trials by Dr. Tuncali and the quantification of probe accuracy. He will contribute to publication and dissemination of these results.

D.1. Domestic Travel Costs, \$1500

The Principal Investigator, Dr. Tuncali will travel to the annual meeting of the Radiological Society of North America, held in Chicago, Illinois, from 28th November – 3rd December 2010. This meeting is the principal clinical and scientific venue for the field of Radiology with a large presence of the most important interventional radiologist groups in the world. Results of first year of research will be presented there, feedback will be obtained from colleagues and new ideas and collaborations will be developed. The total cost is obtained from the sum of a return plane ticket (\$300), four nights at the hotel (\$425), a per diem ($\$75 \times 5 = \375) and registration (\$400).

F.1. Materials and Supplies, \$4932

An interventional 3D multimodality abdominal phantom (Model 057 from CIRS, \$2581 plus transport costs) will be acquired for the tests described in Specific Aims #2. The phantom contains removable abdominal organs and materials which accurately mimic human tissue. Other materials and supplies include data storage devices, electronic components and materials to support phantom studies.

F.5. Subawards, Actiview Ltd, \$124,500

The proposed research is based on the adaptation and integration of a novel video based navigation system. This system is propriety and belongs to Actiview Ltd, who have performed the research and development of the device. This subaward is needed in order to obtain the research goals described in Specific Aim #1, and Actiview Ltd have the relevant expertise and knowledge of the system to add the necessary development to the system for its use in kidney tumor ablation. A separate budget and budget justification is included in the research proposal. Communication between Brigham and Women's Hospital and Actiview Ltd is currently done during weekly tele-conferencing, and will continue to do so for the duration of the project.

Justification of Direct Costs for Second Year**A.1. Tuncali, Kemal, Principal Investigator, 2.4 calendar months**

During the second year of the proposed research Dr. Tuncali will be responsible for enrolling patients for the clinical trials and performing the interventions using the navigation system, as described in Specific Aim #3. He will clearly define the clinical workflow in order to quantify the relevant metrics and clinical surrogates to evaluate procedure outcome. His commitment is substantially increased for this second year.

A.2. Hata, Nobuhiko, Investigator, 1.2 calendar months.

During the second year of the proposed research, Dr. Hata will participate in the design of the clinical study and lead the statistical analysis of the data of the performed interventions as well as the historical data to which the procedures are compared. In this capacity he will supervise a postdoctoral fellow (see B.1. Elhawary below). His effort is reduced from the first year of the application as the technical development of the system will have been completed.

B.1. Elhawary, Haytham, Postdoctoral Research Fellow, 9.6 calendar months.

During the second year of the proposed research Dr. Elhawary will work closely with Dr. Tuncali, giving the technical assistance of the system during each of the clinical trials, and will acquire all the relevant data. He will also work closely with Dr. Hata to perform

the statistical analysis of the data and to extract the results and conclusions of the study. He will contribute to publication and dissemination of these results.

D.1. Domestic Travel Costs, \$1500

The Principal Investigator, Dr. Tuncali will travel to the annual meeting of the Radiological Society of North America, held in Chicago, Illinois, in November 2011. This meeting is the principal clinical and scientific venue for the field of Radiology with a large presence of the most important interventional radiologist groups in the world. Results of the second year of research will be presented there, feedback will be obtained from colleagues and new ideas and collaborations will be developed. The total cost is obtained from the sum of a return plane ticket (\$300), four nights at the hotel (\$425), a per diem ($\$75 \times 5 = \375) and registration (\$400).

F.1. Materials and Supplies, \$665

These materials include electronic components, communication cables and consumables.

F.5. Subawards, Activiews Ltd, \$124,500

The proposed research is based on the adaptation and integration of a novel video based navigation system. This system is propriety and belongs to Activiews Ltd, who have performed the research and development of the device. This subaward is needed in order to obtain the research goals described in Specific Aim #1, and Activiews Ltd have the relevant expertise and knowledge of the system to add the necessary development to the system for its use in kidney tumor ablation. A separate budget and budget justification is included in the research proposal. Communication between Brigham and Women's Hospital and Activiews Ltd is currently done during weekly tele-conferencing, and will continue to do so for the duration of the project.