To: **ATC Steering Committee**

From: **J. A. Purdy, Ph.D.**
ATC Principal Investigator

Date: **October 20, 2006**

RE: **Response to ATC Steering Committee Meeting, Rockville, MD, April 3, 2006**

The ATC wishes to thank the members of the ATC Steering Committee (ATCSC) and the other interested parties that attended this meeting for providing input and review for this important NCI sponsored project. We particularly thank the committee for recognizing the achievements accomplished by the ATC and noting that "the ATC has matured and evolved into the premier image-based therapy clinical trials resource for NIH/NCI." That said, we strongly agree with the ATCSC that there is still more work to be done.

Our response to the various statements and questions posed by the ATCSC is as follows:

1. We agree that the current strategy of utilizing the major portion of ATC's developmental funding to support RCET's software development efforts has not been as successful as anticipated. Since the NetSys/WebSys software still has not passed the first step interoperability tests as performed at the ITC, we have decided to discontinue testing of this system at ITC. Instead ITC, RTOG, QARC, and RPC have begun to interact with industry to explore the possibility of integrating industrial grade software into the into the existing ATC Method 1 software that is in production use. It should be noted though that the NCIC has agreed to continue to work with RCET and test/implement the NetSys/WebSys software as they have made a significant investment in hardware and training for this system. It has been made clear to RCET that they cannot expect continued support in the new ATC grant application at the level the past ATC grant has provided; our strategy will be to move toward integration with industry efforts, caBIG IVI software development efforts, and use ATC development resources for software interface development, and for any clinical trials QA tools that are not available in the caBIG or industrial software packages.

2. We also agree that ATC must work with clinical trial groups to develop a method for prioritization of clinical trials that need ATC resources. As stated by the ATCSC, the NCI and ATC must use caution and be very selective in taking on new initiatives that may be distracting and use scarce ATC resources in a less than optimal manner. We are working with the RTOG IGRT Committee to try and prioritize studies requesting ATC support giving priority to Phase III studies, particularly for those disease sites in which we have no (or limited) treatment planning data in the database, and for new studies that push the informatics developmental effort such as SBRT and studies that utilize multi-modality imaging.

3. Regarding the suggested areas that ATC may explore in selecting future directions, the ATC response is given in *italics*:
   a. Image-guided therapy that does not use radiation, such as surgical image-guidance, rf ablation, high intensity focused ultrasound, image-guided drug delivery, ... *in light of*

item 2 above ATC will not be able to focus on these forms of therapy in the foreseeable future.

b. Use of PET-CT and MRI in treatment planning, where DICOM-RT has not been used before. *ATC is already involved with PET-CT, e.g., ITC and RTOG are working in support RTOG 0515 and ITC, RTOG, and ACRIN are working with NCIA in support of RTOG 0522. Studies such as these are believed to be high priority uses of ATC resources*

c. A more comprehensive clinical record, suitable for FDA review such as that under development by the Clinical Data Interchange Standards Consortium (CDISC). *We agree that ATC should become more knowledgeable regarding CDISC standards. We are interfacing with caBIG via the In Vivo Imaging Workspace and will lend our voice to support linking CDISC to DICOM and for ATC to follow caBIG compatibility guidelines in software development matters.*

d. Integration of image-guidance treatment databases and clinical trials with biomarkers, microarray data, genetic profiles, and other forms of complex biological data. *The ITC is already part of the RTOG Bioinformatics Working Group, which is working to develop such a "derived database."*

e. Enterprise standards for management of clinical trials, such that ATC would oversee a group of sites using IHE - the integrated healthcare enterprise - technology, extended for their needs. *ATC is a full participant in the on-going IHE-RO effort.*

f. Adoption of an open source software strategy, integration of ITK tools, and large scale adoption of caBIG metadata standards. *The ATC is already moving forward to embrace caBIG philosophy to the degree possible in the short run, and most definitely in the long run. In the new grant, we plan to mak use of a modular architecture with well-defined interfaces to: (a) enable integration of a heterogeneous mix of commercial-off-the-shelf, open-source, and custom software components; (b) facilitate testing and maintenance of system components, and (c) allow step-wise implementation and upgrading of system components.*

4. We certainly agree that more publications and presentations documenting the lessons learned by ATC regarding digital data submission, data QA, protocol QA, and software development are needed. However, we believe continued effort is needed to inform AAPM, ASTRO, and RTOG members about ATC activities. Expanding these efforts to the greater biomedical imaging community will be considered.

5. The ATC is very much aware that its developmental efforts must adapt to the rapidly evolving requirements from new technology and must engage experts in image processing and informatics.

Again, we appreciate the significant and thoughtful input of the Steering Committee. It is our intention to integrate the more visionary aspects of that input into the proposed specific aims of the upcoming ATC grant application.