



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

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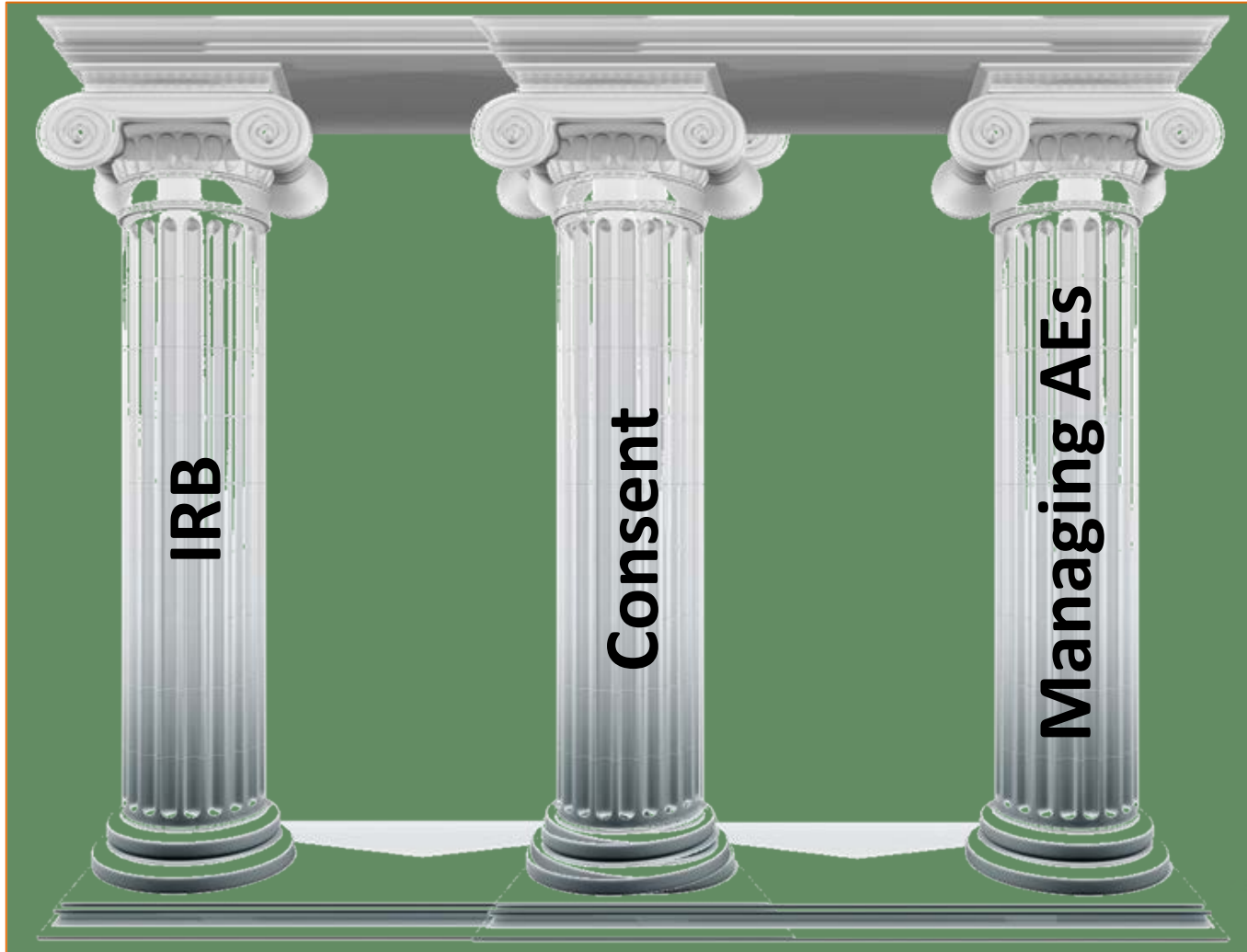
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[www.MiamiCTSI.org](http://www.MiamiCTSI.org)



- ❖ ***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

[www.MiamiCTSI.org](http://www.MiamiCTSI.org)





- ❖ **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



Brody BA. (2001). Making informed consent meaningful. *IRB: Ethics & Human Research* 23(5):1-5.



## ❖ 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*

Morse MA, Califf RM , and Sugerman J. (2001). Monitoring and Ensuring Safety During Clinical Research. *JAMA* 285(9):1201-1205



## ❖ Governing Principle:

*“The Science”  
Societal interests*



*Study Participants’  
Rights  
Safety  
Well-being*

Morse MA, Califf RM , and Sugerman J. (2001). Monitoring and Ensuring Safety During Clinical Research. *JAMA* 285(9):1201-1205





- ❖ Team work
- ❖ Extensive planning and preparation
- ❖ Meticulous implementation
- ❖ Systematic real-time study monitoring



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- ❖ Explain CTSI's role in clinical research process improvement



- ❖ IRB review and approval
- ❖ Consent
- ❖ Managing Adverse Events
- ❖ *Shared responsibility for strong real-time study oversight*





- ❖ 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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- ❖ 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



cancer & black

### Result Categories:

- ICD9 ( 763)
- Disease/DOID ( 235)
- Medication ( 5775)
- Labs ( 8606)
- Patients ( )

Total ICD9 events: 35778

Unique patient count: 4235

Total unique ICD9s : 763

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List View

### Filter By:

Age range: 0 85+

### Date range:

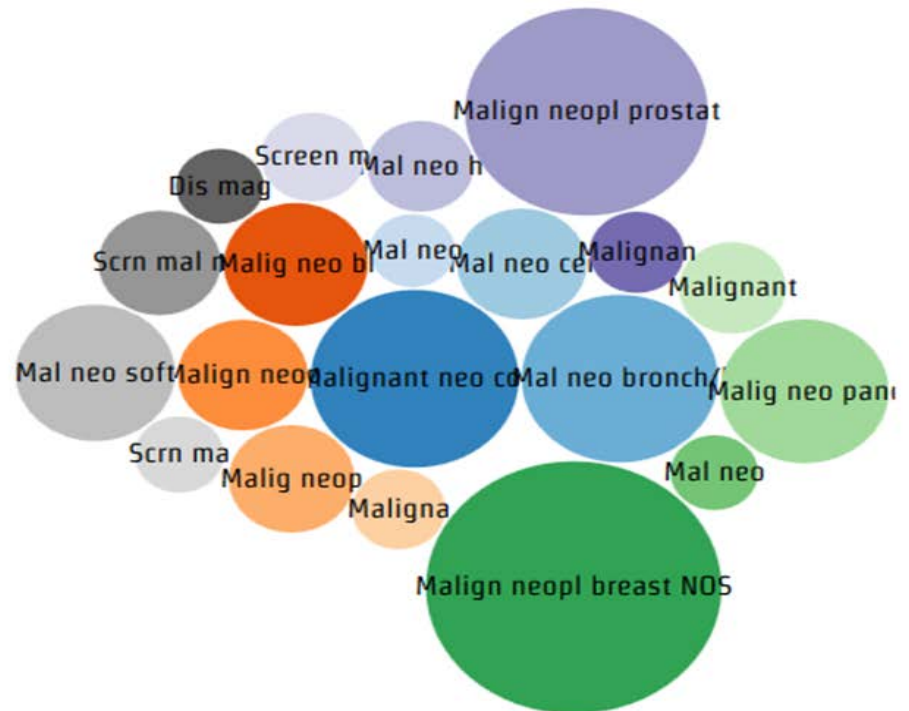
Start Year: Year

End Year: Update Search

Year

Reset

### Top 20 disease(s)





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## CTSI Internal Service Request

### For UM Employees

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

**www.MiamiCTSI.org**

Education Services	Funding Opportunities
<p>Network of Clinical Research Professionals (NCRP)</p>	<p>Pilot Awards</p>
<p>Foundations of Translational Research Boot Camp</p>	<p>KL2</p>
<p>Masters Program</p>	
<p>Mentor Consultation &amp; Matching</p>	
<p>Grant Writing Seminars</p>	



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***Comments?***  
***Questions?***