CTSI Update

José Szapocznik
6 October 2014
Research Cabinet
**Mission**
Serve as the home
to clinical and translational (C/T) science
at the University of Miami.

**Goals**

1) Improve the quality and efficacy (ability to produce a desired effect) of C/T research

2) Advance team science

3) Culturalize health sciences
## CTSI PROGRAM IMPACTS

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<th>To advance team science</th>
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### Regulatory Knowledge and Support

- Formulated process improvement mechanism in place for quality improvement in clinical research RCR, human protections, and protocol integrity
- Clinical Research Professionals' job descriptions, success metrics and career ladder explicitly address:
  - Responsible Conduct of Research (RCR)
  - Human protections
  - Protocol integrity
- Formalized program in place to advocate for the interests of clinical research participants.
- Culturalized consent processes in place
- Cultural competency incorporated into Clinical Research Professionals' job responsibilities and work performance metrics

### Research Education

- C/T nature of:
  - K12 applications and scholarly achievements
  - T32 applications
  - MSCTI graduate scholarly achievements
  - PhD and MD/PhD theses
- Interdisciplinary nature of:
  - K12 applications and scholarly achievements
  - T32 applications
  - MSCTI graduate scholarly achievements
- Culturalized nature of:
  - K12 applications and scholarly achievements
  - T32 applications
  - MSCTI graduate scholarly achievements

### Alianza

- Explicit minimal universal standards and guidelines implemented throughout clinical research sites at UMMSM
- Formal certification process for clinical research sites
- Clinical Research Professionals training program finalized and endorsed by collaborative clinical research site leaders
- Formal certification process for clinical research professionals
- Guidelines for clinical research site standards incorporate culturalized content

### Novel Methods

- Improved sustainability of Research Cores
- Formal support for translation: patents, commercialization, start-ups and JVs with industry
- Increased interdisciplinary collaborations reflected in internal UMMSM awards and scholarly achievements

### Community Engagement and Cultural Diversity

- Increased multidisciplinarity in community projects
- Increased C/T collaboration across existing UM community engagement groups
- Sustainable partnerships with diverse stakeholder communities to facilitate translational and culturalized health science

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### THEMES AND PROGRAM CLUSTERS

<table>
<thead>
<tr>
<th>Programs</th>
<th>6-Oct</th>
<th>17-Nov</th>
<th>8-Dec</th>
<th>12-Jan</th>
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**Culturalized Health Sciences & Team Science**
Miami CTSI

Intersection Project

Using Data to Ethically Integrate the Research and Patient Care Missions

Richard J. Bookman
6 October 2014
BioResource
Research Ethics
Biomedical Informatics
UMMMSM Research Cabinet Presentation: Oct 6, 2014

1.) IT systems to support structured data on specimens
Joe will provide 2 slides highlighting the mTuitive initiative as a tool for providing structured data fields that will facilitate data collection

2.) linking silos thru IT, policies, forms, services
maybe use example/story of 1 champion (e.g., NeuroNext)
Jake will describe the intersection of URIDE and the HIHG component of the BioResource with a use case example of a champion investigator

Research Ethics Activities

8/24: "discussed" is nice; anyone going to take steps to assure this actually happens?
9/22: Research Ethics will reach out to Pilot programs:
1a) Questions to include in Pilot award application
1b) Process and timing of review: should it be before or after award?
1c) For current awardees: pilot test questions with current awardees

Research Ethics/Goals-Aims Crosswalk
HIGHLIGHTS

❖ Synoptic Data to improve Cancer Research
   ♦ The traditional free-text format of pathology reporting was identified as a significant barrier to conducting cancer research.
   ♦ 9-18-2014: Pathology implemented a new synoptic reporting tool called mTuitive for all CAP Cancer Checklists.
     ▪ Nightly export of synoptic data to URIDE (in design phase) with SNOMED and ICD-9/10 encoding
     ▪ Facilitates identification of cohorts in URIDE with specific pathologic staging and tumor types combined with specific clinical laboratory parameters (not possible with free text reports)

❖ Intersection of URIDE and BioResource
   ♦ Dr. Benatar has used URIDE to aid in response to ~35 NeuroNext network feasibility questionnaires for grant submissions
   ♦ Similar data used in preparation of newly funded multi-center collaborative grant
     ▪ “Clinical Research in ALS & related disorders for Therapeutic Development (CREATE)”
     ▪ HIHG Biorepository arm of the BioResource will serve specimen needs across 5 sites.
BioResource Objective: Link biospecimen collections thru IT, governance policies, protocols/forms, and services

- Research Ethics Interactions
  - Harmonize biobanking governance policies across UM
  - Consent for broader patient contact to provide biospecimens for IRB approved protocols

- Bioinformatics Interactions
  - Provide structured data elements for query in URIDE
    - Synoptic data from Pathology
    - Link available biospecimen data (promote collaborative interactions)
Major initiatives for the remainder of the grant

- Continue to improve overall BioResource infrastructure and metric tracking through interactions and harmonization of existing resources
- Provide improved support for university-wide biospecimen collection efforts
- Increase utilization of the BioResource (URIDE, concierge service, etc.)
- Promote and support both institutional and multi-center collaborative research projects
Research Consent and Governance

♦ Plan to strengthen research consent for biobanking
  ▪ Revision of UHealth consent to lay groundwork for research using de-identified clinical data from electronic health record; plan to populate Research Registry via “universal ask” for permission to contact UHealth and JMH patients re future research studies.

♦ Plan for Trusted Governance
  ▪ Establishment of common governance elements for UM research (e.g., common governance policies, structural elements (committees, procedures), exception procedures such as feedback on health-related findings, etc.

Research Integrity

♦ Research Ethics Consultation Service (RECS): electronic access, CTSI Pilot Awards, system reviews (e.g., URIDE, specific collections)
♦ Collaboration with Software Carpentry to incorporate UM expertise in research and electronic system ethics around data management issues into a national scientist training program.
Intersection Project Interactions

- Consent and Governance project significantly involves collaboration with Biomedical Informatics (EHRs, URIDE), Bioresources (Pathology and HIHG); ultimately it will engage with Community Outreach and Marketing.

- Research Integrity efforts aim to “integrate research ethics into all aspects of UM”; as such, it has or will have synergies with all CTSI Programs.
FUTURE INITIATIVES

Major initiatives for the remainder of the grant

- Complete elements of Consent and Governance project.

- Develop additional Research Ethics Consultation projects.

- “Research on Research Ethics” activities
Program Highlight – #1

Enterprise Clinical Data Environment.

HIGHLIGHTS

- Program Highlight – #1
- Enterprise Clinical Data Environment.

Diagram:
- Data Warehouse
- Population Analytics Platform
- Alert Engine
- Patient Risk Score
- Algorithm Development and Testing
- Clinical Care
- Patient Care Intervention
- Care Coordination
- Epic EMR Chronicles
- Epic EMR Clarity
- Meditech EMR
- Genomic Data
- CoPath mTuitive
- DI Engine
- Honest Broker Engine
- Epic EMR
- Email
- SMS
**HIGHLIGHTS**

- **Program Highlight – #1**
  - Population Health Prototype

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**Table 1. Risk Factors for Undiagnosed Diabetes***

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Odds Ratio (95% CI)</th>
<th>P Value</th>
<th>Log (Odds Ratio)</th>
<th>Score Assigned</th>
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</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;40 y</td>
<td>Reference</td>
<td>–</td>
<td>–</td>
<td>0</td>
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<tr>
<td>40–49 y</td>
<td>2.6 (1.3–5.0)</td>
<td>0.004</td>
<td>0.95</td>
<td>1</td>
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<tr>
<td>50–59 y</td>
<td>4.8 (2.2–10.6)</td>
<td>&lt;0.001</td>
<td>1.57</td>
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<tr>
<td>≥60 y</td>
<td>8.1 (3.9–16.9)</td>
<td>&lt;0.001</td>
<td>2.09</td>
<td>3</td>
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<td>Sex</td>
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<td></td>
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<tr>
<td>Female</td>
<td>Reference</td>
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<td>–</td>
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<tr>
<td>Male</td>
<td>2.6 (1.8–3.7)</td>
<td>&lt;0.001</td>
<td>0.96</td>
<td>1</td>
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<tr>
<td>Family history of diabetes</td>
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<td>No</td>
<td>Reference</td>
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<td>–</td>
<td>0</td>
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<tr>
<td>Yes</td>
<td>2.0 (1.5–2.6)</td>
<td>&lt;0.001</td>
<td>0.67</td>
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<td>History of hypertension</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td>1.9 (1.2–2.9)</td>
<td>0.004</td>
<td>0.64</td>
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<tr>
<td>Obesity</td>
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<td>Not overweight or obese</td>
<td>Reference</td>
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<td>0</td>
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<tr>
<td>Overweight</td>
<td>1.3 (0.6–2.8)</td>
<td>0.47</td>
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<td>Obese</td>
<td>3.1 (1.6–5.8)</td>
<td>&lt;0.001</td>
<td>1.12</td>
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<td>Extremely obese</td>
<td>7.3 (4.0–13.4)</td>
<td>&lt;0.001</td>
<td>1.99</td>
<td>3</td>
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<td>Physically active</td>
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<tr>
<td>No</td>
<td>Reference</td>
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<tr>
<td>Yes</td>
<td>0.7 (0.5–1.0)</td>
<td>0.06</td>
<td>–0.34</td>
<td>–1</td>
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**Annals of Internal Medicine**

**Development and Validation of a Patient Self-assessment Score for Diabetes Risk**

Heejung Bang, PhD; Alison M. Edwards, MStat; Andrew S. Bombback, MD, MPH; Christie M. Ballantyne, MD; David Brillon, MD; Mark A. Callahan, MD; Steven M. Teutsch, MD, MPH; Alvin I. Mushlin, MD, ScM; and Lisa M. Keim, MD, MPH

**Background:** National guidelines disagree on who should be screened for undiagnosed diabetes. No existing diabetes risk score is highly generalizable or widely followed.

**Objective:** To develop a new diabetes screening score and compare it with other available screening instruments (Centers for Disease Control and Prevention, "TotalScore", "Reason 1", "Risk Assessment", ...) and AHA guidelines. The new algorithm and other methods were evaluated by standard diagnostic and feasibility measures.

**Results:** Age, sex, family history of diabetes, history of hypertension, obesity, and physical activity were associated with undiagnosed diabetes. In NHANES (ARIC/CHS), the cut-point of 5 or more in the TotalScore predicted a high rate of diabetes diagnosis. The new algorithm and other methods were evaluated by standard diagnostic and feasibility measures.
Your patient may be eligible to participate in a treatment study for her/his CANCER. Is it OK with your patient if a member of the study contacts her/him in person or by telephone to assess their eligibility to participate? If yes, please check the hyperlink below.
HIGHLIGHTS

Program Highlight - #2

♦ PI access to clinical data
  ♦ URIDE: Intuitive search tool for querying de-identified clinical and basic science data
  ♦ Establish Research Advisory committee for URIDE
  ♦ Develop a workflow for investigators to provide access to PHI/LDS data

Study Feasibility → Proposal → Funding → IRB Approval → Patient List → Patient Recruitment

URIDE - Expedites cohort assessments
Accelerates access to PHI – UChart/URIDE interfaces
Strengthens proposals with demonstrated patient populations
Facilitates patient recruitment
Intersection Project Interactions

- Ethics and Bioresource programs
  - URIDE
  - Universal Consent to participate in Research
  - Trusted Broker Organization
  - Biorepository
  - mTuitive
Department of Defense Awards ALS Drug Development Grant to Miller School Researchers

❖ Investigators:
  ♦ Michael Benatar, M.D., Ph.D., associate professor of Neurology and Chief of the Neuromuscular Division, and
  ♦ Zane Zeier, assistant scientist in Psychiatry and Behavioral sciences.

❖ Collaborators:
  ♦ Stephan Züchner, M.D., Ph.D., professor and interim chair of the Dr. John T. Macdonald Foundation Department of Human Genetics and Neurology director of the Center for Human Molecular Genomics at the John P. Hussman Institute for Human Genomics; and
  ♦ Joanne Wuu, Sc.M., research assistant professor of Neurology
You can search using the Search bar
As you type your disease of interest into the search bar, you will get two levels of suggested keywords.

- **Terms** refers to a text search through all the fields in the document
- **Concepts** refers to a search of the specific disease name
The results categories are on the top left.
The filtering options are below that.
The summary statistics of the entire search are on the top center, and the main body of the webpage contains the results, 20 per page.
Click on Update Search to activate these filters.
You can choose to view results in a bubble view by clicking on the button on the top right. The size of the bubble corresponds to the number of events seen under that title. You can click on each bubble to drill down to the information within it.
• You can choose to view a summary statistics page by clicking on the specific disease name on the results page.
You can choose a specific group of blood pressure values by hovering over the graph and interactively update the corresponding Pulse and BMI graphs.
Using Data to Ethically Integrate the Research and Patient Care Missions
Using Data to Ethically Integrate the Research and Patient Care Missions

How should we balance infrastructure investment with demand from funded studies?

How can we improve our consent processes without disrupting the patient experience?

Is it time to bring ‘research’ inside the covered entity?
Intersection Project Team

Jake McCauley
Nick Tsinoremas
Leah Bamford
Robin Fiore
Carmen Gomez
Richard Cote
Janice Adelman
Stephen DeGennaro
Reid Cushman
Luz Maristany
Ken Goodman
Sophie Egea
Joe Zeitouni
David Seo
Nadia Fertil
Paul Braunschweiger
+ many more ...

Rosalina Das
Jonelle Wright
Sylvia Morales
Richard Bookman
Elaine Van Der Put
Patricia Avissar
Daru Ransford
Carlos Sandoval

Calendar Ninja:
Lynn Suarezapecheche
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**Intersection Project**
**Consent and Governance**
- Requires significant collaboration and cooperation to execute
- Multilayered decision-making involving independent institutional actors with different priorities.
- Any change is an investment amortized across time and across institutional units with varying timescales-to-benefit.
- Implementation requires identifiable budget resource and accountable executive.

**Metrics**
- Lack of available or practical metrics for measuring impact on research integrity ... the problem of measuring the negative (actions that did not occur)
- Demonstrating ethics as supportive and not punitive
BioInformatics Program’s major initiatives for the remainder of the grant

- On-going development of the Enterprise and Research Data Environments
- Advance URIDE functionality
- Continue Roll Out of UCHART Clinical Research and Business Intelligence Capabilities
- Extend Educational and Training Programs with new constituencies – School of Nursing.
- Participate and support CTSI programs initiatives
Key BioResource Elements

- A major strength is the diversity of our unique population and the ability to provide biospecimens for multi-center collaborative initiatives.

- Our BioResource collaborative currently supports a number of large “Team Science” projects across a number of NIH-funded disease phenotypes.

- We need to extend our interactions across the state of Florida to increase our overall visibility and to strengthen our collaborative network.
Key Research Ethics Elements

- UM’s Bioethics Program has been and will remain a “universal donor” to other CTSI components
- Research Ethics supports or contributes to all four “strategic goals” in the new RFA
- Research Ethics supports or contributes to efforts to meet IOM recommendations