**FDG-PET/CT draft template**
**GSD, June 29, 2009**

FYI: The complete draft of the QIBA FDG-PET/CT Whole Body protocol is posted at **http://qibawiki.rsna.org/index.php?title=Profile:_FDG-PET_Whole_Body**

**1. Executive Summary, Introduction and Background Information**
- 1.1. Principle
- 1.2. Indications
- 1.3. Relationship with other diagnostic methods
- 1.4. Covariates (*note – please see full FDG-PET document; should this material be in other sections of the document?*)

**2. Claims (what users will be able to achieve)**
- 2.1 Claim #1:
- 2.2. Claim #2:
- 2.3. Claim #3:
- 2.4. Claim #4:
- 2.5. Claim #5: (etc.)

**3. Imaging Protocol: Overview**
- 3.1. Detail: Utilities and Endpoints of the Imaging Protocol within the Clinical Trial
- 3.2. Detail: Management of Pre-enrollment Imaging Tests
- 3.3. Detail: Timing of Imaging Tests within the Clinical Trial Calendar
- 3.4. Detail: Management of On-protocol Imaging Performed Off-schedule
- 3.5. Detail: Management of Off-protocol Imaging
- 3.6. Detail: Subject Selection Criteria Related to Imaging (mainly exclusionary in nature)

**4. Subject Preparation**
- 4.1. Detail: Interval Timing (e.g., oral and/or IV intake, vigorous physical activity, timing relative to non-protocol-related medical interventions, etc.)
- 4.2. Detail: Specific Pre-imaging Instructions
- 4.3. Detail: Prior to Arrival
- 4.4. Detail: Upon Arrival (including ancillary testing associated with the imaging and downstream actions relative to such testing)

**5. Imaging Procedures: General**
- 5.1. Detail: Data that should accompany the request for a PET study
- 5.2. Detail: Imaging Agent Preparation and Specification (Contrast agent or radiopharmaceutical)
- 5.3. Detail: Contrast administration: (agent, dose, route)
- 5.4. Detail: Procedure for performing the PET study
- 5.5. Detail: Protocol alterations permitted in the case of multi-centre studies
- 5.6. Detail: Imaging Data Acquisition
- 5.7. Detail: Subject Positioning
- 5.8. Detail: Instructions to Subject during Acquisition (e.g., breathing)

5.9. Detail: Timing (e.g., relative to previously administered imaging agents / enhancers; inter-time point standardization)

**6. Reconstruction and Reporting**

6.1. Detail: Reconstruction
6.2. Detail: Reporting
6.3. Detail: Interpretation and pitfalls

**7. Archival Requirements for Primary Source Imaging Data**

7.1. Detail: Data should be archived in DICOM 3.0 format or the current version of DICOM recommended by XXX WG YY of the XXX.
7.2. Detail: De-identification / Anonymization Schema(s) to Be Used
7.3. Detail: Archival and Transmission of Image Data
7.4. Detail: Transmission of Imaging Data from Sites to Central Archive
7.5. Detail: Requirements for Local Retention of Imaging Data
7.6. Detail: Requirements for Central Management of Imaging Data and Imaging Metadata (e.g., the results of image analysis)

**8. Post-processing (i.e., anything not done on an acquisition platform that affects DICOM image data and/or pixel / voxel values)**

*None prior to importation into free standing image analysis software package*

**9. Interpretation**

9.1. Detail: Image quality assessment to confirm correctness and completeness of image submission
9.2. Detail: Volume of interest (VOI) Definition
9.3. Detail: Timepoint exams defined by charter re: exam types and dates of inclusion
9.4. Detail: @Open next timepoint for given subject

**10. Radiation Dose and Safety Considerations**

**11. Quality Control**

11.1. Detail: General
11.2. Detail: Quality Control and Inter-institution Cross-Calibration

**12. Required Documentation**

12.1. Detail: Subject preparation
12.2. Detail: Imaging agent dose calculation
12.3. Detail: Imaging agent-related
12.4. Detail: Image data acquisition-related
12.5. Detail: Inherent image data reconstruction / processing
12.6. Detail: Image analysis and interpretation
12.7. Detail: Site selection and Quality Control

**13. Acknowledgements**