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

<table>
<thead>
<tr>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Translation to Humans</td>
<td>Translation to Patients</td>
<td>Translation to Practice</td>
<td>Translation to Populations</td>
</tr>
<tr>
<td>Animal models of human disease</td>
<td>Phase 3 clinical trials</td>
<td>Phase 4 clinical trials</td>
<td>Health policy analyses</td>
</tr>
<tr>
<td>Phase 1 &amp; 2 clinical trials</td>
<td>Uncontrolled observational studies</td>
<td>Comparative effectiveness studies</td>
<td>Social determinants of health</td>
</tr>
</tbody>
</table>
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 NCRR 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**