

Why Use Our Services?

The Duke Multi-Dimensional Image Processing Laboratory provides services to de-identify medical imaging data in accordance with HIPAA, Good Clinical Practice (GCP), and the DICOM Standard. Our expertise in image processing and clinical research ensures that images are properly de-identified in order to:

- Protect the confidentiality of individuals participating in research
- Comply with GCP by providing an audit trail for traceability
- Maintain the integrity of modified image data

Our process removes personally identifying information from the DICOM metadata** as well as identifiers inserted into the pixel data, which are labor-intensive to remove. The resulting de-identified data set may be transferred outside the institution (e.g. to a sponsor or an imaging CRO). All de-identified data is provided on DVD, and our lab retains a copy of each disc created to assist key personnel in resolving issues or questions relating to image data from sponsors or imaging CROs. At a protocol's completion or discontinuation, all disc copies are available to the PI for long-term archival.

Please include the patient's name, Duke MRN, the project study name, IRB number, fund code, modality, date of imaging, and new patient ID for each study request.

You may contact us regarding your project's de-identification needs at:

radiology-deid@notes.duke.edu

De-identification vs Anonymization

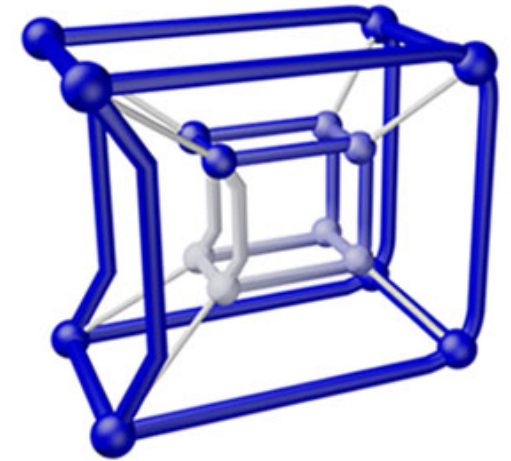
Both de-identification and anonymization remove information belonging to the 18 classes of Protected Health Information (PHI) as defined by the Privacy Rule. The difference is that de-identified data retains a key for re-identifying an individual, such as a patient ID matched to a medical record number. Anonymization retains no mechanism to recover the identity of an individual. De-identified data sets are most often utilized in clinical research, whereas anonymization is typically used for publicly accessible data sets.

Fee Structure

Modality	Cost Per Imaging Exam*
Nuclear Medicine X-Ray Mammography CT MR PET PET/CT Ultrasound	\$25 Non-Industry Sponsored Exam \$50 Industry Sponsored Exam

* All de-identified data sets are provided on DVD media. Fees are effective for the 2014 fiscal year and include media cost.

** DICOM metadata: DICOM refers to Digital Imaging & Communications in Medicine, metadata refers to information inserted into specific fields within the DICOM image file.



Duke Multi-Dimensional Image Processing Laboratory

*Advanced Image Analysis
for Personalized Medicine*

De-identification Services

radiology-deid@notes.duke.edu

(919) 681-0492



Duke Radiology
Duke University Health System

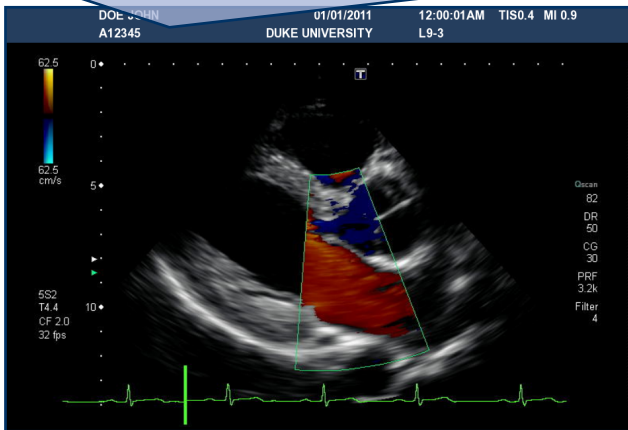


Figure 1. Patient's Name, Medical Record Number, and Institution inserted into image banner pixel data

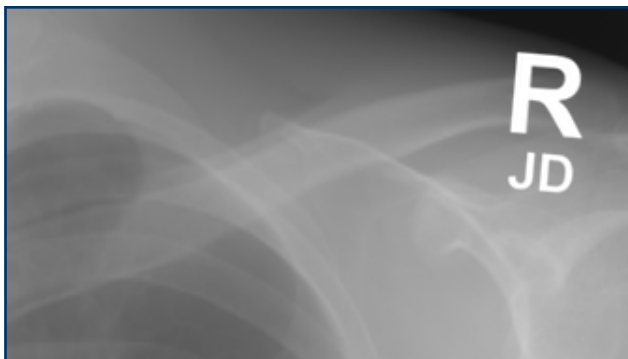


Figure 2. Example of operator initials ("JD") identifying personnel involved in performing the procedure. These must be removed, and it is a labor-intensive process.

PHI Inserted Into Pixel Data

Ultrasound and nuclear medicine images frequently contain personal identifiers such as the patient's name or medical record number within an image banner (see Figure 1) or in other non-standard locations which are labor-intensive to remove (see Figure 2). The process of modifying DICOM image data to "black-out" these areas must be accomplished without interfering with image processing for qualitative or quantitative analysis.

DICOM Metadata

DICOM files include much more information than just the image itself, and any PHI within this metadata must also be removed (see Table 1). In addition to commonly used fields such as patient's name or patient ID, DICOM metadata may contain other identifying information including a patient's home address, accession numbers, or a device's serial number. In order to maintain data integrity, metadata modifications must conform to the DICOM Standard.

Minimum Necessary

A key component of the HIPAA Privacy Rule is the minimum necessary standard, which states that PHI should not be disclosed when it is not necessary to satisfy a particular purpose or carry out a function. To meet the minimum necessary standard, our de-identification process is based on the Basic Application Level Confidentiality Profile as defined in the DICOM Standard. This profile is intended for use in clinical trials and teaching files, taking a conservative approach in protecting an individual's confidentiality by removing the following classes of information:

- Identity and demographic characteristics of the patient or family members
- Identity of any personnel or organizations involved in ordering or performing the procedure

DICOM Attribute	Name	Value
0008,0080	Institution Name	Duke University Medical Center
0008,0081	Institution Address	Erwin Rd, Durham, NC
0008,0090	Referring Physician's Name	Scorpio^Hank^Dr.^
0008,1010	Station Name	DukeNorthRoom227
0008,1060	Name of Physicians Reading Study	Joe^Karen^Dr.^
0008,1070	Operator's Name	Smith^Sallie
0010,0010	Patient's Name	Doe^Jane
0010,0020	Patient ID	B23456
0010,1030	Patient's Birth Date	19550101
0010,1040	Patient's Address	123 Nowhere Lane, Durham, NC 27705
0018,1000	Device Serial Number	001A57

Table 1. Examples of PHI that may be present in DICOM fields

For More Information

- HIPAA Privacy Rule
U.S. Department of Health and Human Services
<http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/>
- DICOM Standard Basic Patient Confidentiality Profile in Annex E of Part 15
<http://medical.nema.org>
- Contact the Multi-Dimensional Image Processing Laboratory at:
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