Education Protocols: Exportability of Yale/Mayo Clinic Content
Background

• This linked collaborative is intended to identify 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 exceptional support resources to our investigative faculty.
  • Aim 1 – identify and assess feasibility of potential areas of collaboration
  • Aim 2 – develop and implement collaboration models
  • Aim 3 – disseminate collaboration models to CTSA consortium
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Participants

• Mayo Clinic
  Lori Carlson RN, MBA, CCRC– Lead
  Operations Coordinator
  Cheryl Nelson
  Associate Director Administration
  David Warner, MD
  Co-PI and Associate Director

• Yale
  Susan Anderson - Lead
  Sandra Alfano
  Fred DePourcq
  Tesheia Johnson
  Jean Larson
Purpose/ Objectives

The overall goal is to improve educational and training opportunities and competency for clinical research staff by:

• Establishing best education practices

• Identifying learning needs at each institution

• Developing processes to share content

• Evaluating the ability to implement at each institution
Projected Impact

• Leverage the strengths of each institution.

• Align job competencies with education and training requirements.

• Share education content between institutions.

• Reduces redundancy between institutions.
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Phase I: Continuing Education

☑ Mayo: Share established comprehensive continuing education and training program content and evaluation data.

☑ Yale: Identify and prioritize Mayo content for transfer and implementation.

➢ Status: Identified existing content developed at Mayo. Yale reviewed and prioritized content to be transported. Jointly developed a license agreement template to enable content to be shared. Yale is collecting survey data to assess currently existing programs/resources and training needs.
Education Topics

✓ Good Clinical Practice
✓ Regulations: The Common Rule
✓ IRB Guidelines
✓ Unanticipated Events
✓ Privacy & Confidentiality
✓ Introduction to Clinical Research
✓ Recruitment Basics
✓ Fundamentals of Data and Safety Monitoring Plans
✓ Financial Roles & Responsibilities
Overall, the stated learning objectives were met and the course met my educational needs/expectations.

This course provided information that will be useful to me in my career, job, position.

The length of the course was too short, just right, too long

What skills, abilities or strategies have you gained or learned that you plan to implement to make improvements in your practice?

What have you learned from this activity that you did not know before?

What did you find MOST/LEAST valuable about this course?

What information was missing that you wanted to learn from this course?

Based on my educational needs, I would like to see the following topics addressed in future educational activities.
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Phase II: CRC Competencies & Job Description

✓ Mayo: Share competencies and draft job descriptions
✓ Yale: Need to develop competencies and standardized job descriptions

➢ Status: Shared existing competencies developed at Mayo with Yale. Mayo plans to share the job descriptions in concept following institution approval.
Mayo Clinical Research Coordinator Competencies

• Protocol Development

• Research Regulations

• Prepare for Study Implementation

• Execute and Manage Project Activities

• Professional Development
Job Description

• Career ladder
  ✓ Current SC I – SC VI
  ✓ Proposed CRC A, B, C

• Minimum Education Required
  ✓ Current high school diploma
  ✓ Proposed Associates degree or 2-3 years experience in clinical setting

• Scope of practice
  ✓ CRC A to obtain informed consent from human subjects
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Phase III: Clinical Research Coordinator Academic Associate in Applied Science & Diploma Program

☑ Mayo: Academic program implemented in 2005

☑ Yale: Explore expanding beyond the CTSA to model the Mayo Clinical Research Coordinator program with their local community college.

➢ Status: Shared initial steps to developing the program at Mayo and lessons learned.
Deliverables

✓ Sharing continuing education content
✓ Sharing agreement template
✓ CRC competencies and job descriptions
✓ Develop a process to facilitate sharing with other CTSA’s
✓ Explore the feasibility of implementing a Clinical Research Coordinator academic program
Deliverables

• Develop a process to facilitate future sharing with other CTSA’s
  ✓ Timelines for implementation
  ✓ Resource needs and costs
  ✓ Identify content that can be easily transferred
  ✓ Unforeseen obstacles
  ✓ Learner feedback
  ✓ Overall satisfaction
Metrics

• Mayo & Yale evaluation data effectiveness to address
  ✓ Learning needs
  ✓ Competencies and job descriptions

• Sharing with other CTSA’s
  ✓ Sharing agreement template
  ✓ Process
  ✓ Course content
  ✓ Ability to adapt institutional specific course content
Lessons learned

• Time barrier – getting legal authorization to allow sharing.

• Identify infrastructure resources to implement and maintain.

• Survey data is critical to identify staff needs and evaluate existing resources to better consolidate programs within the institution.
Projected Timeline

✓ Phase I: Continuing Education
  December 31, 2010

✓ Phase II: CRC Competencies & Job Description
  • July 1, 2011

✓ Phase III: Clinical Research Coordinator Program
  • Estimated 3-4 years
Goals of Face to Face Working Session

• Review Mayo evaluation tool and data

• Identify student and institutional outcome metrics and to assess sharing content.

• Review Mayo CRC competencies & job description concept.

• Begin to develop methods for sharing programs with other CTSA’s.