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PERFORM Operating Document

IMAGING PARTICIPANT TRACKING

PC-POD-IM-002-v01

Revision History

Version	Reason for Revision	Date
01	New POD	May/05/2015

Summary

The content of this PERFORM Operating Document (POD) provides guidelines for the tracking of research participants that are involved with the imaging platforms at PERFORM. The goal is to maintain confidentiality for the participant while ensuring the ability to track results both for research and regulation purposes.

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1. Definition of Terms

Term	Definition
DEXA	Dual Energy X-ray Absorptiometry
Incidental findings (IFs)	Unexpected discoveries or observations of potential clinical significance detected during the course of a study/activity that are outside the scope, or unrelated to the purpose or variables, of the study/activity
Magnetic Resonance Imaging (MRI)	A technique using intense magnetic fields in combination with radiofrequency EMR to generate images of internal anatomical structures
PACS	Picture archiving and communications system
Participant	Person who is enrolled in community programs/projects and/or research programs/projects
PERFORM	The PERFORM Centre at Concordia University
PET-CT	Positron Emission Tomography - Computed Tomography
Platform Coordinator	Person responsible for all activities in a given area of PERFORM such as the athletic therapy clinic, clinical analysis laboratories, conditioning floor, etc.
Principal Investigator (PI)	Head researcher who is responsible for all aspects of a given research project or program at PERFORM
User	Person using space or equipment at the PERFORM Centre that has received adequate technical and safety training
RIS	Reservation Information System
SPECT-CT	Single-photon emission computed tomography – Computed Tomography
Tomography	A method of producing a three-dimensional image of the internal structures of a solid object
Ultrasound	A method of producing images of internal structures of organs using high frequency sound waves

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2. Introduction

In order to effectively track research participants who come through the Bio Imaging Suite a process had to be developed that maintains confidentiality but allows for traceability. The importance of traceability relates to multiple issues. First, in the event an incidental finding is discovered, it will need to be reported to the Principal Investigator who will need to relate it to a specific individual. Also, PERFORM Centre has obligations under its licensing agreements to be able to report on ionizing radiation exposures received by human research participants. Finally, proper interpretation of research results may necessitate specific identification of a research subject.

2.1. Purpose

The purpose of this POD is to educate and demonstrate the method by which the booking of a Bio Imaging Suite platform and naming of files will be handled.

2.2. Scope

This POD applies to all PERFORM users who will be working with human participants in any of the Bio Imaging Suite platforms: DEXA, MRI, PET-CT, SPECT-CT, or Ultrasound.

2.3. Responsibilities

It is the responsibility of all PERFORM users of the Bio Imaging Suite to follow this POD in order to protect the confidentiality of the participants and maintain system integrity.

2.4. Relevant documents

- PC-POD-GA-001: PERFORM Centre Booking System for Facilities and Equipment
- PC-SOP-GA-011: Guidelines for Management of Incidental Findings at PERFORM

NOTE: This POD defers to Concordia's policies at all times.

3. Procedure

The following is the procedure to be used once a research participant has been selected to participate in a research study involving one of the Bio Imaging Suite platforms at the PERFORM Centre.

3.1. Principle Investigator

It will be the responsibility of the Principle Investigator to maintain a master list of their research participant's information and develop a naming convention to create anonymous identification for use in the Bio Imaging Suite platforms and archival.

- First name: Project defined (Default: PERFORM)
- Last name: Project code*
- Patient ID: Automated system created code
- Referring Physician: Principle Investigator
- Height, weight will be real values
- A date of birth value representing the age of the research participant

*Projects involving the PET-CT with respiratory gating will have to use alphabetical values only. The Varian system doesn't allow numerical values in the name field.

3.2. Participant booking and details

The Principle Investigator or delegate will book the platform using the online site and send the platform coordinator a minimum of the first four values listed above (First Name, Last name, Patient ID, and PI name). The height and weight can be evaluated on site if required. These details are required in the RIS system prior to starting any imaging procedure in order to provide the Principle Investigator access to their images once archived in the PACs system. The RIS system creates a work list for the individual platforms (DEXA, MRI, PETCT, SPECTCT, Vivid Ultrasound) being used and the user will be able to select the research participant from that list.

Please note that the LOGIQ-E Ultrasound is not connected to the network and users will be responsible for adding the participant details directly into this system as well as removing and archiving their data from this unit once their session is terminated.

3.3. Safety Screening Questionnaires

The user will use the following information when entering details on the safety screening questionnaires as determined by the Principle Investigator:
- First name: Project defined (Default: PERFORM)
- Last name: Project code*
- Patient ID: Automated system created code
- Referring Physician: Principle Investigator

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- Height, weight will be real values
- Date of Birth value representing the age of the research participant

*Projects involving the PET-CT with respiratory gating will have to use alphabetical values only. The Varian system doesn't allow numerical values in the name field.

The user will sign and date the Safety Screening Questionnaires and provide it to the platform coordinator to have it scanned into the PACS system to be stored with the archived images.

3.4. Imaging system

The user will verify that the information on the work list profile for the participant is accurate. If changes are required they will need to be done on the RIS system by the platform coordinator. This is important to ensure the proper transfer of information into the PACS system for archiving. At no time should there be a research participant's name added anywhere in the systems.

3.5. PACS – Archiving

Once imaging is completed the user will transfer the images for each research participant to the PACS system for archiving. The DEXA system will use an external hard drive for archiving raw data and use the Dicom format when transferring information to the PACS system.

The LOGIQ-E ultrasound does not have archiving capabilities, so it will be up to the user to back-up their own data from this device and to delete it from the machine once the session is complete. The recommended archiving protocol is from the LOGIQ-E to USB, from USB to the Echopacs software installed on desktop in room S.1.110, Echopacs to the PACs for archival.

APPENDIX I:

POD Training Record Form

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POD Title

IMAGING PARTICIPANT TRACKING

POD Code

Ownership	Document type	Area	POD Number	Version
PC	POD	IM	002	01

Training Record

Full Name	
Institution	
Contact (email or phone number)	

Signature

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Sign here   Date