May 18, 2009

Clinical and Translational Science Activities Program  
National Center for Research Resources  
National Institutes of Health  
6701 Democracy Blvd., MSC 4874  
Bethesda, MD 20892-4874

To Whom It May Concern:

Enclosed is a request for a Recovery Act Administrative Supplement to the Mayo Clinic Center for Translational Science Activities (CTSA) grant in response to the CTSA Consortium Strategic Goals topic. This is a linked collaborative project with the Yale Center for Clinical Investigation.

Mayo Clinic CTSA Parent Grant: UL1 RR024150  
Title: "Mayo Clinic Center for Translational Science Activities"  
Principal Investigator: Robert A. Rizza, MD  
Rizza.Robert@mayo.edu  
(507) 284-7571

Project Leader: Michael J. Joyner, MD  
joyner.michael@mayo.edu  
(507) 255-4288

Total Request: $300,000

Yale University CTSA Parent Grant: 1 UL1 RR024139  
Title: Clinical and Translational Science Award  
Principal Investigator: Robert S. Sherwin, MD

Sincerely,

Allison Hart  
acting for  
Cheryl Nelson  
Institutional Official  
Mayo Clinic Rochester  
Office of Sponsored Projects Administration  
200 First Street SW  
Rochester, MN  55905  
researchadmin@mayo.edu  
(507) 284-4715
May 14, 2009

Robert Rizza, M.D.
Principal Investigator and Director
Mayo Clinic Center for Translational Science Activities
200 First Street SW
Rochester, MN 55905

Re: NCRR Administrative Supplement for CTSA Consortium Strategic Goals

Dear Bob,

I am writing to express my delight and appreciation that the Mayo Clinic CTSA has agreed to participate in the Yale CTSA and Yale Center for Clinical Investigation administrative supplement application under the area of CTSA Consortium Strategic Goals, addressing Goal # 1 — Clinical and Translational Research Management Capability. This linked collaborative project between our two CTSA institutions will be a great opportunity to exchange best practices, regulatory programmatic support models, and technologies that can reduce regulatory and administrative barriers to the initiation of research protocols and to ensure quality assurance and access to support resources for our investigative faculty.

As part of the first cohort of the CTSA consortium, the Mayo Clinic and Yale University enjoy a unique working relationship and is another example how two institutions both with successful research track records can work together in the common interest of promoting and advancing translational research through out the nation. We look forward to exchanging and sharing best practices models and lessons learned for practical support services for investigators, including our quality assurance and compliance program, integration with our Cancer Center (CCSG), and our regulatory toolkit to facilitate IRB approval and partnerships to promote community-based research. We on the other hand are tremendously excited to draw upon the Mayo Clinic's strengths in IND development and compliance, disparities outreach and patient recruitment and retention strategies, and the Mayo Clinic's technologies developed specifically to support clinical research management functions.

This linked effort between the Mayo Clinic and Yale University will ultimately benefit other CTSAs struggling to in these areas also. We offer our appreciation to the Mayo Clinic with a firm commitment to deepening our collaboration relationship and disseminating the resulting collaboration throughout the consortium.

Sincerely,

Robert Sherwin, M.D.
Director, Yale Center for Clinical Investigation
Grant Application

Do not exceed character length restrictions indicated.

1. TITLE OF PROJECT (Do not exceed 81 characters, including spaces and punctuation.)
   Mayo Clinic Center for Clinical and Translational Research

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION
   (If “Yes,” state number and title)
   Number: 93.701.93.702
   Title: NCRR ARRA Supplement - CTSA

3. PROGRAM DIRECTOR/PRINCIPAL INVESTIGATOR
   3a. NAME (Last, first, middle)
       Rizza, Robert A.
   3b. DEGREE(S)
       MD
   3c. POSITION TITLE
       Professor of Medicine
   3d. MAILING ADDRESS (Street, city, state, zip code)
       Mayo Clinic Rochester
       200 First Street SW
       Rochester, MN 55905
   3g. TELEPHONE AND FAX (Area code, number and extension)
       TEL: 507-255-6515
       FAX: 507-255-4828

4. HUMAN SUBJECTS RESEARCH
   4a. Research Exempt
       Yes
   4b. Federal-Wide Assurance No.
       FWA00005001
   4c. Clinical Trial
       Yes
   4d. NIH-defined Phase III Clinical Trial
       Yes

5. VERTEBRATE ANIMALS
       A3291-01

6. DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)
   From 07/01/2009
   Through 06/30/2011
   7a. Direct Costs ($) 7b. Total Costs ($)
       $111,159 $167,961
   8a. Direct Costs ($) 8b. Total Costs ($)
       $198,544 $300,000

9. APPLICANT ORGANIZATION
   Name: Mayo Clinic Rochester
   Address: d/b/a Mayo Clinic College of Medicine
            200 First Street SW
            Rochester, MN 55905

10. TYPE OF ORGANIZATION
    Public:  
    Federal  
    State  
    Local  
    Private:  
    Private Nonprofit
    For-profit:  
    General  
    Small Business  
    Woman-owned  
    Socially and Economically Disadvantaged

11. ENTITY IDENTIFICATION NUMBER
    41-6011702
    DUNS NO. 00-647-1700
    Cong. District MN-01

12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE
    Name: Cheryl A. Nelson
    Title: Institutional Official
    Address: Mayo Clinic Rochester
             d/b/a Mayo Clinic College of Medicine
             200 First Street SW, Rochester, MN 55905
    Tel: 507-284-4715
    FAX: 507-284-4288
    E-Mail: researchadmin@mayo.edu

13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION
    Name: Cheryl A. Nelson
    Title: Institutional Official
    Address: Mayo Clinic Rochester
             d/b/a Mayo Clinic College of Medicine
             200 First Street SW, Rochester, MN 55905
    Tel: 507-284-4715
    FAX: 507-284-4288
    E-Mail: researchadmin@mayo.edu

14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

Signature of Official: ____________________________ Date: 5/15/09

Cheryl A. Nelson
acting for Form Page 1
PROJECT SUMMARY (See instructions):

The CTSA Consortium Strategic Goal #1 seeks to improve clinical and translational research management capability. The administrative and regulatory infrastructure supporting clinical research is often a key determinant of the success of funding applications, and is crucial to the efficient implementation of safe and effective protocols. One of the most commonly expressed frustrations for investigators is the length of time it takes to initiate a protocol. In addition to external regulatory requirements, there are often institutional barriers, inefficiencies and service gaps that create weeks or even months of delay. Areas such as study design, minority inclusion, IRB approval and study coordinator support all offer opportunities to either accelerate or hinder protocol initiation. This administrative supplement application, the Mayo Clinic Center for Translational Science Activities [Mayo Clinic CTSA] proposes a two-year linked collaborative project with the Yale Center for Clinical Investigation [YCCI] to develop models for leveraging the strengths in each institution to create best practices for streamlined protocol initiation. As a result of the collaboration Mayo Clinic CTSA and YCCI will disseminate the collaboration model(s) we develop to the rest of the CTSA consortium members.

In keeping with the overarching NCRR goals of "accelerating the tempo of scientific research/scientific activities" and "advancing basic and translational research and collaborations," our specific aims are to:

**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.

This application will build upon the strong relationships developed between the leadership of the Mayo Clinic CTSA and YCCI as well as the institutional strengths of each in order to further the strategic goal of the CTSA consortium of improving clinical and translational research management capabilities.

RELEVANCE (See instructions):

The speed at which new treatments to improve health are made available to doctors and patients is impacted by the time it takes a researcher to implement a research protocol in a safe and effective manner. In this project, the Mayo Clinic Center for Translational Science Activities and Yale Center for Clinical Investigation, will partner to develop models for leveraging the strengths in each institution to create best practices for streamlined protocol initiation.

Project/Performance Site(s) (if additional space is needed, use Project/Performance Site Format Page)

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Additional Project/Performance Site Location

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| Street 2: |
| City: |
| County: |
| State: |
| Province: |
| Country: |
| Zip/Postal Code: |
**SENIOR/KY PERSONNEL.** See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Program Director(s)/Principal Investigator(s). List all other senior/key personnel in alphabetical order, last name first.

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<td>Rizza, R. A., MD</td>
<td>rizza.robert</td>
<td>Mayo Clinic</td>
<td>Principal Investigator</td>
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<tr>
<td>Joyner, M. J., MD</td>
<td>mjoyner</td>
<td>Mayo Clinic</td>
<td>Project Leader</td>
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**OTHER SIGNIFICANT CONTRIBUTORS**

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<th>Name</th>
<th>Organization</th>
<th>Role on Project</th>
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**Human Embryonic Stem Cells**  
- [x] No  
- [ ] Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: [http://stemcells.nih.gov/research/registry/](http://stemcells.nih.gov/research/registry/). Use continuation pages as needed.

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

**Cell Line**
Improving Clinical Research Study Initiation and Management: A linked collaborative project proposal from Mayo Clinic Center for Translational Science Activities and Yale Center for Clinical Investigation

SIGNIFICANCE AND RATIONALE
The CTSA Consortium Strategic Goal #1 seeks to improve clinical and translational research management capability. The administrative and regulatory infrastructure supporting clinical research is often a key determinant of the success of funding applications, and is crucial to the efficient implementation of safe and effective protocols.

One of the most commonly expressed frustrations for investigators is the length of time it takes to initiate a protocol. In addition to external regulatory requirements, there are often institutional barriers, inefficiencies and service gaps that create weeks or even months of delay. Areas such as study design, minority inclusion, IRB approval and study coordinator support all offer opportunities to either accelerate or hinder protocol initiation.

In this administrative supplement application, the Mayo Clinic Center for Translational Science Activities (Mayo Clinic CTSA) proposes a two-year linked collaborative project with the Yale Center for Clinical Investigation (YCCI) to develop models for leveraging the strengths in each institution to create best practices for streamlined protocol initiation. YCCI is submitting a complementary supplement application with similar, linked objectives. Furthermore, as a result of the collaboration facilitated by these complementary supplements, Mayo Clinic CTSA and YCCI will disseminate the collaboration model(s) we develop to the rest of the CTSA consortium members.

SCOPE AND SPECIFIC AIMS
While there are many aspects of research management that impact the success of clinical and translational research, this project focuses on administrative, regulatory and research support services involved in the initiation of clinical research protocols. As Mayo Clinic CTSA and YCCI have worked together over the past three years since we joined the first cohort of CTSA institutions, we have discovered that each institution has unique areas of strength in protocol initiation and management – strengths that could complement each other and assist with bridging expertise and service gaps that slow the initiation of studies. This linked collaborative project offers an opportunity to assess the feasibility of “importing and exporting” best practices between institutions and to develop one or several collaboration models that could be used by other CTSA institutions.

In keeping with the overarching NCRR goals of “accelerating the tempo of scientific research/scientific activities” and “advancing basic and translational research and collaborations,” our specific aims are to:

**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.

The research project plan discusses possible pilot projects for collaboration and their relationship to the parent CTSA grant in more detail.

RESEARCH PROJECT PLAN
Background
Since launching our CTSAIs in October 2006 as part of the first cohort, Mayo Clinic and Yale University have enjoyed a close working relationship. In particular, our administrative directors (Ms. Sheila Olson at Mayo Clinic and Ms. Tesheia Johnson at Yale) have kept in close communication and developed a strong understanding of each other's institutions. This collaboration has been strengthened by Ms. Olson’s participation on the YCCI External Scientific Advisory Board, and Ms. Johnson's participation on the Mayo Clinic CTSA External Advisory Committee.

The opportunity to review the inner workings of each organization led to a recognition that Mayo Clinic and Yale each have research management strengths that could benefit the other institution – if those strengths...
could be exported in a way that makes them adaptable (customizable) and adoptable (feasible within differing budget and cultural constraints). In some cases, a successful program could potentially be replicated at the other institution; in other cases, it might be more effective for one institution to increase its own staffing levels to offer expert consulting to the other institution, rather than duplicate infrastructure at both sites. The goal of this project is to determine the best model(s) for these interinstitutional collaborations, recognizing that more than one model may be necessary to accommodate a variety of programs, services and best practices.

In the broadest sense, the proposed project is encompassed by Goal 6 of the Mayo Clinic CTSA parent grant: “Continued and Expanded Institutional Support for Clinical and Translational Research, featuring an ‘academic home’ that includes spatially consolidated administrative and regulatory offices to support clinical and translational research.” The proposed project will lead to improved administrative, regulatory and research support for our investigators and study teams as we adopt best practices from YCCI. Furthermore, developing effective collaboration models will position Mayo Clinic CTSA to learn from other institutions and to make new outside resources available to our study teams.

As outlined below, this project is also directly tied to several other goals from our parent CTSA grant.

Proposed Pilot Collaborations (Aims 1 and 2)
To simplify the “linked collaborative” aspect of this project, the Mayo Clinic CTSA application contains the best practices, expertise and/or technologies that we could offer to YCCI. Yale’s application contains the elements they could offer to Mayo Clinic. This allows each institution to offer evidence of its expertise in the proposed area to help reviewers assess the merit and feasibility of the proposal.

Pilot Collaboration 1: Assist YCCI with strengthening its FDA regulatory support to investigators.
Connection to parent grant:

Goal 3 of the original Mayo Clinic CTSA application focused on compliance and regulatory affairs support for study teams. With grant funding and extensive institutional support, the CTSA has launched a new Office of Research Regulatory Support (ORRS) that provides oversight and consulting services on FDA regulatory issues to the entire Mayo Clinic research enterprise. Key ORRS services include:

- Consultation for IND/IDE initiation, maintenance and reporting
- Development of an IND/IDE tracking database
- FDA audit support
- Education and training on regulatory issues, including updates on new/revised regulations

Medical/scientific leadership for ORRS is provided by Michael J. Joyner, M.D., a co-PI of the Mayo Clinic CTSA and co-chair of the national CTSA Clinical Research Management KFC. His administrative partner is Karen Hartman, RN, MSN, CCRP, a member of the Regulatory Knowledge KFC. Ms. Hartman has been providing FDA/regulatory consulting services through the CTSA Service Center since early 2007, and led the efforts to develop a business plan and administrative structure for the enterprise-wide ORRS. The new ORRS expands the reach of Mayo Clinic’s regulatory consulting services, combining current CTSA services with those offered by the Office for Research Compliance, the Cancer Center Clinical Research Office and other institutional resources.

A top priority of ORRS has been the development of a well-defined process for initiation of INDs and IDEs. Investigators can be overwhelmed by the prospect of navigating the FDA’s IND/IDE application process, creating a barrier to the development of novel therapies and drugs desperately needed by patients. By providing professional guidance and ongoing support, ORRS can encourage investigators to take that important first step toward translating their novel ideas and research findings into real-world treatments.

Working with CTSA-supported programmers and informatics specialists, ORRS has developed an IND/IDE tracking database to allow for better monitoring and reporting. Like many institutions, Mayo Clinic has struggled to keep a current listing of all IND/IDE holders since FDA communicates directly with the PIs, often bypassing the institution. The lack of institutional involvement can create risk for both the institution and the PI, and hinders the ability of the institution to offer critical expertise, training and support to its PIs. With the combination of an up-to-date tracking database and trained regulatory specialists, the Mayo Clinic ORRS is equipped to provide oversight, education and support for current and potential IND/IDE holders. YCCI has expressed interest in implementing similar oversight and consultative services for its investigators.
Proposed collaboration elements:

- Mayo Clinic CTSA will provide assessment, expertise and training to help YCCI launch a similar Office of Research Regulatory Support (.25 FTE – Regulatory Specialist)
- Mayo Clinic CTSA will share its IND/IDE tracking database with YCCI (programming time included under Pilot Collaboration 3)

Pilot Collaboration 2: Assist YCCI with minority inclusion, health disparities and community engagement efforts.

Connection to parent grant:

Goal 4 of the original Mayo Clinic CTSA application focused on community affairs, including efforts to increase the diversity of our scholars, faculty, staff and research subject base. To accomplish this, Community Engagement became one of the four “pillars” or basic components of the Mayo Clinic CTSA. Within the Community Engagement component, our diversity and health disparities efforts are spearheaded by the Office for Diversity in Clinical Research (ODCR), an existing function that was revitalized and expanded with CTSA grant funding and significant institutional support.

Medical/scientific leadership for Community Engagement/ODCR is provided by David O. Warner, M.D., a co-PI of the Mayo Clinic CTSA and a member of the national CTSA Community Engagement and Evaluation KFCs. The ODCR is directed by Miriam Marquez, Ph.D., a leader in minority inclusion and health disparities efforts.

Dr. Marquez and her staff of specialists provide consulting, education and community services in four main functional areas:

- Community Outreach and Partnerships
- Research Recruitment and Retention
- Health Disparities Research
- Data Linkages, Collection and Evaluation

Much of this effort is directed specifically to educate and support investigators in developing and executing effective strategies to ensure that research participants reflect the composition of the surrounding community. YCCI is interested in strengthening its community engagement and diversity efforts, and has expressed interest in replicating the Mayo Clinic CTSA ODCR model at Yale.

Proposed collaboration elements:

- Mayo Clinic CTSA will provide assessment, expertise and consultation to help YCCI establish a similar Office of Diversity in Clinical Research (ODCR Director or equivalent FTE covered by parent grant)
- Mayo Clinic CTSA will provide “train the trainer” educational opportunities to help YCCI staff its new diversity office (RN Study Coordinator FTE covered by parent grant)
- If needs assessment/feasibility analysis shows that establishing a Yale ODCR is not practical, explore establishing a consulting relationship that would allow Mayo Clinic ODCR staff to assist YCCI investigators with minority inclusion, health disparities research, community outreach and data collection/reporting.
- Mayo Clinic will provide on-site consultation for Yale diversity staff (travel expenses)

Pilot Collaboration 3: Assist YCCI with development of web-based tracking and reporting tools.

Connection to parent grant:

Goal 1 of the original Mayo Clinic CTSA application focused on clinical research core services to support the conduct of clinical/translational research. In addition to the scientific/technical cores, the Mayo Clinic CTSA has invested considerable resources into developing tools that allow investigators and program administrators to track, manage and report various aspects of clinical research and management functions. These tools are made available to staff through both the Service Center and Research Resources components of the CTSA.

Dr. Michael Joyner, a Mayo Clinic CTSA co-PI, is currently leading institutional efforts to consolidate and prioritize all research-related IT needs and resources. To accomplish this formidable task, he draws on the expertise of Mayo Clinic’s leaders in biomedical informatics, IT/systems analysis, web analysis and programming. CTSA funding and institutional support have allowed for the doubling of dedicated CTSA
IT/programming resources, which has facilitated the development of several custom data collection/reporting tools, including:

- Identification and reporting of relevant publications and grants for the Annual Progress Report
- IND/IDE tracking and reporting
- Utilization tracking and reporting of consultative services
- Utilization tracking and reporting for Clinical Research Unit and Core Facility services

YCCI is interested in using several of these tools to strengthen its tracking and reporting capabilities.

*Proposed collaboration elements:*

- Mayo Clinic CTSA will share its customized tracking/reporting tools with YCCI, and provide programming support for customizing to Yale's administrative needs and IT platforms (*0.25 FTE programmer/system analyst*)
- Mayo Clinic CTSA will provide on-site training for Yale programming staff (*travel expenses*)

**Pilot Collaboration 4: Assist YCCI with education and training of study coordinators.**

*Connection to parent grant:*

**Goal 2** of the original Mayo Clinic CTSA application focused on **career development and educational programs** to prepare investigators and support staff for excellence in clinical/translational research. While Mayo Clinic may be better known for its well-established K12 and K30 programs which are now the KL2 and Postdoctoral programs within our CTSA, we also offer one of the few **formal degree programs for clinical research coordination** in the nation. The Mayo Clinic CTSA administers a unique collaboration between the Mayo School of Health Sciences and Rochester Community and Technical College to provide a two-year Associate in Applied Science (AAS) degree and one-year Diploma in Clinical Research Coordination. Fieldwork takes place in Mayo Clinic research labs, and graduates quickly find positions at Mayo Clinic or other research institutions.

This degree/diploma program is part of the Research Management Programs within CTSA Education Resources. Research Management Programs are directed by Dr. David O. Warner, a CTSA co-PI, with administration provided by Lori Carlson, RN, MBA, an experienced research nurse and educator. The director of Mayo Clinic CTSA Education Resources is Sherine Gabriel, M.D., M.Sc., a CTSA co-PI and national leader in clinical research education. Both the 60-credit AAS degree and 35-credit diploma contain professional, clinical and practical education components.

YCCI is interested in exploring collaboration opportunities with its local community college to establish a similar degree/diploma program. In the short term, YCCI would also like to participate in Mayo Clinic CTSA one-week research practicums for study coordinators, and access some of the excellent online modules that CTSA Education Resources has developed for study coordinator continuing education.

*Proposed collaboration elements:*

- Mayo Clinic CTSA will send its CRC program director to assess feasibility and share expertise regarding collaboration between Yale and its local community college (*Education Operations Manager, FTE covered by parent grant*)
- Mayo Clinic CTSA will offer study coordinator practicum opportunities to YCCI study coordinators
- Mayo Clinic CTSA will share online coursework (study coordinator modules, CME modules) with YCCI
- Mayo Clinic will provide on-site consultation for Yale coordinator education staff (*travel expenses*)

**Ideas/Programs From YCCI To Be Implemented by Mayo Clinic CTSA**

**Pilot Collaboration 5: Transform CTSA Service Center per the model of YCCI Office of Research Services (ORS).**

- Conduct needs assessment/survey of Mayo Clinic investigators to identify service gaps
- Expand staffing and services to address known gaps: navigating the IRB process; identifying funding sources for junior investigators; increased assistance with protocol development, study design, informatics
Pilot Collaboration 6: Assess need/feasibility of developing a study coordinator pool.
- Conduct needs assessment/survey of Mayo Clinic investigators and study teams to determine unmet demand for study coordinator services
- Work with YCCI consultants to develop a shared resource model for study coordinator services

Pilot Collaboration 7: Develop a Community Research Site Toolkit based on YCCI model.
- Create new position – Community Based Participatory Research (CBPR) Coordinator – to work with YCCI consultants and community research partners (.8 FTE RN Study Coordinator)
- Develop a toolkit of processes, training, forms and templates to assist community partners in setting up fully compliant clinical research operations
- Explore methods for community outreach to identify and launch productive, compliant, diverse and representative community-based research sites

ACCELERATING THE TEMPO OF SCIENTIFIC RESEARCH
Mayo Clinic CTSA and YCCI believe that this linked collaborative proposal would accelerate the tempo of scientific research at both institutions by:
- Removing procedural and administrative barriers to protocol development and initiation
- Streamlining the progression of protocols through the IRB and other regulatory oversight processes
- Providing professional development and training for study team members to help them in the conduct, monitoring and reporting of research
- Expanding potential sites for community-based clinical/translational research

JOB CREATION AND RETENTION
It is anticipated that this proposal will create new FTEs at Mayo Clinic (see budget justification for details).

EVALUATION (Aim 2)
Because this is a linked collaborative project, there are two distinct areas requiring evaluation:
- The effectiveness of the methods/programs/services adopted by each institution
- The effectiveness of the collaboration model(s) developed and used by the two institutions

Evaluation of the adopted programs/services is fairly straightforward. Each institution will use its existing metrics and evaluation methods to evaluate the new programs (e.g., improved review cycle time, less rework, increased investigator satisfaction, etc.). Evaluation of the collaborative model(s) may be more challenging; it must focus on the perceived mutual benefit of the collaboration: i.e., does Yale feel that it has gained enough knowledge, methodology and tools to make its efforts in exporting its expertise to Mayo Clinic an equitable and sustainable investment – and vice versa? And is the model reproducible by other institutions, such that they would also gain mutual benefit?

Mayo Clinic CTSA and YCCI will jointly develop a survey tool to be used with PIs, administrators and program directors at both institutions to measure quality, effectiveness and satisfaction with the collaborative process. The survey will be administered at the end of the first grant year, and results will be used to adjust the collaboration model as needed for Year 2. The same survey will be administered at the end of the project period to assess the effectiveness of midstream adjustments.

DISSEMINATION (Aim 3)
Mayo Clinic CTSA and YCCI intend to disseminate the collaboration model(s) developed during the project to the rest of the CTSA consortium. Because the research plan calls for the two institutions to explore different collaboration models (e.g., comparing the effectiveness of contracting for consulting services vs. replicating a successful service/program), it is not yet certain which model(s) will be shared with the consortium.

Dissemination methods will include a joint presentation at a future Administration KFC face-to-face meeting; presentations as requested at other KFC meetings; and articles and/or white papers for NCRR/CTSA publications as requested.
# Detailed Budget for Initial Budget Period

**Direct Costs Only**

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**Subtotals**

**Consultant Costs**

**Equipment (Itemize)**

**Supplies (Itemize by category)**

**Travel**

**Patient Care Costs**

- Inpatient
- Outpatient

**Alterations and Renovations (Itemize by category)**

**Other Expenses (Itemize by category)**

**Consortium/Contractual Costs**

**Direct Costs + Subtotal Direct Costs for Initial Budget Period (Item 7a, Face Page) $**

**Consortium/Contractual Costs**

**Facilities and Administrative Costs**

**Total Direct Costs for Initial Budget Period**

$
# Detailed Budget for Initial Budget Period

## Direct Costs Only

### Personnel (Applicant organization only)

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<td>Regulatory Affairs Specialist</td>
<td>3.00</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>To Be Named</td>
<td>RN Study Coordinator</td>
<td>9.6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Subtotals**

- Salary Requested: $59,177
- Fringe Benefits: $19,410
- Total: $78,587

### Consultant Costs

<table>
<thead>
<tr>
<th>Equipment (Itemize)</th>
</tr>
</thead>
</table>

### Supplies (Itemize by Category)

<table>
<thead>
<tr>
<th>Supplies (Itemize by Category)</th>
</tr>
</thead>
</table>

### Travel

<table>
<thead>
<tr>
<th>Travel</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,439</td>
</tr>
</tbody>
</table>

### Patient Care Costs

- Inpatient
- Outpatient

### Alterations and Renovations (Itemize by Category)

<table>
<thead>
<tr>
<th>Other Expenses (Itemize by Category)</th>
</tr>
</thead>
</table>

- Other Internal Fees & Services – Programmer TBN at HSR charge out rates, 365.5 x 71.50/hour

**Subtotal Direct Costs for Initial Budget Period**

<table>
<thead>
<tr>
<th>Subtotal Direct Costs for Initial Budget Period (Item 7a, Face Page)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$111,159</td>
</tr>
</tbody>
</table>

**Total Direct Costs for Initial Budget Period**

<table>
<thead>
<tr>
<th>Total Direct Costs for Initial Budget Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>$111,159</td>
</tr>
<tr>
<td>BUDGET CATEGORY</td>
</tr>
<tr>
<td>-----------------</td>
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<tr>
<td></td>
</tr>
<tr>
<td>PERSONNEL: Salary and fringe benefits. Applicant organization only.</td>
</tr>
<tr>
<td>CONSULTANT COSTS</td>
</tr>
<tr>
<td>EQUIPMENT</td>
</tr>
<tr>
<td>SUPPLIES</td>
</tr>
<tr>
<td>TRAVEL</td>
</tr>
<tr>
<td>PATIENT CARE COSTS</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>ALTERATIONS AND RENOVATIONS</td>
</tr>
<tr>
<td>OTHER EXPENSES</td>
</tr>
<tr>
<td>CONSORTIUM/ CONTRACTUAL COSTS</td>
</tr>
<tr>
<td>SUBTOTAL DIRECT COSTS</td>
</tr>
<tr>
<td>CONSORTIUM/ CONTRACTUAL COSTS</td>
</tr>
<tr>
<td>TOTAL DIRECT COSTS</td>
</tr>
</tbody>
</table>

TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD $198,544

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.
Personnel

Michael J. Joyner, MD, Project Leader (No additional effort requested)
Dr. Joyner is the Program Director of the Mayo Clinic CTSA Service Center leading the Study Design, Biostatistics, Ethics, Biomedical Informatics, Regulatory Affairs and Research Subject Advocate components. He also serves in several institutional research leadership roles including one of two Deputy Directors for Research at Mayo Rochester and member of both Rochester and Mayo wide Research Committees. In these roles, much of Dr. Joyner’s institutional administrative efforts have been directed at improving compliance and regulatory related services to investigators and improving the infrastructure that supports research in general and clinical and translational research in specific. He is currently leading institutional efforts to consolidate and prioritize all research-related IT needs and resources. Dr. Joyner will serve as the Project leader for this linked collaborative project.
Sheila Olson, Administrative Director (No additional effort requested)
Ms. Olson is the Director of Administration for the Mayo Clinic CTSA. She has 15 years experience with Mayo Clinic administration and policies and brings the expertise of administering the CTSA grant as a whole. Ms. Olson is actively involved in the institutional administrative efforts directed at improving clinical research management and provides a connection between the CTSA and the broader institution. She has worked collaboratively with the YCCI since the inception of the CTSA grant and is a leader on several CTSA national consortium groups.

Karen Hartman, RN, MSN, CRRP, Manager, Mayo Clinic Office of Research Regulatory Support (No additional effort requested)
Ms. Hartman joined the Mayo Clinic CTSA shortly after its inception providing FDA/regulatory consulting services through the CTSA Service Center to investigators. In addition, Karen led efforts to develop a business plan and administrative structure to expand these services to all of Mayo Clinic through an Office of Research Regulatory Support (ORRS). Ms. Hartman was instrumental in the development of the IND/IDE tracking database. In this project, Ms. Hartman will provide expertise to YCCI in developing and launching a similar ORRS. The To Be Named Regulatory Affairs Specialist requested will report to Ms. Hartman.

Miriam Marquez, Director, Office for Diversity in Clinical Research; (No additional effort requested)
Dr. Marquez oversees the inclusion and care of the multicultural communities in clinical research activities of Mayo Clinic Rochester, directing the activities of the office and interfacing with individual investigators. Responsibilities include:
- Plays a leadership role in assisting investigators to conceptualize and develop culturally sensitive research.
- Supports clinical investigators in conducting research studies involving minority subjects, and in protecting the rights and safeguarding the welfare of research subjects.
- Promotes and participates in the design of health disparities research studies and minority health grant applications.
- Develops tactical plans for community outreach to recruit and educate potential research subjects; and evaluates plan implementation procedures and outcomes.

Dr. Miriam Marquez will provide assessment, expertise and consultation to help YCCI establish a similar Office for Diversity in Clinical Research.

Catherine E. Dvorak, RN, Nurse Study Coordinator, Office for Diversity in Clinical Research (No additional effort requested)
Ms. Dvorak is an experienced nurse study coordinator with several years of experience in clinical research coordinator in the Department of Cardiology before joining the Mayo Clinic CTSA’s ODCR in 2007. She has extensive experience working with investigative teams on appropriate research recruitment and retention strategies. She will provide training to the YCCI staff of the new diversity office.

Laurel (Lori) A. Carlson, RN, MBA, Manager, Research Management Programs (No additional effort requested)
Ms. Carlson joined the CTSA in 2007 to lead its research management programs within CTSA Education Resources. Prior to working in the CTSA, Ms. Carlson worked as a nurse study coordinator in the Division of Cardiology for six years. Her experience in study coordination, as well as managing research education initiatives, gives her great expertise in educating research study coordinators. She will share Mayo Clinic’s expertise to assist Yale in assessing the feasibility regarding collaboration between Yale and its local community college in establishing a similar program. Both Ms. Carlson and her staff will be involved in sharing study coordinator practicum opportunities to YCCI study coordinators and online coursework.

To Be Named, Regulatory Affairs Specialist (3.0 calendar months).
Support is requested for 3.0 calendar months for a Regulatory Affairs Specialist to provide assessment, expertise, and training to YCCI in launching an ORRS. The Regulatory Affairs Specialists at Mayo Clinic advise and support Mayo Clinic investigators in the preparation, submission, and maintenance of U.S. Food and Drug Administration (FDA) Investigational New Drug (IND) and Investigation Device Exception (IDE) applications as well as monitoring of regulatory statutes, providing regulatory information to leadership, communicating with FDA and other regulatory bodies, and participating in regulatory audits. Candidates for this position will possess a bachelor's degree (BA, BS) in a science related field (e.g. biology, nursing, etc) or business and 5-7 years relevant experience in the application of laws, regulations, and guidance relating to FDA regulated research, Good Clinical Practices, and clinical trials. The Regulatory Affairs Specialist will report to Ms. Hartman.

**To Be Named, RN Study Coordinator** (9.6 calendar months).
Support is requested for an RN Study Coordinator at Mayo Clinic to work with YCCI staff and community partners. This person will develop a toolkit for Mayo Clinic community partners containing processes, training, forms and templates to aid community partners in setting up fully compliant clinical research operations. He/she will also explore methods for community outreach to identify and launch productive, compliant, diverse and representative community based research sites based on the advice contributed by YCCI staff experienced in these collaborations.

**Travel:**
Support in the amount of $6,439 is request per year for travel of Mayo Clinic employees to Yale University as part of this collaboration.

**Other Expenses**
Support in the amount of $26,133 is requested for 365.5 hours of Programmer time available through the Mayo Clinic department of Health Sciences Research. Although Mayo Clinic CTSA staff have completed development of several information technology tools that will be of use to the YCCI, programmer effort will be required in order to make sure the tools can be incorporated into the Yale IT architecture.
CHECKLIST

TYPE OF APPLICATION (Check all that apply.)

☐ NEW application. (This application is being submitted to the PHS for the first time.)

☐ RESUBMISSION of application number:
   (This application replaces a prior unfunded version of a new, renewal, or revision application.)

☐ RENEWAL of grant number:
   (This application is to extend a funded grant beyond its current project period.)

☐ REVISION to grant number: UL1 RR024150
   (This application is for additional funds to supplement a currently funded grant.)

☐ CHANGE of program director/principal investigator.

   Name of former program director/principal investigator:

☐ CHANGE of Grantee Institution. Name of former institution:

☐ FOREIGN application ☐ Domestic Grant with foreign involvement
   List Country(ies) Involved:

INVENTIONS AND PATENTS (Renewal appl. only) ☐ No ☐ Yes
   If "Yes," ☐ Previously reported ☐ Not previously reported

1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. If program income is anticipated, use the format below to reflect the amount and source(s).

<table>
<thead>
<tr>
<th>Budget Period</th>
<th>Anticipated Amount</th>
<th>Source(s)</th>
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<tbody>
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</table>

2. ASSURANCES/CERTIFICATIONS (See instructions.)
In signing the application Face Page, the authorized organizational representative agrees to comply with the policies, assurances and/or certifications listed in the application instructions when applicable. Descriptions of individual assurances/certifications are provided in Part III and listed in Part I, 4.1 under Item 14. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

3. FACILITIES AND ADMINISTRATIVE COSTS (F&A)/INDIRECT COSTS. See specific instructions.
   ☒ DHHS Agreement dated: 02/08/2008 ☐ No Facilities And Administrative Costs Requested.
   ☐ DHHS Agreement being negotiated with Regional Office.
   ☐ No DHHS Agreement, but rate established with Date
   CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

   a. Initial budget period:
      Amount of base $111,159 x Rate applied 51.10 % = F&A costs $56,802
   b. 02 year
      Amount of base $87,385 x Rate applied 51.10 % = F&A costs $44,654
   c. 03 year
      Amount of base $ x Rate applied % = F&A costs $
   d. 04 year
      Amount of base $ x Rate applied % = F&A costs $
   e. 05 year
      Amount of base $ x Rate applied % = F&A costs $
   TOTAL F&A Costs $101,456

*Check appropriate box(es):
☐ Salary and wages base ☒ Modified total direct cost base ☐ Other base (Explain)
☐ Off-site, other special rate, or more than one rate involved (Explain)
Explanation (Attach separate sheet, if necessary):

4. DISCLOSURE PERMISSION STATEMENT: If this application does not result in an award, is the Government permitted to disclose the title of your proposed project, and the name, address, telephone number and e-mail address of the official signing for the applicant organization, to organizations that may be interested in contacting you for further information (e.g., possible collaborations, investment)? ☐ Yes ☒ No