

Group 4

Access to databases – security, confidentiality, ownership, integrity

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Charges

- **Management of Data Access Rights**
- **Portable Clinical Imaging Records**
- **Individual Access to their own Images**
- **Images in Clinical Trials, Just Another form of Data?**
- **Teaching Files**

Overview

- **Management of Data Access**
- **Security**
- **Ownership**
- **Portable Clinical Imaging Records**
- **Teaching Files**
- **Recommendations**

Management of Data Access

- Individual patients should have access to their own data
- Should investigators have **exclusive** access rights to clinical trials data?
 - Is access a necessary incentive for participation?
 - Staged access for research data/timing
 - PIs
 - All participating investigators
 - All US investigators
 - All International investigators
 - Who should investigators make it available to?
 - Compulsory
 - Prohibited

Management of Data Access

- **Depends upon purpose of data**
 - Spectrum from anonymized teaching files to clinical trials data to an individual's images in an ePR
- **For NCI research should NCI set rules for accessibility of data?**
 - What rules apply after completion of trials?
 - Should NCI just take over management of data?
 - Set guidelines for sharing APIs, schemas, etc?
 - How important is the data? For how long?
 - Mammo
 - Chest
 - Others
 - Seven year rule like paper world?

Security

- **HIPAA: Does it change the rules?**
 - **“Common Rule” applies**
 - **Should there be a single, clear federal standard for security in clinical trials (enforced by NCI?)**

Security

- **HIPAA takes a “good practice” approach**
- **Integrity: necessary to guard against falsified data?**
 - **Watermarking**
 - **Encryption**
 - **Digital image signatures**
- **Does security for clinical trials need to be more stringent than for clinical care?**

Ownership

- **Who owns patient images?**
- **Who owns clinical trials data?**
 - Researchers
 - Institutions gathering data
 - Patients: can demand that copies be made available to them
 - NCI or other sponsors
 - Public
- **Does ownership = publication rights?**
- **Who is responsible if the information is lost?**
 - Institution

Ownership

- **Uncertainty about rules and burden of security policies a barrier to clinical trials participation?**
 - **Federal/Private/International**

Portable Clinical Imaging Records

- **Privacy/confidentiality/integrity concerns of patient data**
- **Same rules should apply as for other electronic data**
- **HIPAA rules**
- **Proper use depends on to whom the record is given (physician, patient)**

Teaching Files

- **Rules more relaxed than clinical trials**
- **Confidentiality: anonymized; but relevant demographics not scrubbed**
- **Access: “owner” determines**
- **Security: sufficient to control access**
- **Integrity: author/institution responsible for policies**
- **Ownership:**
 - **Author responsible for securing permission for any borrowed materials**
 - **Fair use allows reproduction for educational purposes**

Recommendations to NCI

- **Commission study of security practices and access policies of current NCI trials**
- **Generate good practice guidelines**
 - **Coordinate discussions with other groups working on standards/security**
 - **CDISC, ANSI HISB, NCVHS, HL7, DICOM, IHE, HIPAA, I3 group**
- **Review specifics of recommendations for lung nodule study, BIRN**

Recommendations

- **Agree upon guidelines for encryption, watermarking, etc.**
- **Consider requiring new studies to maintain images for public access**
 - Policy on legacy databases
- **Consider funding specific trial studies for standardized access mechanisms**
- **Evaluate additional costs of any access and security requirements on investigators**

Thank you