



Update on the Clinical and Translational Science Award (CTSA)

Gary E. Rosenthal, MD

*Professor of Internal Medicine and Health
Management and Policy*

*Interim Director, Institute for Clinical and
Translational Science*

February 10, 2011



Overview of Presentation

- Key objectives of the NIH CTSA initiative
- Individual components of the award and the specific activities encompassed within components
- Major accomplishments during initial funding cycle
- New directions and priorities



Overview of NIH CTSA Initiative

- Overarching Goal
 - Create integrated infrastructure in universities for promoting clinical and translational research and eliminate intra-institutional silos
- Consolidate legacy programs funded by NCRR supporting clinical research (GCRC, K30, & K12)
- 55 awards nationally with plan to increase to 60
- UI funded in 2007 (2nd cohort)
 - **\$34.1 M total costs**
 - **\$25.0 M direct costs / \$9.1 M indirect costs**

Key Aims of NIH CTSA Initiative

- Incubate new cross-disciplinary collaborations and high impact research across the spectrum of translational science

T1



Translation to Humans

- *Animal models of human disease*
- *Phase 1 & 2 clinical trials*

T2



Translation to Patients

- *Phase 3 clinical trials*
- *Uncontrolled observational studies*

T3



Translation to Practice

- *Phase 4 clinical trials*
- *Comparative effectiveness studies*

T4



Translation to Populations

- *Health policy analyses*
- *Social determinants of health*

Key Aims of NIH CTSA Initiative (cont.)



- Decrease administrative and regulatory barriers to translational research
- Recruit & train outstanding scholars from diverse disciplines and support their career development
- Build bidirectional relationships with community organizations using participatory research models
- Enhance public trust in clinical research enterprise

Components of CTSA Award

- **K Component** – career development awards for junior investigators
 - *9 concurrent awardees; ~ \$1.0 M per year*
- **T Component** – stipends for PhD students in Translational Biomedicine and other programs
 - *7 concurrent awardees; ~ \$ 200K per year*
- **U Component** – research support functions, pilot grants, community-based research, informatics initiatives, development of novel translational research methods
 - *~ \$ 3.9 M per year*



Key Accomplishments: Governance and Collaborations

- Developed cross-disciplinary education and research programs involving investigators and trainees from 9 UI colleges → ***Medicine, Public Health, Dentistry, Nursing, Pharmacy, Liberal Arts, Engineering, Education, & Law***
- Seamlessly integrated UI's 3 NCRRL legacy awards (GCRC, K30, K12) and established new governance structure that reports to UI Provost
- Established synergistic relationships with Holden Cancer Center and other UI centers to better leverage resources → ***Oncology trials in CRU***



Key Accomplishments: New Services and Training Programs

- Expanded and increased access to consultative services that span the research continuum:
 - *study planning and design;*
 - *regulatory approval;*
 - *study coordination;*
 - *data management and statistical analysis;*
 - *bioinformatics and genomics support;*
 - *dissemination of findings;*
- Created new education and training programs for graduate students, fellows, junior faculty, & research personnel → **~ 150 participants**



Key Accomplishments: Community Engagement

- Established new partnerships with federally qualified health centers (FQHCs), which serve socially and economically disadvantaged patients, in four Iowa communities → ***Des Moines, Sioux City, Davenport, and Waterloo.***
- Developed new partnership with the ISU Extension Service and have initiated projects in the areas of nutrition and obesity prevention.



Key Accomplishments: Additional ARRA Funding

- Obtained funding for 5 ARRA CTSA supplement awards → **\$2.8 M in total costs**
 - *Develop institutional capacity in CER*
 - *Develop online library of courses in key areas of clinical and translational research*
 - *Expansion of existing pilot grant program*
 - *Pilot program for new collaborations between faculty from basic science & clinical departments*
 - *Community-based registry of patients with sarcoidosis*



Key Accomplishments: Novel Translational Methods

- Developed protocols for creating biorepositories and completed in-depth study examining Iowans' attitudes about using stored tissue samples for future research and on how to structure informed consent process
- Fostered new cross-disciplinary work between faculty in Chemistry and Medicine and Dentistry in nanotechnology that led to development of new materials (*nanocrystalline zeolites*) and 2 patents



Key Accomplishments: Informatics

- High performance cluster computing network to store data for high volume users (genetic and imaging data)
- Automated process that integrated applications for obtaining IRB and CRU approval
- Implemented new software for storing imaging data from variety of modalities (CT, MRI, US, PET)
- Developed prototype disease registries from the UI's Epic EMR



New Priorities and Directions

1. Build capacity in areas that are likely to be well funded over next 5-10 years
 - *Comparative effectiveness research → focus of new agency (PCORI) with \$700M annual budget*
 - *Drug discovery and development → focus of new NIH center (NCATS)*
2. More actively support commercialization of promising discoveries
 - *Educational conferences and consultation on invention disclosure and patent application processes and protection of intellectual property*
 - *Development of vignettes on investigators who have successfully filed patents and started companies*
 - *Pilot grants for work on invention disclosures*

New Priorities and Directions

3. Revise Clinical Research Unit business model
 - *Currently 50% of “U” budget supports CRU*
 - *Implement new cost recovery model for industry & NIH grants and lower personnel costs via UIHC partnership*
 - *Use savings to provide broader range of services (e.g., study coordination, data analysis)*

4. Partner with VPR and colleges and centers to overcome barriers to translational research
 - *VPR → more effective IRB for community-based studies*
 - *CCOM, COPH, COE → capacity in bioinformatics*
 - *VPR, CCOM, COP → high throughput analysis*
 - *CCOM, Cancer Center → biorepository development*

New Priorities and Directions

5. Improve communications with collegiate leadership and faculty to disseminate information about ICTS programs and services
6. Maintain institutional commitment (nationally 35% of CTSA budgets derived from institutional sources)
7. **Submit successful reapplication in June 2011**