Overview of DICOM

- DICOM: Digital Imaging and Communications in Medicine (DICOM) standard
- Medical Images:
  - pixel data: potential for ‘burned in’ PHI
  - meta data: over 3500 DICOM tags with interspersed PHI
  - accompanying documentation: may contain the very identifiers you’re stripping from the image

DICOM Metadata

- Metadata
  - A set of data that describes and gives information about other data.
- DICOM Metadata
Protected Health Information (in imaging metadata)

18 HIPAA Identifiers for “Safe Harbor”

- Names (including initials)
- Geographic locations smaller than a state
- All elements of dates (except year)
- Telephone numbers
- Fax Numbers
- E-mail addresses
- Social Security numbers
- Medical record numbers
- Health Plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers (serial numbers, license plate numbers)
- Device identifiers and serial numbers
- Web URLs
- IP addresses
- Biometric identifiers
- Full face photos and comparable images
- Any other unique identifying number, characteristic, or code (accession number, etc.)

PHI & Imaging Data: Where HIPAA meets DICOM

- Imaging data presents unique challenges
- HIPAA does not provide a list of relevant DICOM tags (there are over 3500 DICOM tags)
- Various unique identifiers (UIDs) for image, study, series, etc.
- Burned-in PHI
- Private DICOM tags
- Must modify data while maintaining DICOM compliance

Data Conditioning

Types of Data Sets

- Anonymized: All 18 elements removed; no re-identification link
- De-Identified: All 18 elements removed; separate key for re-identification exists
- Limited Data Set: 16 direct elements removed; key exists; dates and some location intact; Data Use agreement is necessary
- Informed Consent Use: ICF or waiver states which identifiers will be retained; key exists
WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Study records that identify you will be kept confidential as required by law. Federal Privacy Regulations provide safeguards for privacy, security, and authorized access. Except when required by law or as outlined in this consent, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier in study records disclosed outside of Duke University Health System (DUHS). For records disclosed outside of DUHS, you will be assigned a unique code number. The key to the code will be kept in a locked file in Dr. [PI]'s office.

As part of this study, you will have [image tests]. For the tests to be useful, limited identifiers like test dates [include other identifiers as necessary, e.g. date of birth, initials] are necessary. By signing this consent form, you authorize Dr. [PI] to send these specific identifiers in the images to [Sponsor Name] and their designated affiliates.


DATA CLASSIFICATION: RESTRICTED

Why add “designated affiliates?”

How do I know what identifiers to include in my informed consent?

- Work with the group that will be processing your images. Ask them to list which of the 18 identifiers will be present after “de-identification.”
- If using sponsor provided software and uploading images to the web for de-identification, make that clear using explicit language in the IRB and RDSP submissions.
- Verify remaining identifiers by working with ISO and/or Compliance office on a test image or using a locally installed DICOM viewer (e.g. MicroDicom).
- If you are planning to de-identify images yourself, work with ISO office prior to licensing/downloading DIY software.
Special Thanks!

- Duke DICOM SMEs
  - Duke Image Analysis Lab (DIAL)
  - Multi-Dimensional Image Processing Lab (MultiD)
  - Department of Radiology
  - Heart Center
- School of Medicine Compliance Office
- Duke Medicine Institutional Review Board

Questions

- Information Security Office
  - Shelly Epps, Information Security Officer
  - 919-613-0910
- School of Medicine Compliance Office
  - Lawrence "Doc" Muhlbaier, School of Medicine Privacy Officer
- Institutional Review Board
  - Jody Power, IRB Executive Director
- Clinical Research Units
  - Research Practice Managers
  - IT support teams