



Center for Clinical  
& Translational  
Science & Training



## How to Leverage CTSA Resources for Research

James E. Heubi, M.D.  
NASPGHAN Workshop  
October 10, 2015



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## Financial Disclosures

- Equity interest in Asklepiion Pharma, LLC.
- Funding: NCATS, NIDDK, NICHD, and CFF
- Consultant to Nordmark, Retrophin
- Supported by grants from NCATS, NICHD, NIDDK, CFF



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## CTSA Consortium Mission/Vision: CTSA Version 2.0

- Mission: To strengthen and support the entire spectrum of translational research from scientific discovery to improved patient care
- Efforts directed at:
  - Translational research training
  - Data sharing and informatics tools
  - Innovative collaborations
  - Multi-study regulatory hurdles
  - Patient recruitment
  - Other key areas related to research in humans






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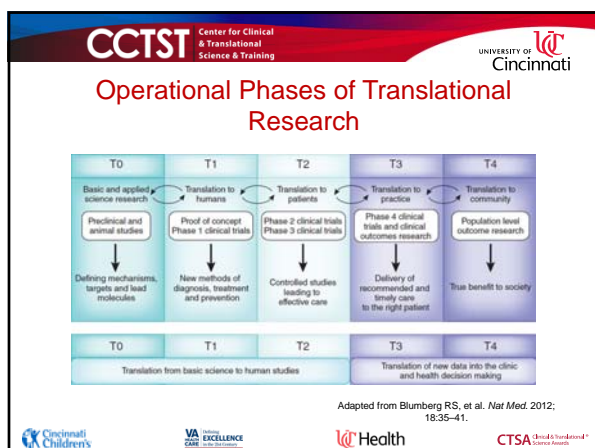
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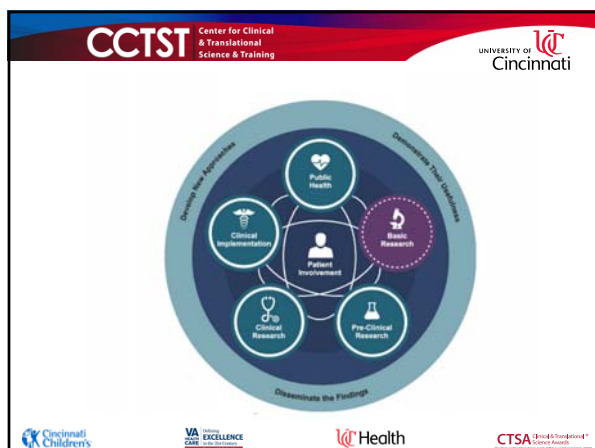
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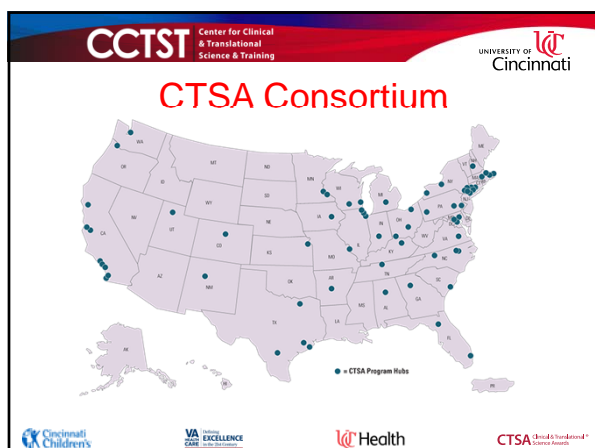
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- CCTST** Center for Clinical & Translational Science & Training
- CTSA Hub Services**
1. Workforce Development
  2. Pilot and Collaborative Studies
  3. Biomedical Informatics
  4. BERD (Biostatistics, Epidemiology, and Research Design)
  5. Participant and Clinical Interactions (aka GCRC)
  6. Regulatory Knowledge and Support
  7. Community Engagement and Research
  8. Multicenter trials
  9. Recruitment support(special populations)
  10. Optional Modules
- Logos at the bottom: Cincinnati Children's, VA Medical Center, University of Cincinnati, Health, and CTSA (Broad & Translational).

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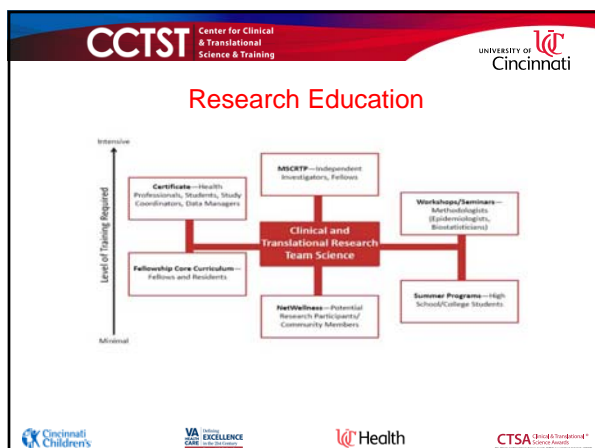
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## Research Education

- MS in Clinical and Translational Research
  - 30 hours + thesis
  - Tracks
    - Clinical epidemiology/clinical effectiveness
    - Molecular epidemiology
    - Clinical trials
    - Translational research
    - Clinical research informatics
- Certificate in Clinical and Translational Research
  - 14 credit-hours
  - Course available on-line version and can be applied to MSCTR if desired

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## Career Development

- K23 Development Award preparation program
  - Library of funded grants
  - Technical writing assistance
  - Internal reviews
- KL2 program
  - Funding for career development as intermediate between faculty appointment and individual K or R award
  - Support for 75% protected time with \$25K for supplies
  - Number of scholars dependent upon size of program
  - 2-year appointments with some programs longer
- K Club
- Mentorship training

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## Research Education

- Research on Demand
- Fellowship (and residents) research training
  - Covers 14 competencies as defined by ABP/ACGME
- High school, college, and health professional student programs
- Educational Forums

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## Pilot Grants

- Funding priorities
  - New clinical/translational investigators
  - Basic scientist/clinician collaborations
  - Interdisciplinary studies, esp. multi-institutional (UC-CCHMC-VAMC)
- New initiatives
  - Processes/Methods
    - Novel methodologies in informed consent, streamlining review process, returning results of genetic studies, tools to enhance research at bedside, enhanced recruitment techniques






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## Examples of Pilot Grants at CTSA's

- T1 grants @ \$50-100k
- "Junior" T1 grants @ \$25K
- Processes/Methodology Grants (NEW)
- Methodology/Research Ethics grants @ ~\$8-10K
- GCRC CReFF grants @ \$20K
- Just-in-Time core grants @ \$7,500K
- Retreat grants @ \$3K (+ departmental match)
- Community Health grants: @ ~ \$10-15K
- Outcomes/Health Services grants @ \$60K

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## Biomedical Informatics

- Data warehousing
  - De-identified or identified i2b2 datasets
  - Genomics datasets
  - Protein modeling/small molecule screening datasets
- Support for other functions with the Hub
- Education
- REDCap

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- Secure, web-based application designed to support data capture for prospective clinical research studies, built using open source products PHP and MySQL with an EAV data model.
- Metadata-driven software which relies upon a unique metadata-gathering methodology and automated code writing.
- REDCap was initially developed at Vanderbilt University, which holds the copyright, and is now licensed to partner institutions that provide collaborative support.
- Today REDCap supports 191,000 projects with 263,000 users from 1,573 institutions in 92 countries from all of REDCap's collaborating institutions <http://project-redcap.org>

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## What REDCap provides

- A simplified methodology for building databases quickly and easily: modifications are available in 2 working days
- An intuitive interface for data entry (with data validation)
- Audit trails for tracking data manipulation and export procedures (HIPAA compliant)
- Automated export procedures for seamless data downloads to common statistical packages (SPSS, SAS, Stata, R)
- Create surveys to collect data with analysis capabilities
- Library of surveys that can be used for research

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## REDCap Practical Matters

1. Submit Project Intake Form
2. Requirements
  - System Access
  - Non-employee REDCap access for external users
  - Training (~2 hr) for primary contact
  - Responsible use of a limited resource
3. Cost to investigator
  - Cite grant for support
  - No direct cost to investigator
  - Ask PI to request funds in new grant
4. <http://redcap-project.org>






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## Biostatistics, Epidemiology, and Research Design (BERD)

- One-stop shopping through Research Central – National model
  - Serves as a concierge service to support investigators working to develop careers in biomedical research with focus on grant submissions
  - 1 hour consultant service to define needs of investigator
    - Support focused on faculty with promising careers with K awards or working on R series awards
  - Vouchers for up to \$2,000 given for needed services with biostatistical, study design and data management

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## Regulatory Knowledge & Support

- Identify efficient methods to expedite time from development of protocol to first enrolled subject
  - Reliance agreements between sites
  - Templated contract language across sites
- Special symposia on topics relevant to research ethics, e.g. conflict of interest, responsible authorship, research vs. standard of care



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## Participant and Clinical Interactions

- Support patient oriented research across the AHC and community
- Inpatient/outpatient facilities
  - Specialized services: metabolic kitchen, DXA, imaging, processing samples, core laboratory
- Scatter bed facilities
- Voucher support for ancillary studies/services
- Identify opportunities in the community

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## Community Engagement

- Bidirectional partnership between AHC and community designed to foster CBPR
- Broader definition of "community" to include initiatives developed by PCOR and Learning Health Networks like ICN
- Educational opportunities: CBPR on-line module: Introduction to Community Based Participatory Research
- Practice-based research networks
- Speaker Series
- Community training:
  - Leaders Institute – National model
- Community Health Grants
- Research Match






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## What is *researchmatch.org*?

- A national partnership to create a centralized, web-based recruitment registry that will connect willing volunteers with researchers and their studies
  - An initiative funded by the NCATS Clinical & Translational Science Awards
  - Launched September 2009








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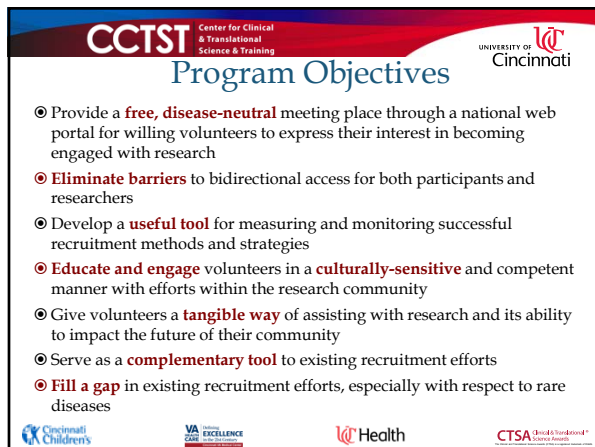
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## How will *researchmatch.org* work?

**Step 3:** (Volunteer's privacy is maintained – researcher cannot yet see personally identifiable information)

**Step 4:**

**Logos:** Cincinnati Children's, VA Medical Center, University of Cincinnati Health, CTSA

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## How will *researchmatch.org* work?

**Step 5:** YES NO

**Step 6:** YES

**Logos:** Cincinnati Children's, VA Medical Center, University of Cincinnati Health, CTSA

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## Additional Questions?

For more information, please contact

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

**Logos:** Cincinnati Children's, VA Medical Center, University of Cincinnati Health, CTSA

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Multisite Study/Recruitment

- Specific emphasis on supporting multicenter trials funded by PHS or foundations
- Provides support for regulatory issues and recruitment
- Support for recruitment of specialized populations
- Each Hub will have specific response to this requirement






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Optional Modules

- Up to 3 areas that CTSA hub focuses efforts
  - Acute Care
  - Diseases across the lifespan
  - CHAMP: Multiple pediatric sites working together for multisite trials
    - Dan Cooper, UC Irvine; Lisa Guay-Woodford, National Children's-GW

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Regional/National CTSA Networks

- Emphasis on CTSA hubs working together
  - Support multicenter trials through TICs
  - Support recruitment efforts through RICs
  - IRB reliance agreements
  - cIRBs
  - Common contracting language






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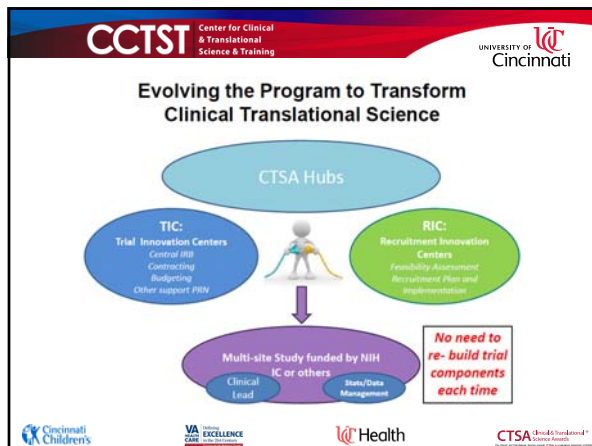
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### Support for Multicenter Trials

- New elements within CTSA FOA for support of multicenter trials and recruitment:
- RICs
  - Fund up 3 sites to support recruitment across CTSA consortium
- TICs
  - Fund 3 central cores to support multicenter trials including creating cIRB and common contracting
  - Plans for geriatric, adult and possibly pediatric

Cincinnati Children's, VA Medical Center, Health, CTSA Award & Translational

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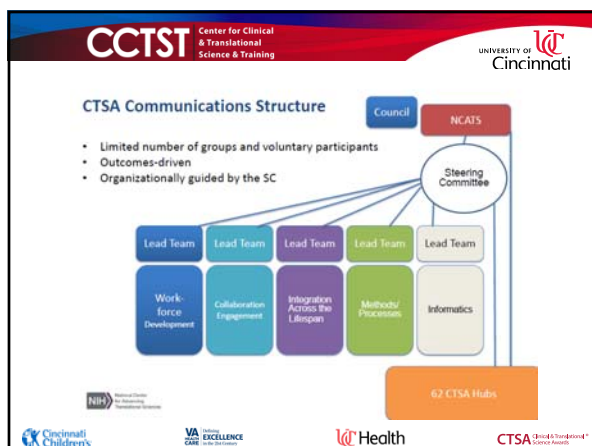
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