

University of Pennsylvania  
**CAMRIS**  
(Center for Advanced Magnetic Resonance in Science)

## Standard Operating Procedure for Archival on the Trio or Sonata Research Scanners

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Table of Contents

Scope & Application .....3

Overview .....3

Definitions .....3

Information Requirements .....4

Entry of Patient Information .....4

Personnel Qualifications .....4

Archival HUP5 Sonata .....4

Archival HUP6 Trio .....5

RAW DATA .....5

Filming .....5

Data and Records Management .....5

Quality Control and Quality Assurance .....5

## 1.0 Scope & Application

- 1.1 This standard operating procedure is applicable to any MR imaging procedure on the Trio or Sonata MR systems housed in the Basement of Rhoads and Founders buildings at the Hospital of the University of Pennsylvania. These standards pertain to all individuals performing these scans in the MRI facility.

## 2.0 Overview

- 2.1 This SOP is intended to provide direction and information about conducting consistent, HIPPA compliant data storage and retrieval for Investigators performing studies in the MR facility.

## 3.0 Definitions

- 3.1 **Study** is the overall set of images reconstructed during a session of MR scanning. There are three types:
- 3.1.1 **Human Study** - Images generated while scanning a patient or normal volunteer during a session. These studies can be one of two sub-types:
    - 3.1.1.1 **Anonymous Trial Study** – These studies require no information to be generated on the header information.
    - 3.1.1.2 **Routine Trial Study** - These studies require the header information to contain pertinent patient identifying information.
  - 3.1.2 **Animal Study** – Images generated scanning an animal on the MR systems.
  - 3.1.3 **Phantom or Specimen Study** – Images generated scanning ex-vivo tissue or a prepared substance or object.
- 3.2 **Header Information**- Information entered into the MR system specifying demographics or other information about the subject being scanned.
- 3.3 **PACS (Central Archive)** – Picture Archiving and Communicating System is the standard central archiving system.
- 3.4 **CD-ROM** – Write only CD archival available on the Trio and Sonata system.
- 3.5 **Centricity Exam Manager** – (GE supported) Exam management tool available on the MR Research Computers in the Trio and Sonata control areas. This tool is used to verify arrival of the images to PACS.
- 3.6 **Centricity Viewer** – (GE supported) This tool is provided for image viewing of studies archived in PACS. It is available on the MR Research Computers in the Trio and Sonata control areas.
- 3.7 **MRN** – Medical Record Number- This is an 8-digit identification number used for patient identification and tracking throughout the University Hospital System.
- 3.8 **Verification** – Process using Centricity exam management tool to confirm the presence of the correct number of images for the appropriate study sent to PACS.
- 3.9 **DOB** – Date of Birth
- 3.10 **HIPAA** – The Health Insurance Portability and Accountability Act addresses the security and privacy of health data.
- 3.11 **DICOM** – Digital Imaging and Communication in Medicine
- 3.12 **Raw Data** – data that is taken and stored on the disc in some other format that does not enter it as an image in the image database.

#### 4.0 Information Requirements

- 4.1 All Patients must have an established MRN. No person will be scanned without this number. To establish this number call Central Registration (215)-615-2240.
- 4.2 All animal research must contain identifiers for both the ULAR number and Investigator.
- 4.3 All scans are documented as entries in the logbook.

#### 5.0 Entry of Patient Information

- 5.1 All Human Studies are entered as routine studies. All appropriate patient information is entered into the appropriate fields.
  - 5.1.1 Anonymous header information is applied to the subject data fields after the original data is placed on CD-ROM and sent to PACS.
- 5.2 Animal Studies must have information entered in the header which allows identification of the animal scanned and the investigator managing the session.
  - 5.2.1 No entries in the header fields for Animal Research can be in a form that may be seen as human subject data. Any questions about this issue are handled through the technologists. If you are uncertain what is acceptable the technologists can assign identifiers.

#### 6.0 Personnel Qualifications

- 6.1 All individuals operating within the MRI environment will be trained Radiologic Technologists or approved users recognized by CAMRIS.
- 6.2 All individuals responsible for entering, copying, or transferring Human Study data will have an understanding of HIPAA regulations pertaining to the data transfers as set forward by the University of Pennsylvania and HUP.

#### 7.0 Archival HUP5 Sonata

- 7.1 All data scanned by technologists are sent to PACS. All Human Studies are verified within the PACS. All Human Studies are archived to the local CD-ROM and stored on site.
  - 7.1.1 Animal Studies that involve MRI Technologists will be backed up on CD-ROM upon request. Investigators are responsible for their Animal Research Data.
  - 7.1.2 Phantom and Specimen archival is the responsibility of the investigators.

#### 8.0 Archival HUP6 Trio

- 8.1 All data scanned by technologists are sent to PACS. All Human Studies are verified in PACS. Studies involving images other than FMRI are written to CD-R and stored on site.
  - 8.1.1 FMRI Data is written to CD-R for the investigator and is not stored on site. The data taken during a FMRI session will be kept on the TRIO System as long as possible before being deleted. The average time before deletion is approximately 5 days. Upon receiving the data it is the

responsibility of the Investigator to verify it is complete. Incomplete sets of data must be reported immediately to the MRI Technologists.

- 8.1.1.1 FMRI data groups that are very large may have difficulty reaching PACS in their entirety. At this time there is no fix for this problem. This makes it imperative that investigators check their data sets in an expeditious manner.
- 8.1.2 Animal Studies that involve MRI Technologists will be backed up on CD-ROM upon request. Investigators are responsible for their Animal Research Data.
- 8.1.3 Phantom and Specimen archival is the responsibility of the investigators

## 9.0 RAW DATA

- 9.1 All raw data archival is the responsibility of the investigator unless otherwise arranged through CAMRIS.
- 9.2 No raw data will be stored on the systems. Raw data found on the systems can and will be deleted.

## 10.0 Filming

- 10.1 No filming is available for images acquired on the research scanners.
- 10.2 A CD with image viewer included can be made if requested for studies done on the Sonata or Trio systems.

## 11.0 Data and Records Management

- 11.1 Header information entered into the scanner must be specific to each animal (e.g. animal ULAR number) and cannot be in a form that the central archive can register as a patient.
- 11.2 MRI is not responsible for animal research studies going to PACS.
- 11.3 The investigator's name must appear in the header information.
- 11.4 Header information, operator, and investigator's name must be entered into the system log book.
- 11.5 All data involving patients will be burned to a CD for storage in the MR facility. Investigators are given a copy if requested.
- 11.6 Data from a study are not kept on the system disc for more than one week.
- 11.7 No films are generated for any animal research study.

## 12.0 Quality Control and Quality Assurance

- 12.1 Quality Assurance of the system is done through routine Preventative Maintenance done by the MR manufacturer (Siemens).
- 12.2 Intermittent failure of writing to CD is often fixed through a system reboot.
- 12.3 Archival problems that arise when Technological support is not available can be routed through the SIEMENS uptime service. The number is posted in the control area of each scanner.