Excellence in Clinical Research
Good Research Practice = Great Science

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Issues to be Addressed

- Investigator/Staff Education
- Study Design
- Form Design
- Consent Form Issues
- Patient Eligibility/Withdrawal
- Study Performance/Monitoring
- Adverse Event Monitoring
- Confidentiality
Education/COI/HIPAA

- Failure to disclose financial interest to subjects as required by Disclosure Review Committee
- CITI program for PIs and research staff
- HIPAA training
Investigator-Initiated Studies

- Share protocol with coordinator
  - Too complicated to execute
  - Can all the observations be performed
  - Can participants tolerate the intervention and collection of all endpoint data
Assuring Data Quality and Protocol Compliance

- Design protocol to be practical (feasible subject recruitment, end point data acquisition, monitoring procedures)
- Review protocol with entire team during design, approval process, subject recruitment and study performance
- Monitor study internally for data quality throughout the study
Design Helpful Forms

- Inclusion/exclusion criteria
- Subject screening form/log
- Data collection forms for each visit
- Data collection forms for scheduled contacts
- Data collection forms for each key endpoint
- Adverse event forms
Eligibility/Withdrawal

Documentation of Child-Bearing Status
- On sponsor forms
- If no sponsor form – create one and document!

Lack of documentation of subject eligibility
- Medical records; Imaging reports
- Source documents must be kept available for review
Consent Process Issues

- New risks (typically drug studies)
  - May require additional consent in light of new risks
- Confusion of the Patient vs. Research Subject Role
- Clarity in pediatric study around 1 vs. 2 parental signatures
Consent Form Issues

- **Signature**
- **WU individual obtaining consent**
  - Appropriate for protocol
  - Appropriate training
  - PI or physician if HRPO requires
- **HIPAA**
  - Notice of privacy practices
  - Restrictions
- **Any initials required for opt-in or opt-out portions**
  - Subject should initial every spot with either yes or no
- **Crossing out-adding in to approved document**
Monitoring Findings

- **Consent Issues**
  - Virtually every protocol – ranging from documentation to subject safety issues

- **Confidentiality – Monitoring – AEs**
  - 4 protocols – Serious issues & Subject Safety Issues

- **Withdrawals & Eligibility**
  - Lack of consistency recording withdrawal/enrollments
  - Subject Safety Issues surrounding eligibility

- **Interventions-Observations-Outcomes**
  - Failure to follow the HRPO-approved protocol

- **HIPAA/COI/HS Education**
  - Failure to comply with Disclosure Review Committee management strategies
Intervention/Observation

- All participants should receive any/all testing outlined in the protocol
  - Any exceptions/deviations should be noted in the participant records
- Document performance of pregnancy testing as required in protocol
- Changes in protocol must be HRPO approved prior to implementation
Monitoring/Unanticipated Events

- AE/SAE submitted to DSMB but not to WU
Confidentiality

Failure to disclose sharing of data with outside entity in consent document
Miscellaneous

When new risks arise – notify subjects and HRPO
  – Revise consent to reflect new risk
  – Addendum to consent (short explanation)
  – Letter to participants (sign and return)

Changes in protocol require notification of HRPO (revision/amendment)
  – Unless immediate safety issue

Submit progress reports with annual renewal paperwork (complete logs in real time make this less onerous)
How to Avoid Problems

- PI Statement of Commitment
- Sensitivity to issues
- Education for PI & Coordinator
  - Formal coordinator education
  - Mentoring
- Create forms to include all data to be captured
  - Notes to file
  - Inclusion/Exclusion
- Use current consent document
Adopt this Compliance Philosophy

- University is at risk for compliance
- Penalties for noncompliance are high (civil & criminal)
- Compliance happens at the local level
- “I am the local level”