The Clinical and Translational Science Award program is a new NIH (NCRR) program designed to transform the conduct of clinical and translational research in academic medical centers.

The CTSA program derived from the NIH Roadmap and reflects a new federal approach.

CTSA sites will replace GCRC sites:
- Our GCRC will / would have expired 31 Mar 2010
- We do not have the option of doing it the old way

Our CTSA is housed within the UT Institute for Translational Sciences [ITS]
Focus on MTT

- Translational science ever more requires many sets of expertise – rarely does a single investigator have all the requisite skills.
- MTT projects are expected to result in extramural funding:
  - R01 applications may result, but..
  - P01 and P50 applications will have a head-start due to the team’s productivity.
- Publication strategy can take advantage of the varied expertise in the team, resulting in more papers from a given body of work.
Advantages of the Team Approach

- Complementarity
- Redundancy
- Synergy
- Multiplicity
- Training and Education
- Management
## Comparing GCRC and CTSA

<table>
<thead>
<tr>
<th>Attribute</th>
<th>GCRC</th>
<th>CTSA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovative human research</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Inpatient focus</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Outpatient focus</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Resources to support ancillaries, personnel</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Ancillaries, personnel, resources from your grant</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Strong infrastructure to encourage innovation, efficiency</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Business management for projects</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Multidisciplinarity encouraged to support complex projects</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Range of support available for projects</td>
<td>narrow</td>
<td>broad</td>
</tr>
</tbody>
</table>
Multi-disciplinary Translational Team [MTT]
Project Flow

<table>
<thead>
<tr>
<th>Phase</th>
<th>Concept</th>
<th>Design</th>
<th>Implementation</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal</td>
<td>Investigator-initiated / ICSTA-identified opportunity</td>
<td>Innovation</td>
<td>OnTime OnBudget</td>
<td>New Funding</td>
</tr>
<tr>
<td>ICTSA Resources</td>
<td>Technology (new approaches)</td>
<td>Cost-Efficiency Feasibility</td>
<td>Quality</td>
<td>Commercialization</td>
</tr>
<tr>
<td></td>
<td>Novel Methodology (innovative analytics)</td>
<td></td>
<td>Data Quality</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td>Ethics (framing research question)</td>
<td></td>
<td>Regulatory (monitoring)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td>Pilots (fiscal support)</td>
<td></td>
<td>Bioinformatics (data mining)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td>Writing Resource (document preparation)</td>
<td></td>
<td>Pilot (funding)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PCIR (Recruitment)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Novel Methods (sample analysis)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Community (awareness of project)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evaluation (metrics)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Regulatory (FDA interface)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Ethics (subject protection)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Evaluation (metric achievement)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Community Engagement</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(convey results of study)</td>
<td>New Funding</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Commercial Partners (product development)</td>
<td>New Funding</td>
</tr>
</tbody>
</table>

Resources Released for New Projects
Overview of the MTT Process

- Team Conception
- Team Initiation and Project Selection
- Project Management
  - Needs Assessment
  - Resource Allocation
  - Timeline Agreement
  - Project Management Processes
  - Project Completion
- New Project Identification

NOTE: The MTT is not the same as an MTT Project
One MTT may design and execute several projects
MTT May Execute Several Projects
CTSA Resources Support Projects
Steps to Success

MTT Initiation Mtg
[Plans, Concepts]

MTT Workgroup
[Internal clarifications for Project]

MTT Followup Mtg
[Operations, Resources, Metrics, Timelines, Deliverables]

CTSA Operations Cmte Mtg
[Formal request for CTSA Resources for Project]

CTSA Resource Allocation
[Fiscal, logistical, technologic, human resources]

Project Initiation
[IRB, role assignments, space, timing of resource delivery]

Project Execution
[Data collection, interim and final analyses, ‘mid-course corrections’]

Project Completion
[Manuscript, funded grant application, patent, commercial product]

Measurement, Feedback, Resources
Terms and Definitions

- **Vision**
  - A concise statement of why your MTT exists, **focused on improving health outcomes**, and provides guidance for strategic decision making.
  - Our vision is to improve the health of patients with ____, by developing valid biomarkers of disease and using them to improve patient care.

- **Goal / Aim / Mission**
  - The purpose for which your MTT exists, and what you aim to accomplish; specificity is key.
  - We will analyze serum from patients with _____ and from healthy controls to define differentially expressed proteins that associate with disease presence.
Terms and Definitions

- **Metric**
  - A quantitative means of measuring progress
  - *Number of subjects enrolled*

- **Milestone**
  - A qualitative achievement
  - *Paper published, grant funded, etc*

- **Benchmark**
  - An external reference point against which to judge your MTT
  - *JHU developed a biomarker for lung cancer in 3 years*

- **Timeline**
  - A framework of objective achievement scaled to the project duration
  - Timelines are estimates, and can be modified, but should not be viewed as completely elastic
  - *We will enroll 200 subjects in the first 12 months. We will enroll 100 controls in the ensuing 6 months. We will complete the analysis of our samples by month 24. We will publish our findings by the end of year 3.*
Terms and Definitions

- **Success Criterion (criteria)**
  - Succinct description of an outcome which would define success for your MTT
  - Our MTT project generated preliminary data which resulted in funding for an R01 grant application

- **Failure Criterion (criteria)**
  - Description of circumstances or outcome which would reasonably predict that the project (not the MTT) should not expend further CTSA resources
  - Insufficient patients with _____ can be identified in the Houston-Galveston metro area to complete this work
Terms and Definitions

SWOT ANALYSIS

<table>
<thead>
<tr>
<th>Internal origin</th>
<th>Helpful to achieving the objective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strengths</td>
<td></td>
</tr>
<tr>
<td>Weaknesses</td>
<td>Harmful to achieving the objective</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>External origin</th>
<th>Opportunities</th>
<th>Threats</th>
</tr>
</thead>
</table>

(Attributes of the organization)
Outline the changing landscape of NIH/NCRR programs

Highlight differences between the old GCRC and the new CTSA

Provide a framework for understanding how MTTs will function in the CTSA

Establish common language for discussing project management

Generate a list of next steps and actions