Application for QIBA Project Funding

Title of Proposal: Inter-scanner/inter-clinic comparison of reader nodule sizing in CT imaging of a phantom		
QIBA Committee/Subgroup: QIBA Volume CT/Group 1C		
NIBIB Task Number(s) which this project addresses:		
Project Coordinator or Lead Investigator Information:		
Last Name: Fenimore	First Name: Charles	Degree(s): PhD
Institution/Company: National Institute of Standards and Technology		

Please check the primary category for this proposal from among the following: - 1.d.

- ☐ 1. Identification of Technical Characteristics and Standards
  - ☐ a. Creation and refinement of protocols for image acquisition, analysis, quality control, etc., for specific clinical utility
  - ☐ b. Phantom development and testing
  - ☐ c. Identification and assessment of intra-reader bias (1) and variance across scanners and centers
  - ☐ d. Identification and assessment of inter-reader bias and variance across scanners and centers
  - ☐ e. Other
- ☐ 2. Clinical Performance Groundwork
  - ☐ a. Assessment of intra-reader sensitivity and specificity
  - ☐ b. Assessment of inter-reader sensitivity and specificity
  - ☐ c. Other
- ☐ 3. Clinical Efficacy Groundwork
  - ☐ a. Assessment of correlation between new biomarker and 'accepted-as-standard' method
  - ☐ b. Characterization of value in clinical trials
  - ☐ c. Characterization of value in clinical practice
  - ☐ d. Development/merger of databases from trials in support of qualification
  - ☐ e. Other

- ☐ 4. Resources (money and/or people) committeed from other sources.

Please provide a one-page summary that includes the following information:

Project Description
Inter-scanner / inter-clinic comparison of reader nodule sizing in CT imaging of a phantom.

Primary goals and objectives
In support of QIBA profile development, this reader study will characterize uncertainty in volume and other reader-based sizing of phantom nodules in CT imagery collected on scanners from several vendors. We will:

1. Develop an imaging protocol that includes:
 - a standard multi-scanner branch (based on ACRIN 6678)
 - an image quality-based, device-independent branch

2. Analyze the accuracy and precision of sizing measures for all design factors including: site/device, imaging protocol factors, nodule characteristics & reader, and

3. Determine the minimum detectable level of change that can be achieved when measuring nodules in phantom datasets.

Deliverables
1 - **Define the imaging protocol**: the imaging protocol is required for all 5 CT imagers.
2 – **Develop a general design for the study:** Draft study plan is complete. Critical review and possible modifications remain.
3 - **Execute the imaging protocol** on the FDA phantom and make the imagery available for markup.
4 - **Read the imagery** – Recruit and work with a CoRe lab to develop and carry out a reader study.
5 - **Analyze the data** - develop a mature analysis of the effects of factors including CT device and imaging site on the uncertainty in phantom lesion sizing. The analysis will rely on both NIST and UCLA statisticians.

Timeline [with intermediate measureable milestones.]
1. Imaging protocol delivered by 12/31/10
2. Final study design 1/31/2011
3. Imaging completed 2/28/11
4. Reading study completed: 4/30/11
5. Analysis and draft report completed: 6/30/11.