QIBA Process Committee

July 1, 2015 at 3:00 PM CT

Call Summary

Attendees:			**Staff:**
Kevin O'Donnell, MASc (Chair)	Brian Garra, MD	Eric Perlman, MD	Joe Koudelik
Daniel Sullivan, MD (co-chair)	Lisa Karam, PhD		Susan Weinmann

General Discussion (Mr. O'Donnell)

- Feedback requested re: the collection of imaging data in support of the Technically- and Clinically-confirmed Profile stages
- Profile development stages were discussed
- Round 5 Projects
    - Due to federal restrictions regarding human subjects, no clinical projects will be considered for this round of funding; this applies to any project requiring an IRB approval
    - A discussion on possible reasons for this guideline ensued
    - Reanalyzing retrospective clinical data is allowed, but a prospective clinical trial with patient accrual and image/data acquisition is not

- The collection of human data is likely an issue for Technical Confirmation of all profiles. Drs. Jackson and Bresolin may look into a possible contract modification in the future to allow human subjects while addressing any IRB/Risk Management concerns NIH may have.

- QIBA Profile Template
    - The following key documents were displayed and discussed and can be found on the QIBA wiki: http://qibawiki.rsna.org/index.php?title=QIBA_Profile_Template
        - QIBA Profile Template Version 2.2
        - QIBA Profile Template Improvements 2015 (contains issues and changes proposed by the BCs
    - The following open issues were discussed:
        - FDG-PET: How to address requirements on a device:
            - as it leaves the manufacturer

        - requirements to perform Quality Control of that device upon installation (initial versus maintenance)
        - requirements on a human actor or a task which involves iteration between an individual and a device

- FDG-PET: Would like claims to be agnostic of vendor and device, but devices do contribute to variability:
    - since devices may contribute to variability, differences among devices need to be characterized and compensated for
    - a standardized QC process remains challenging because each BC may have different QC requirements

Next Steps

- Mr. O'Donnell made an addition to the "Current Work" section on QIBA wiki process page, adding the item: Revise QIBA Profile Template & "How to develop a Profile Guidance"
- For all "Current Work" items, see: http://qibawiki.rsna.org/index.php?title=Process_Coordinating_Committee
- Mr. O'Donnell suggested that the front page of the QIBA wiki be made cleaner

Next Call: Wednesday, July 15, 2015 at 3 PM CT