Administrative Supplement Progress Report  
UL1RR024150-04S1  
NCRR ARRA funded Administrative Supplement for CTSA Consortium Strategic Goals  
Linked supplement with the Yale Center for Clinical Investigation  
Project Leader: David O. Warner, MD

A. Specific Aims  
This linked collaborative project between the Mayo Clinic Center for Translational Science Activities (Mayo Clinic CTSA) and the Yale Center for Clinical Investigation (YCCI) explores opportunities to exchange best practices, administrative and regulatory support models, and related infrastructure supporting clinical research to minimize barriers to the initiation of research and provide timely access to exceptional support resources for our investigative faculty.  
Aim 1: Identify and assess feasibility of potential areas of collaboration that leverage the unique strengths of Mayo Clinic CTSA and YCCI in the initiation and support of research protocols  
Aim 2: Develop and implement a collaboration model(s) for the sharing of specific best practices, expertise and technologies between Mayo Clinic CTSA and YCCI  
Aim 3: Disseminate the collaboration model(s) to CTSA consortium members  

B. Progress on Specific Aims  
Dr. David Warner, CTSA Associate Director and Director, Community Engagement assumed primary responsibility as project leader as of January 1, 2011 replacing Dr. M. Joyner. Ms. Jaci Gosse assumed the project lead role for Project 4, Diversity and Patient Care Recruitment Strategies. Mr. Muhnaz Hirzallah replaced Ms. M. Andresen-Reid as project lead for Project 6, IRB Process Mapping. See Table 1 for list of projects and project leads. The Oversight Group determined that the scientific collaboration project (Project 2, Cancer Center Integration) will be pursued separately as it falls outside of the scope of this supplement.

### Table 1: Current Project Work Teams and Leads

<table>
<thead>
<tr>
<th>Project</th>
<th>Mayo Lead</th>
<th>Yale Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project 1: Leveraging Mayo Action Project</td>
<td>C. Nelson</td>
<td>S. Scirocco</td>
</tr>
<tr>
<td>Project 3: Education Protocols</td>
<td>L. Carlson</td>
<td>S. Anderson</td>
</tr>
<tr>
<td>Project 4: Diversity &amp; Patient Recruitment</td>
<td>J. Gosse</td>
<td>F. DePourcq</td>
</tr>
<tr>
<td>Project 5: ORS/Service Center</td>
<td>K. Hartman</td>
<td>S. Scirocco</td>
</tr>
</tbody>
</table>

Project oversight is accomplished through an Oversight Group (Table 2) which continues to meet on a monthly basis via conference call. The group ensures progress on agreed milestones and deliverables, coordinates face-to-face meetings, addresses barriers and communicates with CTSA leadership. Project teams also met regularly buttressed by the following face-to-face meetings:  
- Ad hoc meeting in conjunction with June 21-22, 2010 NCRR sponsored Clinical Research Management Workshop in Washington, DC  
- November 3-4, 2010 meeting at YCCI  
- May 5, 2011 meeting at Mayo Clinic (scheduled)  
- September 2011 at YCCI (planned)  

In addition, YCCI and Mayo personnel presented interim results for two projects – Education Protocols (Project 3) and ORS/Service Center (Project 5) at a Regional Clinical Research Management Workshop sponsored by YCCI on February 22, 2011 in New Haven, CT.

### Table 2: Oversight Group

<table>
<thead>
<tr>
<th>Member</th>
<th>Organization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tesheia Johnson, Chief Operating Officer</td>
<td>Yale CCI</td>
</tr>
<tr>
<td>Cheryl Nelson, Associate Director Administration</td>
<td>Mayo Clinic CTSA</td>
</tr>
<tr>
<td>Michael Pfenning, Director Administration</td>
<td>Mayo Clinic CTSA</td>
</tr>
<tr>
<td>Stacey Scirocco, Associate Director</td>
<td>Yale CCI</td>
</tr>
<tr>
<td>Robert Sherwin, MD Director</td>
<td>Yale CCI</td>
</tr>
<tr>
<td>David Warner, MD Associate Director, Community Engagement</td>
<td>Mayo Clinic CTSA</td>
</tr>
</tbody>
</table>
Grant Number: RR024150
Principal Investigator: Robert A. Rizza, M.D.

Substantial progress has been made in the second year of this supplement. In general, all remaining projects are pursuing implementation and evaluation strategies as reported below. See Table 3 for a summary of progress and accomplishments to date across all specific aims.

Specific Aim 1 Progress Update
- Knowledge overview and transfer completed; project assessments completed; benchmarking completed; internal administrative and/or legal reviews completed; and project adoption determinations completed for all projects

Specific Aim 2 Progress Update
- Program implementation strategies have been developed for all projects and are being implemented or have been completed
- Implementation lessons learned and evaluation plans are in active development

Specific Aim 3 Progress Update
- Interim results associated with projects 3 (Education) and 5 (ORS/Service Center) were shared at a regional clinical research management workshop.
- As project implementation proceeds increasing emphasis will focus on evaluation and dissemination to the broader community

Table 3: Summary of Progress

<table>
<thead>
<tr>
<th>Project List</th>
<th>Yale Knowledge</th>
<th>Mayo Knowledge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project 1 – Leveraging the Mayo ACTION Project</td>
<td>Share project tasks and timelines</td>
<td>X</td>
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<tr>
<td></td>
<td>Quality Academy (out of scope project addition)</td>
<td>X</td>
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<tr>
<td>Project 2 – COC Integration</td>
<td>Integration strategies for COC/CTSA collaborations</td>
<td>X</td>
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<tr>
<td></td>
<td>Quality Assurance</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Scientific Collaboration (out of scope project addition)</td>
<td>X</td>
</tr>
<tr>
<td>Project 3 – Education Protocols</td>
<td>Continuing education and professional development content</td>
<td>X</td>
</tr>
<tr>
<td>Project 4 – Diversity and Patient Recruitment</td>
<td>Development of support infrastructure to assist investigators</td>
<td>X</td>
</tr>
<tr>
<td>Project 5 – ORS/Service Center</td>
<td>Yale Office of Research Services</td>
<td>X</td>
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<tr>
<td></td>
<td>Research staff post</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>clinical trials gov. management</td>
<td>X</td>
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<tr>
<td>Mayo Statistical Center</td>
<td>X</td>
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<td></td>
<td>FDA audit guide and site prep</td>
<td>X</td>
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<tr>
<td></td>
<td>Study File management</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>clinical trials gov. management</td>
<td>X</td>
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<td></td>
<td>Automated Publication Tracking (Phase I)</td>
<td>X</td>
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<tr>
<td></td>
<td>IND/DC tracking database (Phase II)</td>
<td>X</td>
</tr>
<tr>
<td>Project 6 – IRB Process Mapping</td>
<td>IRB process improvements</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Time Study Regulatory Collaboration</td>
<td>X</td>
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<tr>
<td></td>
<td>Template application language</td>
<td>X</td>
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<tr>
<td></td>
<td>Quality improvement initiatives</td>
<td>Y</td>
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<tr>
<td></td>
<td>Research Subject Advocate program</td>
<td>X</td>
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<tr>
<td></td>
<td>Community partner tech I</td>
<td>X</td>
</tr>
</tbody>
</table>

C. Accomplishments - By Project

Project 1
This project focuses on sharing information, practices and tools developed by Mayo Clinic as part of an in-depth assessment/process improvement of business processes associated with clinical protocol development through protocol activation.

- Share project charter, deliverables and findings with YCCI team - complete
- Identify tools of interest to YCCI – in process

Project 3
The overall goal of this project is to improve educational and training opportunities and competency for clinical research staff by establishing best education practices, identifying learning needs, developing processes to share content, and evaluating the ability to implement at each institution.

- Comprehensive continuing education and training program content and evaluation
Grant Number: RR024150
Principal Investigator: Robert A. Rizza, M.D.

- Share program content and evaluation data - complete
- Identify and prioritize content for transfer and implementation at YCCI – complete
- Developed license agreement template - complete
- Collect YCCI survey data to assess current program resources and training needs – in process
- Develop evaluation and dissemination plan to facilitate sharing/adoption by other CTSA's (e.g., implementation timelines, resource needs, content transferability, barriers, learner feedback) – in process

**Clinical research coordinator competencies and job descriptions**
- Share Mayo competencies and draft job descriptions (protocol development, research regulations, study implementation, study management/execution, professional development) - complete
- Evaluate and develop YCCI specific job descriptions and competencies – in process
- Develop evaluation and dissemination plan to facilitate sharing/adoption by other CTSA's (e.g., implementation timelines, resource needs, content transferability, barriers, learner feedback) – in process

**Clinical research coordinator Academic Associate in Applied Science and Diploma Program**
- Share Mayo/local community college clinical research coordinator program with YCCI – complete
- Assess feasibility of adapting program with YCCI/local community college – in process (Note: this is a long-term project expected to take three or four years to implement)
- Develop evaluation and dissemination plan to facilitate sharing/adoption by other CTSA's (e.g., implementation timelines, resource needs, content transferability, barriers, learner feedback) – in process

**Project 4**
The goal of this project is to identify and share practices and strategies for effective diversity and patient recruitment.

- **Infrastructure to assist investigators in community engaged research**
  - Share Mayo Ambassadors Program with YCCI - complete
  - Assess program adaptation at YCCI – complete
  - Develop program implementation plan at YCCI – complete
  - Implement Ambassadors Program at YCCI – complete at two community organizations
  - Develop and evaluate implementation and assess broader adoption by other CTSA's – in process

- **Marketing to promote clinical trials**
  - Share YCCI marketing campaign to promote clinical trials – complete
  - Develop legal agreements with third party – complete
  - Assess program adaptation at Mayo – complete

- **We-based resource/tool development**
  - Share respective strategies for assisting investigators with completing target recruitment tables – in process
  - Share Mayo developed criteria for review community engaged research – in process

**Project 5**
This project's aim is to enhance the research regulatory support services available to clinical and translational research. Next steps for all elements of this project are to (i) develop lessons learned and (ii) assess broader application and dissemination strategies for the consortium.

- **Centralized coordination for FDA audits**
  - Share Mayo tools and templates with YCCI – complete
  - Assess and develop implementation plan – complete
  - Implementation – in process pending new hires

- **Study file management**
  - Share Mayo tools, templates and knowledge with YCCI – complete
  - Assess and develop YCCI implementation plan – in process with initial web based implementation complete

- **Research assistant/nursing pool for investigators**
  - Share YCCI process and knowledge with Mayo – complete
  - Assess opportunity - complete
  - Implementation strategy – complete with decision by Mayo not to implement

- **Informatics solutions**
D. Challenges

- Time pressures occasioned by the pending submission of respective CTSA competitive renewals was effectively managed via a coordinated project management approach note above.
- Mayo Clinic CTSA’s continued efforts to recruit a Director for its Office of Community Engaged Research has slowed progress on this project.
- Internal legal review of agreements and related documents has led to substantive delays.

E. Status of all milestones on timeline

In general, all projects continue to make excellent progress. However, it is estimated that an unobligated balance greater than 25% of the current year's budget will remain at the end of the grant period. It is anticipated that a request for a no-cost extension will be made. The remaining unobligated balance is primarily due to absences in key personnel positions such as the Office of Community Engaged Research director, delays in internal review of agreements, and efforts for both sites on the CTSA competitive renewal.

F. Plans for Balance of Project Period

- Complete evaluation template and conduct evaluations of all projects
- Complete dissemination strategies and communicate findings to consortium