How the Miami CTSI helps advance human protections and quality in clinical research

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Objectives

- Illustrate key strategies for promoting the safety of clinical research study participants
- Learn a participatory approach to developing your study’s human subject protection plan
- Explain CTSI’s role in clinical research process improvement
Three Pillars of Safety

IRB
Consent
Managing AEs
**Independent** body comprised of a wide variety of faculty, research experts, and public representatives

- Review research activities involving human subjects to ensure that:
  - Ethical standards for the care and protection of human subjects have been established
  - Research activities are in compliance with pertinent regulations (federal, state, local, and institutional)
Continuous process vs. signing a consent form

Understanding relevant information
- General comprehension vs. appreciating relevance to personal situation
- Need to manage personal factors such as anxiety, desperation

Intentionality
- Seeking one more chance for a cure
- Wanting to help future patients and promoting scientific knowledge

Voluntariness
- Clinician-researchers, family, or fellow patients
- Incentive pay or only way to get affordable treatment

Adhering to regulations

- Regulations can be confusing, differing across federal agencies

Determining if risk-benefit ratio changes

- Severity is judged by the PI and relevant data are often unavailable
- Different descriptors and care standards can make clinical significance hard to interpret
- Hard to evaluate specific circumstances not considered endpoints

Paramount decision:

- Foreseeable Sacrifice
  - Risk
  - Cost
  - Inconvenience

- Anticipated Benefit
  - Participant
  - Study
  - Society

Governing Principle:

“The Science”
Societal interests

Study Participants’
Rights
Safety
Well-being

Essential Elements of Good Studies

- Team work
- Extensive planning and preparation
- Meticulous implementation
- Systematic real-time study monitoring
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New Paradigm: 4 Pillars of Safety

- IRB review and approval
- Consent
- Managing Adverse Events
- Shared responsibility for strong real-time study oversight
Data and Safety Monitoring Plan

- Responsibility for safety
- **Risk minimization**
- Adverse events and study deviations
- Monitoring study implementation and progress
- Study termination
- Confidentiality, data integrity, and security
Protocol planning in light of:
- Study participants – Target disorder, severity of illness
- Risks and side effects associated with investigational intervention
- Invasiveness and risks accompanying protocol procedures
- Research roles and licensure

Real-time monitoring program
- Study participant safety
- Data integrity

Active feedback loop – protocol modification from monitoring results
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Process Improvement Activities

- CRORS-CTSI Collaboration
- Clinical Research Quality Champions
- Research Professionals’ networking and communications – NCRP
- “UWay” orientation and CBLs
- Research Subject Advocacy Champions
- Liaison to facilitate UM research at JMH
  - Facilitating UM research at JMH
  - Marisabel Davalos – CTSI senior manager working with Drs. Heros and Velazquez
- Research recruitment initiatives
Nation-wide research competencies and training curriculum ($6M NIH Award)

REDCap: Tool for clinical study management & data capture

- Creates standardized online surveys; databases
- Easy data transfer, export data into a variety of statistical programs
- Translated into multiple languages for use worldwide
- Google-like” tool
- De-identified EPIC data for research
- User agreement required
  - CTSI biostatistics support
  - Brief Steering Committee review prior to dissemination of research product
- Instructional CBL
Result Categories:
- ICD9 (763)
- Disease/DOID (235)
- Medication (5775)
- Labs (8606)
- Patients ()

Filter By:
- Age range: 0-85+

Date range:
- Start Year: 
- End Year: [Update Search]
- [Reset]

Total ICD9 events: 35778
Unique patient count: 4235
Total unique ICD9s: 763

Top 20 disease(s):
- Malign neopl prostat
- Screen mal
- Mal neo h
- Mal neo c
- Malignant
- Mal neo soft
- Malignant neo o
- Mal neo bronch
- Mal neo pan
- Malign neopl breast NOS
- Malign neopl breast
- Mal neo
- Malignation
- Mal neo
- Mal neo cerv
- Malignant
- Mal neo o
- Mal neo bronch
# CTSI Services

**CTSI Internal Service Request**

**For UM Employees**

**Research Support & Consults**

- Research Navigator/General Requests
- BioResource
- Clinical Research Center (CRC)
- Community Engagement & Cultural Diversity
- Novel Translational Methods
- Regulatory Support
- Research Design & BioStatistics
- Research Ethics
- Research Subject Advocate (RSA)
- ResearchMatch

**Education Services**

- Network of Clinical Research Professionals (NCRP)
- Foundations of Translational Research Boot Camp
- Masters Program
- Mentor Consultation & Matching
- Grant Writing Seminars

**Funding Opportunities**

- Pilot Awards
- KL2
Comments? 
Questions?