CTSA Imaging Working Group Bi-monthly Update WebEx
Monday, October 19, 2009
3:00 PM CDT

Call Summary

In attendance:

Daniel Sullivan, MD (moderator)
John Boone, PhD
Jeffrey Carr, MD
Zahi Fayad, PhD
James Frost, MD, PhD, MBA
Vahe Ghahraman
Gordon Harris, PhD
Michael Knopp, MD, PhD
John Kotyk, PhD
Tin Lee
Weili Lin, PhD
Katarzyna J. Macura, MD, PhD
Daniel Marcus, PhD
David Miller, PhD
P. David Mozley, MD
J. Anthony Parker, MD, PhD
Andrea Perrone
Brian Reynolds, PhD
Joseph Roebuck, MD, PhD
Wendy R. Sanhai, PhD
Ann L. Scherzinger, PhD
Annick D. Van den Abbeele, MD
Linda Velasquez, MS, CCRC
Jeffrey Yap, PhD
Walter Wolf, PhD

RSNA
Fiona Miller
Susan Anderson
Mary Cerceo

Update on the CTSA IWG Steering Committee (Dr Sullivan)

- Inaugural call with Steering Committee held September 21, 2009
- IWG activities include:
  - Developing an inventory of core imaging services and charges
  - Tracking education resources, identifying gaps and developing new resources
  - Suggestion that face to face meetings CTSA IWG should have a focused deliverable.
  - CTSA IWG calls are bimonthly; will discuss and share information on a single topic such as protocol review

Update on ACRIN fall meeting 2009

- A CTSA IWG business lunch was held September 30
- The business meeting was followed by afternoon educational sessions which were well-received

Save the Date: April 5-7, 2010

- A CTSA IWG meeting in conjunction with the Association for Clinical Research Training and the Society for Clinical Translation and Science on April 5 – 7, 2010 in Washington, DC is under consideration.

CTSA Site Update - University of North Carolina at Chapel Hill (Weili Lin, PhD)

- University of North Carolina at Chapel Hill, Biomedical Research Imaging Center (BRIC), www.med.unc.edu/bric
  - PI and Director of the BRIC, Etta Pisano, MD
  - Imaging Core, Weili Lin, PhD
- The University of North Carolina, Chapel Hill, has:
  - Human imaging core
  - Animal imaging core
  - Image and statistical analysis core
- Not specifically affiliated with the CTSA program but all cores have been providing imaging services to all investigators.
- Services include:
- Human Imaging Core
  - Protocol Development/Implementation
  - Image acquisition and archiving
  - Subject training
  - Dedicated nurse for support
  - Safety training

- Animal Imaging Core
    - Protocol development/implementation
    - Image acquisition and archiving
    - Animal preparation/monitoring
    - IACUC approval
    - Data analysis
    - Core assumes rights and care of animals during study, then re-transfer animals to PI at end of study
- Image and Statistical Analysis
    - Image Analysis
    - Segmentation
    - Co-registration
    - Visualization
    - Statistical analysis
    - Experimental design
    - Power calculation
    - General statistical analysis
- BRIC and CTSA investigators have good relationship; BRIC offers pilot funding for CTSA and pilot grants funded by CTSA come to BRIC and CTSA pays charges
- The institution does not provide any direct support to the imaging core; each core is financially independent

Update on charges survey

- Compiling de-identified responses to determine averages and ranges
- Will separate Animal and Human services
- Have not requested information for specific sites, e.g. head, neck, but may consider in future
- Results will be posted to website when complete

Update from CTSA sites facing grant renewal

- Twelve sites are completing renewal applications
- Duke University (Dr Sullivan)
    - In initial application, Duke listed a core (technology resource) and had funding to develop software for managing clinical trials and for salary support
    - In renewal application, scope will not change in part because a search for a new chair is underway
    - Renewal will include support for salary, small animal imaging but not for software development
- Mayo Clinic (Dr Erickson)
    - Addressing past political challenges in which CTSA assisted in preparation but got only a fraction of funding
    - Seeking assurances that imaging will receive funding
- UC Davis (Dr Boone)
    - Works more with cancer center than CTSA
    - Suggest that cancer center be expanded to include non-cancer
    - Does not anticipate much focus on imaging in renewal

Cancer Center grant review

- In cancer centers grant review, imaging has been deemed important
- Interest in going beyond oncology
- There is a need to expand support for resources, e.g. private grants
- Include an NCRR staff person on CTSA IWG calls to request a stronger message to reviewers and also inclusion of imaging in announcement
    - Announcement mentions key function areas such as phenotyping but does not specifically mention imaging

RSNA 2009 Activities

- CTSA IWG working meeting, Tuesday, December 1, 3:30-5:00pm, Room S104B (South Bldg.) will include updates from Cores/Education (charges survey), Imaging Informatics (white papers) and UPICT (proffered protocol extractions and review).

Focused Discussion: Protocol Review Processes

- Institution 1: Duke
- Site based research (SBR)

- Catchment area for radiology review if protocol includes imaging
- Currently reviewing about 150 protocols per year that include significant imaging component, primarily oncology
- Medical center has policy that services must be paid
  - Payment is not an issue in industry-sponsored trials
  - For NIH trials, may be subsidized by funds collected from industry-sponsored trials or can write radiology salary support into grant which lessens need for protocol review
  - In January 2010 will begin charging approx $250 for service
- Ctte in most departments must review clinical research components before IRB

- Washington University (Dr Kotyk)
  - Have clinical trials, informatics, clinical research and other cores and units resources by CTSA
  - All provide resources for setting up research studies and receive guidance before review
  - Center for clinical studies human imaging unit has check-box or referral to imaging center so HIV and CCRI unit triggers review
  - Two types of users:
    - Expert users who have used imaging
    - Novice users, e.g. integrating an industrial protocol
    - Role in review, especially for novices, is 'hand-holding'
  - CCIR can address safety, dosimetry, practicality and feasibility and also data analysis
    - Other groups also provide review, e.g. clinical research lab coordinates, electronic radiology lab assists collaboratively with analysis and processing, neurology lab also assists
  - Costs for protocol review shared by radiology and a small amount of CTSA funds which supports staff and faculty
    - In 2008, 100-150 protocols included imaging as a component
    - Currently, there are approximately 300 protocols which have been reviewed
  - Turnaround time ranges from less than a week for well-planned protocol to 2-3 months if protocol needs revision
    - There is pressure from industry for quick turnaround
  - Tracking is done by MS workflow software, data bases and excellent staff support.
    - Human intervention is being replaced with automated tracking processes, e.g. expiration on consent forms with e-mail reminders.

Next Steps:

- Charges survey follow-up questions from Dr Sullivan to be distributed by RSNA staff
- Invite renewing CTSA sites to provide an update during the bi-monthly calls
- NCRR:
  - Invite NCRR staff to CTSA IWG Steering Committee calls
  - Include NCRR staff on December CTSA IWG call for discussion on whether imaging comes up in study sessions and to get a stronger message to the reviewers
  - Invite NCRR staff to attend CTSA IWG session at RSNA 2009
  - Suggest adding imaging to the Cancer Center program announcement
- CTSA IWG asked to Save the Date for a meeting under consideration: April 5 – 7, 2010 in Washington, DC