

# Background

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# Best Practice Issues

## CTSA Education Session Topics

### Extracted info from Echo Cores Best Practices doc Topics to consider for Imaging Cores Education Sessions

1. Trial Design and Support
  - Interactions with clinical research organizations and sponsor
  - Trial design
  - Biostatistics
  - Ongoing communications
  - Post-trial support
  - Representation on committees
  - Site Selection
  - Site Personnel
  - Site Manual
  - Site Training
  - Site Qualification and Initial Site QA
  - Ongoing Site QA
2. Image acquisition
  - Develop protocol, site policies and procedures
  - Develop and implement study materials
  - Develop and implement training programs
3. Image analysis
  - Data receipt and uploading · ~~deidentification~~
  - Data analysis
    - Measuring Precision and Accuracy
    - Handling of Missing and Censored Data
    - Adjudication Process: When and How
  - Image Analysis Plan
  - Image Analysis Personnel
  - Primary Reader Role and Qualifications
  - Physician ~~Overreader~~ Role and Qualifications
  - Inclusion of New Personnel
  - Principles and Practices for Image Review and Analysis
4. Quality Assurance
  - Study data
  - Reviewers
  - Equipment
  - Standard operating procedures
  - Compliance
  - Audits

### 5. Information Technology

- Image management
- Data transfer and management
- Image Transfer Standard
- Image Management
- Data Management

### 6. Results communication

- Manuscript authorship
- Intellectual Properties
- Representation to Trial
- Publication Rights
- Independent Analysis
- Secondary Use of Research Image

### 7. Measurement of Core Lab Efficiency and Accuracy

- Operations and Workflow
  - Sites, Image and data handling, Data completeness

Reproducibility and validation

Regulatory compliance

# Discussion Topic-Best Practices

*Overview in 10 Minutes*

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- Prospectively describe process.
- Be sure “authorities” (sponsor/FDA) understand details of the process and intent.
- Do exactly what you say you will do
- Document and explain any deviations to the process.
- Prove you did what you said you were going to do.

*If you think you did everything correctly you probably missed something*

# Example-“On Boarding” a New Radiologist

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- Credentialed
- CME
- IT Training
- VR Training
- Peer Review
  - RadPeer
  - Monthly
- Mentor Program
- SOP-“On boarding”
- Credentialing
- CME
- IT Training and documentation
- VR Training and documentation
- Peer Review-“Reader Metrics”

# Example-New Radiologist

## *The Core Lab List Goes On*

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- Test Cases reviewed and documented
- Protocol Training documented
- Source Documentation (forms completion)  
Training
- CFR 21 Part 11
- GCP (Yearly renewal)
- HIPPA (Yearly renewal)
- Audit Trail (Read and Changes)

# Example-Process Development

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- Developed new review process with Sponsor
- Authored document describing process
- FDA approved process for this particular trial
- I was user of process
- Where are the training records?

- Describe
- Understand
- Perform
- Deviations
- Prove

# Where Are the Training Records?

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- No one to “train” me-I knew process best.
- Should have: Written a “training document” that explained why training was not needed and signed off on it.
- Who is the “trainer”
  - Check JD and qualifications of trainer.

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# Help?

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