Clinical Research Informatics Systems Project
Final Report

March 29, 2010
Rev. 8.30.2010

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Clinical Research Informatics Systems Project (CRISP)

Executive Summary
In February 2009 Dr. Joyce Mitchell convened a group to review our current processes related to clinical and translational research and develop an improvement plan that includes less cumbersome and more consistent processes; enhances innovation and collaboration; and provides access to data that is secure and compliant with federal, state and institutional guidelines and regulations. The Task Force began this work with a goal of streamlining clinical trials data acquisition and ensuring compliance throughout the investigator-initiated process of clinical trials. We recognize that the information can be broadly applied to industry sponsored trials, translational research, basic research and health services research. While the focus of the Task Force is on the Health Sciences, collaboration with university processes is essential.

Task Force Charge:
1. Establish a task force with representation from all recognized stakeholders, including clinical and translational research, epidemiology, informatics, health services, outcomes, regulatory administration, and hospital/clinics.
2. Describe the clinical research process.
3. Identify obstacles related to the initiation, administration and data acquisition.
4. Propose a strategic direction to support the clinical research process with specific recommendations that address the obstacles identified by the task force.
5. Create a report for the Senior Vice President for Health Sciences, includes:
   - Recommendations for changes to existing policies and procedures (as needed)
   - Strategic plan to implement the recommendations including timeline, cost estimates and how the plan will integrate with ongoing strategic initiatives (FURTHeR, Biospecimen/BioBank Repository, UU Health System)

More specifically, the Task Force was asked: Who regularly orient new faculty, fellows, students and others about what resources are available to assist them as they begin their research careers at the University of Utah? Who are active clinical researchers? What are common obstacles or sources of frustration to initiating and conducting clinical research in terms of both compliance and data acquisition? What can the institution provide to address these issues? This work was undertaken from a new investigator perspective.

Background
Interventional clinical trials are the recognized standard to demonstrate the effectiveness of therapies, drugs and devices. During the conduct of clinical trials, protocols are followed that adhere to accepted standards of safety, patient care and data acquisition and interpretation.
The oversight of clinical research protocols by scientific review committees, safety monitoring boards and state and federal agencies provides assurances regarding the scientific merit, safety and ethics of modern clinical trials. This same oversight activity adds significant cost to the sponsor, institution and investigator. While the institution has invested considerable resources to support clinical research, a major driver of this investment has been compliance. An unintended result of this focus is that too often ‘barriers’ are created that inhibit the creation and conduct of clinical research.

*Scientific rigor, safety and privacy have been enhanced by the focus on compliance and oversight; removing these ‘barriers’ is neither justified nor desirable. However what is required is a proportional investment in infrastructure to guide investigators through developing their science and enhancing access to existing clinical data while still meeting these requirements.*

To do this, it is necessary that investigators, bench scientists, health care providers, information scientists, biostatisticians, administrators and others work collaboratively in an enterprise environment. This requires an infrastructure that guides investigators in designing, initiating and conducting clinical research within the framework of oversight and compliance; and that it is intuitive, time sensitive and efficient.

*Though the longer-term goal of coordinating activities to initiate and conduct clinical research may present a significant challenge to the research community, the task force takes the view that it also represents an opportunity to be an agent of change and cultural transformation for the University.*

Initiating a clinical research project requires a series of actions across several University entities:

- Formation of a research question (investigator with mentor)
- Hypothesis generation (investigator)
- Identifying appropriate funding sources (investigator, mentor, others)
- Preliminary data (investigator with mentor/collaborators)
- Determination of study population(s) (investigator with mentor, biostatistician)
- Human use approval(s) (investigator, IRB, OSP, etc.)
- Recruitment of research participants (investigator, clinical research coordinator)
- Data collection (clinical research coordinator)
- Data Analyses (investigator, mentor, biostatistician)
- Data dissemination (investigator +/- mentor)

Each of these actions can be broken down into much greater detail. In addition, even though each occurs over a period of time they are not predictably linear in the sense that action A always occurs before action B and/or once an action has been completed it won’t be revisited.

*It is highly unlikely that a new or even seasoned investigator will be aware of all of the actions that must be taken and/or entities that must be involved in the research process.* This could be especially true as we have investigators moving from “the bench
to the bedside”: different regulations apply as one moves from the lab and begins to involve human research participants. Also, because each of these actions/entities can be related to science, administration, data acquisition or regulatory domains, it is unlikely that any one person will have expertise across all domains. To further complicate the processes, the rules and regulations are not static.

Here are some simple examples of each domain:

**Idea Generation**: Who else has looked at this problem or similar problems/questions?

**Science – Sample Size**: How many subjects are required to complete a study and provide enough data to test the hypothesis? Is it feasible to achieve the sample size?

**Funding Sources**: Has a Request for Application (RFA) been published? What dollars are available? From where? To what agencies should the investigator apply? What are the deadlines?

**Administration – Clinical Trial Budget**: Which patient charges are “standard of care” and billable to insurers and which are “research” and must be paid by the sponsor? Who assists with budget development? Who can assist in tracking and reconciling the budget?

**Data Acquisition**: Data from regular clinic visits, including laboratory tests are part of the electronic medical record but (may) not (be) accessible to the research data management system. What data sources exist? What has to happen to gain access to data bases? How is access to data achieved?

**Regulations – Research Participant Approval**: What information is required by the Institutional Review Board (IRB) for approval of the project? Which studies require IRB approval (e.g. retrospective chart reviews? De-identified data?)

Many of these domain activities are interdependent, which introduces a temporal component to the process model. Above examples can illustrate interdependency: while determining sample size (scientific) involves biostatistics, it is also required by the IRB (regulatory). Two key components of this process are to 1) identify required actions and activities tied to regulations and required practices, and 2) identify available resources to fulfill the requirements.

There should be enough data about the process (meta-data) to enable the investigator and institution to learn from the collective experience, and subsequently spend less time in “process discovery.” Whether the activity is study design or data sharing, both the investigator and institution have interest in leveraging the experience.
Key:

Red: Approval and oversite
Yellow: Data step
Blue: Services
Green: FURTHeR
Vision
The ideal research environment will encourage, identify and support interdisciplinary collaboration opportunities; maintain an inventory of resources available, both central and individual department-based; increase opportunities for senior investigators to mentor junior investigators; provide or identify programs or resources to assist investigators with complex compliance and oversight requirements; reduce or eliminate unplanned or unnecessary redundancy; and facilitate greater integration of resources.

Current status
While many exceptional research resources exist within the health sciences, there is currently no systematic approach that either new or experienced investigators learn as they launch or continue their careers in clinical investigation. Learning is inconsistent, mentor-specific/dependent with the full range of resources unknown to investigators. New investigators often rely on their mentors, who may or may not be up-to-date with the latest processes, procedures or requirements. A centralized or standardized orientation to the clinical research arena for new investigators is absent. Investigators learn more often than not by “see one, do one, teach one”. While this model may have been effective in the past, the regulatory requirements have become increasingly complicated and onerous. In addition, while on-line resources available to assist investigators may have increased, knowledge about them, or more specifically, knowledge about which are relevant, may be absent. Sorting through the myriad of resources on a “trial by error” basis can be both time consuming and frustrating. Simultaneously, competition for federal and other grant dollars has become increasingly fierce. In addition, reporting and documenting progress on federally funded projects has become more frequent, complex and tedious. An investigator who can access efficiently those support services and information available to him or her will have an advantage.

Having said this, the University of Utah Center for Clinical and Translational Science (CCTS) builds on the University's strengths in genetics and biomedical informatics to translate promising bench science into practices that improve human health. The CCTS, which resides under the Associate Vice President (AVP) for Clinical and Translational Research, serves as an academic home for clinical and translational research, developing innovative health services for the community and health researchers, and training a new generation of clinical and translational investigators. The CCTS and its partners will increase the visibility, volume, and quality of participatory research by connecting investigators at the University with other health care institutions, clinical practitioners, public health personnel, patients, and research participants. The CCTS will also formally link research activities across systems that together provide health care coverage to 80 percent of Utah's population as well as patients in surrounding states.

Additionally, there are pockets of innovation such as the Huntsman Cancer Institute Clinical Trials Office (CTO), the John A. Moran Eye Center, and the Pediatric Clinical and Translational (P-CAT) Research Scholars Program (see appendix I) that we should learn from, and programs through the Vice President for Research such as the Research and Training Series (RATS) (see appendix II) that need to be exploited.
In addition to broadening successful clinical research programs that we already have, programs should be coordinated and available as broadly as possible, either for investigators or to serve as models for the organization.

Findings

- There are educational opportunities within the Health Sciences and the University research enterprise that are not systematically taken advantage of, either by investigators or administrators. As a result, there are many local interventions (SILOs: Scientific Investigation with the Least Obstacles) to address the problems described above.
- There is neither a central point of accountability nor a widely used institutional orientation describing resources available to new clinical researcher at University of Utah Health Sciences.
- Various segments of the investigative process (e.g. IRB, OSP) have developed educational web resources; however they can appear uncoordinated and fragmented to the new investigator.
- There is uncertainty about who is looking at the whole picture.

Recommendations

1. Develop a clear organizational chart of the research enterprise (Clinical, Basic, Translational and Health Services) in the Health Sciences.
   a. Link it to the University research structure
   b. Link to the AVP for Clinical and Translational Research
   c. Link directly or indirectly to the AVP for Health Sciences Information Technology
   d. Link with CCTS as appropriate (see above)
   e. Describe briefly roles and responsibilities of each person or unit
   f. Identify Core Facilities
   g. Identify redundancies or gaps in the research infrastructure

2. Form a Research Steering or Oversight Committee (if one does not exist) that includes leadership representation from the University, the Health Sciences Schools and Colleges (deans or VPs), CCTS, Informatics, Compliance and others as needed. This group would focus on the Health Sciences and verify the problems, set priorities for improvement interventions, identify funding, oversee coordination efforts, and generally set the strategic direction for research activities. If a committee such as this exists at the University, then perhaps that agenda could be broadened as appropriate to include a Health Sciences focus.

3. Form a SWAT Team to help develop the infrastructure for the CCTS that would:
   a. Develop and implement a formal and coordinated orientation for new faculty, fellows, techs, nurses and others to the clinical research arena under the auspices of the AVP for Clinical and Translational Research. (Timeline: 6 months). Included:
b. Develop a clear description of the research enterprise (how each component contributes and interacts together) and

c. Implement additional recommendations below.

4. Identify and connect with successful ventures within the organization; adapt and coordinate as feasible (see Appendices)

   a. Pediatric Clinical and Translational (P-CAT) Research Scholars Program
   b. Salt Lake Veterans Health Care System Research Administration
   c. Research Administration Training Series (RATS)
   d. Federated Utah Research and Translational Health e-Repository (FURTHeR)
   e. Introduction to University Tracking of Clinical Research (uTRAC)
   f. Master of Science in Clinical Investigation (MSCI)
   g. Huntsman and Moran Clinical Trials Offices

5. Define the oversight and coordination functions for clinical research that could be under the AVP for Clinical and Translational Research. Identify a lead administrator and informatics expert to partner with the AVP for Clinical and Translational Research. The roles would, among other things, be to:

   a. Serve as the focal point in the clinical research arena for (bi-directional) communication and problem solving.
   b. Serve as a reliable and accessible resource for investigators in all the pre- and post award processes.
   c. Develop consistent job descriptions for those within the research enterprise, including departmental research coordinators. The purpose is to ensure consistency across the enterprise, allow for a standardized education program, clarify who does what (reduce redundancy) and to reduce confusion among investigators.
   d. Meet regularly as an administrative unit to solve problems, learn and communicate new rules and regulations, to achieve consistency and to continually update the curriculum. Include Compliance and Informatics/Technology representatives in the meeting.
Appendix I

Pediatric Clinical and Translational (PCAT) Research Scholars Program
Pediatric Clinical and Translational (PCAT) Research Scholars Program

PCAT is the clinical and translational research-training arm of the Department of Pediatrics. Established in January 2007, the program is led by Carrie Byington, MD, Director and Heather Keenan, MDCM, MPH, PhD, Assistant Director. The PCAT program accepted its inaugural class of 14 junior faculty in July 2007. The goals of the PCAT program are to:

1. Support clinician investigators
2. Enhance pediatric research quality
3. Increase extramural funding available to clinician investigators.

The PREP office staff and senior faculty provide scientific and career development support to PCAT scholars. All scholars meet with Drs. Byington and Keenan in July to establish research goals and a realistic timeline for the academic year. The PCAT directors carefully monitor the progress of each scholar and meet frequently with scholars and mentoring committees each year. In June the PCAT directors meet with each scholar individually to review annual progress and provide formal feedback to the scholar, the mentoring committee, and the scholar’s division chief. The PCAT program also provides scholars with access to critical services including biostatistical consultation, research coordination, research database support, proposal review and editing, and grants and contracts research administration. In addition to these support services, the PCAT scholars are part of a larger community of scientists. The scholars receive peer mentoring through the monthly PCAT seminars. In addition, PCAT scholars are integrated into the CHRC and interact with basic scientists at weekly Research in Progress, the annual All Pediatric Research Conferences, the Departmental Grant Writing Workshops, and annual research luncheons. In the first year of the PCAT program, over $9 million in extramural applications were submitted. New scholars are chosen in July of each year through a nomination process and competitive review. Scholars remain in the program for two-years.

In July 2008, new support staff were hired to offer services to investigators department wide. The office name was changed to the Pediatric Research Excellence Partnership (PREP) Office to recognize its expanded services to investigators department wide.

In October 2006, the National Institutes of Health (NIH) launched the Clinical and Translational Science Awards (CTSA) to help institutions form a transformative, novel, and integrative academic home for Clinical and Translational Science. The University of Utah was awarded the CTSA in May 2008. Dr. Carrie Byington serves as Associate Director of the CTSA and is responsible for Minority and Vulnerable Populations including children. The Department of Pediatrics Research Enterprise is well aligned with the University’s program.

The future goal of the Department of Pediatrics is to create a research institute that supports all phases of the research cycle and integrates our research strengths with those of the University of Utah Department of Obstetrics and Gynecology and Intermountain Healthcare. The CHILD Institute is an acronym for Children’s Health: Investigation, Leadership, and Development. The CHILD Institute will consist of a group of investigators, leaders, caregivers, and supporters who are dedicated to improving the health of children throughout the world. The focus of the CHILD Institute will be to understand, develop, and implement strategies that positively affect the
foundations of adult life. Several critical stages that determine adult health including: preconception, conception, embryonic, fetal, neonatal, infancy, childhood, and adolescence will be the focus of all research activities.

**Mentored Program in Pediatric Research**

This program pairs senior level medical students interested in a pediatric career with experienced academicians and mentors with expertise in pediatric research. The in-depth, mentored experience provides students with the opportunity to 1) develop a relationship with the mentor, 2) develop skills in pediatric research methods and scientific oral and written presentation, and 3) enhance their pediatric career development. The program is led by Carrie L. Byington, MD.
The **CHRC**, directed by Gary C. Schoenwolf, Ph.D., serves as a catalyst for developing research partnerships between clinicians and basic scientists. Both have unique qualities important for solving the difficult problems associated with the prevention, diagnosis, and treatment of diseases in children. Fellows and junior faculty in pediatrics are partnered with basic scientists in cell biology, genetics, developmental biology, molecular biology, cancer research and neurobiology, who serve not only as colleagues but also as mentors.

### CITI Training/Human Subjects/IRB

University of Utah investigators and study staff who conduct human subject research must complete one of the following training initiatives before the IRB will approve a project(s):

1. **Collaborative IRB Training Initiative (CITI)**
2. **VA Good Clinical Practice Training**
3. **Human Participant Protections Education for Research Teams**

Please Note: The IRB will not waive the training requirement for those who have viewed the NIH training video or NIH web training.

The University of Miami Collaborative IRB Training Initiative is an interactive set of modules designed to improve knowledge of the Common Rule, HIPAA Privacy Rule, and Good Clinical Practices for individuals involved in human subjects research.

### Deer Valley Grant Writing Workshop

The Department of Pediatrics and Primary Children’s Medical Center Foundation sponsors a weekend **Grant Writing Workshop** that provides grant writing training and review of scientific writing by senior investigators. Participants have blocks of time to write, have their work reviewed by senior investigators, work with statisticians on study design and analysis, and to re-write. The weekend culminates in a peer review of your work similar to the review process conducted at the National Institutes of Health (NIH). The workshop is limited to 12 participants.

### HIPAA Training

The University's Institutional Review Board (IRB) has been charged with implementing **HIPAA** for the research enterprise at the University of Utah. If you are a member of the Health Sciences Center, please remember that the UUHSC HIPAA Policies and Procedures apply as well as the IRB’s policies and procedures. Note that the IRB has specific forms for research.

### Intermountain Institute for Health Care Delivery Research

The vision of the **Institute for Health Care Delivery Research** is to improve quality and reduce the cost of health care services by providing technical support and education for clinical research and process management within the Intermountain Healthcare system.

### K30 Training Program in Clinical Investigation (TPCI)

The University of Utah School of Medicine has a new, two-year post-graduate training program in clinical investigation with an emphasis on the inherited basis of human disease. The **Training Program in Clinical Investigatiuon** (TPCI) is funded by a Clinical Research Curriculum Award from the National Institutes of Health. The program consists of formal didactic coursework, a
longitudinal seminar series, and a mentored clinical research project.

**Mentored Program in Pediatric Research (Pediatrics 7260)**

The Mission of the [Mentored Program in Pediatric Research](#) is to pair senior level medical students interested in a pediatric career with experienced academicians and mentors with expertise in pediatric research. The in-depth, mentored experience will provide the student with the opportunity to 1) develop a relationship with the mentor, 2) develop skills in pediatric research methods, scientific oral and written presentation, and 3) enhance their pediatric career development.

**Public Health Program of the University of Utah**

The [Public Health Program of the University of Utah](#) is leading the way in advancing public health in the Intermountain West. Considered one of the top public health programs in the United States *(US News and World Report, 1999-2003)*, the University offers degree programs for the Master of Public Health, MS in Public Health, and a Ph.D. in Public Health.

**Research Administration Training Series (RATS)**

The Office of the Vice President for Research offers a [Research Administration Training Series](#) (RATS) providing education and training courses designed to support, develop, and maintain a standardized body of knowledge and best practice methodology for research faculty and staff. The curriculum includes traditional classes and lectures, interactive workshops, online instruction, and educational resources to ensure compliance with federal regulations and to enhance the overall productivity of researchers.
Research Administration Training Series (RATS)
Research Administration Training Series (RATS)

The Office of the Vice President for Research offers several continuing education and training opportunities designed to support, develop and maintain a standardized body of knowledge and best practice methodology for all research personnel at the University of Utah. The curriculum includes traditional classes and lectures, interactive workshops, online instruction and educational resources provided to ensure compliance with federal regulations and to enhance the overall productivity of researchers.

Program Goals

- To facilitate a trained workforce in research administration supporting the academic mission of the University of Utah
- To provide coordinated education and training programs which assist faculty and staff in the management of research activities
- To advance professional development and high performance standards for all research administrators at the University of Utah
- To promote a culture of compliance and research integrity at the University of Utah

The Office of the Vice President for Research conducts several ongoing education and training activities designed to keep the University research community informed about current trends and issues throughout the broad field of research administration.

https://education.research.utah.edu

**RATS Participation**

Research Education
Research Administration Training Series (RATS)
Fall, 2005 - Spring, 2009

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**Grand Totals:** 7927 5035 1710 965 217
The following classes are available:

(Click on a class title to view the description.)

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

B:

- Basics of Good Clinical Practices
- Biosafety Level 2 (BSL-2) Training
- Bloodborne Pathogens Training
- Budget Preparation and Development

C:

- Chemical Hygiene Training
- Clinical Research Budget Development, Negotiation and Oversight
- Clinical Research Coordinator (CRC) Orientation
- Clinical Research Coordinator (CRC) Sponsored Projects (OSP) Training

D:

- Developing Your Chemical Hygiene Plan

E:

- Electronic Application through Grants.Gov

F:

- Financial Management in Clinical Research
- Fundamentals of Effort Reporting, Audits and Recharge Centers
G:

- Getting Published in Biomedical Science: Pointers for Publishing Your Pièce de Résistance
- Governing Regulations for Grants and Contracts
- Grant-Writing Workshop: Foundations and Charities
- Grant-Writing Workshop: The National Institutes of Health (NIH)
- Grant-Writing Workshop: The National Science Foundation (NSF)
- Grants Management Essentials

I:

- Informed Consent in Research
- Institutional Review Board (IRB) and Human Subject Research
- Introduction to Community of Science (COS)
- Introduction to Environmental Health & Safety (EHS) and Radiological Health
- Introduction to eProposal
- Introduction to Technology Commercialization & Intellectual Property
- Introduction to the IRB, the IACUC and the IBC
- Introduction to the Office of Sponsored Projects (OSP)
- Investigator Training Workshop: Clinical Research Session
- Investigator Training Workshop: Post-Award Session
- Investigator Training Workshop: Responsible Conduct in Research
- Investigator Training Workshop: Pre-Award Session
- Investigator Training Workshop: Researcher Resources and Funding Searches

L:

- Laboratory Leadership and Staffing

M:

- Mandatory Effort Reporting (PAR) Training
- Mentoring for Fun and Profit

O:

- Overview of Research Administration

P:
- Pandemic Flu: What to Know & What to Do
- Patent and Trademark Searching
- Preparation for Association of Clinical Research Professionals (ACRP) Certification Examination
- Preparation for Investigator-Initiated Drug and Device Studies
- Principles of Contracts, Subcontracts and SubAwards
- Project Management: Implementing the Award Process
- Proposal Preparation, Processing and Review
- Protocol Billing Grids (PBG) and Medicare Coverage Analysis (MCA)
- Publishing Smart: How to Make Your Article Visible
- Purchasing and Procurement

R:

- Researcher Resources and Funding Searches
- Responsible Conduct in Research / Conflict of Interest

S:

- Seminar in Teamwork and Motivation
- Shipping Category B Infectious Substances and Dry Ice
- Small Business Innovation in Research (SBIR) / Small Business Technology Transfer (STTR) Grant Programs
- Source Documentation for Clinical Data Management

U:

- Understanding IRB Applications in ERICA - New Studies, Amendments, Continuing Review, and Report Forms

For assistance please contact:
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tony.onofrietti@hsc.utah.edu
Federation Utah Research and Translational Health e-Repository (FURTHeR)
FURTHeR

Informatics Architecture Overview

As shown in the figure below, we serve a very broad constituency: researchers, patients, community providers, institutional partners, and the Utah State Department of Health. At the front end, the entrée for the user community, is a Web portal. This portal provides the interface to the backend resources, the **Federated Utah Research and Translational Health e-Repository (FURTHeR)**.

[Diagram of FURTHeR architecture]

http://www.ccts.utah.edu
Introduction to uTRAC
University TRAcking of Clinical Research
Introduction to uTRAC
University TRAcking of Clinical research

Clinical Research Compliance and Education
Karen Wilson, Executive Director

Clinical Research Compliance Officers are here to guide you.
Objectives

• Introduction of uTRAC to Psychiatry Faculty and Staff

• Dates of importance

• Training and contact information

Overview of uTRAC application

• Centralized software application for clinical research management and compliance risks

• Provides comprehensive integration of day-to-day research activities

• Decreases duplication of data, provides automation of data, integrated with IRB module

• Universalizes research tasks and documentation across institution

• Allows primary (researchers) and secondary (reviewers) user assignments
Why take a proactive approach?

Federal billing compliance regulation audits and misbilling to participant’s insurance

- illegal to bill Medicare incorrectly, needed compliance measures to ensure accurate billing
- historically clinical research has lived outside of the clinical care model and needs to be law abiding
- creation of Protocol Billing Grids (PBGs): Standard of Care (SOC) with modifiers, study billing, study effort, study charge
- Medicare Coverage Analysis (MCA): Prospective Reimbursement Analysis and National Coverage Determination (PRA/NCD)
- creation of internal budget from PBGs and PRA reviews

Proactive approach, cont.

Benefits

- automatic Institutional outpatient procedural prices
- prompt to include: start-up, maintenance, close-out and invoices
- budget deduction/addition of real time monetary outflow and inflow
- single entry of CT.gov information for federally required studies
- increased accuracy through application of modifiers in PBG to automate EPIC billing system and participant tracking
CRCE uTRAC Initiatives

- uTRAC limited deployment go-live 08Sept09
  - trainings available through class and workshop settings
  - encouraged for all researchers to attend
- Integration with IRB
  - other systems to incorporate in FY 2010: OSP and EPIC
- uTRAC full deployment and required utilization 10Nov09
  - required to attach a uTRAC application in the IRB
  - will not hold up IRB approval, encouraged to complete uTRAC pre-IRB submission
  - new studies, continuing reviews and amendments

Overview: uTRAC states and sub-modules
Overview: Primary Role Assignment

Study Staff

- **Principal Investigator (PI)**
  - Conducts all study tasks or delegates tasks to study staff
  - Reviews, corrects, approves crucial study documentation (billing plan, budget)

- **Clinical Research Coordinator (CRC)**
  - Delegated by PI to conduct participant visit activities
  - Logs participant visits for actual events

- **Financial Analyst (FA)**
  - Delegated by PI to conduct study financials
  - Creates billing plan, budget and submits to PI for approval
  - Tracks debits; invoices sponsor; tracks sponsor payments

Other

- **Manager (Mgr)**
  - Has ability to read, edit and request changes
  - All studies within their dept./div can be accessed

- **Department Chair/Chief (Dept. Chair)**
  - Has ability to read, edit and request changes
  - All studies within their dept. can be accessed

- **Participant Tracker**
  - Has ability to enter participant tracking information

Overview: Primary Activities

1. **Draft State (study demographics)**
   - creation of protocol Billing Grid
   - includes auto-analysis for clinicaltrials.gov and Medicare Coverage Analysis

2. **Budget Development State (pre-study financial management)**
   - includes budgeting and pricing according to PBG and MCA/NCD completion

3. **Active State (study management)**
   - includes participant tracking, study accounting, invoicing, adverse events and amendment accounting
Overview: Secondary Role Assignments

- **Department Reviewer** (DEPT)
  Reviews and approves/disapproves studies before study commencement

- **Ancillary Service Reviewer** (Cardiology, Pharmacy, ARUP, Recharge, etc.)
  Reviews and approves studies using pre-determined ancillary services

- **Clinical Research Compliance & Education** (CRCE)
  Reviews studies as IRB ancillary committee; audits studies randomly, for cause

- **Billing Reviewer** (BR)
  Reviews study billing invoicing for accuracy

Overview: Secondary Activities

1. **MCA/NCD and Pricing Review**
   - CRCE Reviews information when applicable

2. **Ancillary Services Feasibility Review**
   - Review accurate coding by services needed per protocol (e.g. cardiology/ARUP)

3. **Departmental Feasibility Review**
   - PI’s department approves study or requires changes

4. **Compliance Review, Audit**
   - CRCE reviews study for federal compliance, assistance
Approval Workflow

Additional Information

- Training and user guides will be available to all primary and secondary users

- Additional training for Dept./Div approvers on uTRAC submodule approvals will be provided

- User accounts for PIs and all other research staff must be completed by their manager through:
  - HSC account management
  - Suggestion: each division has one person to provide user accounts
Additional Information, cont.

- Training schedule available
  [http://medicine.utah.edu/crce/training/index.htm](http://medicine.utah.edu/crce/training/index.htm)

- uTRAC URL
  [https://hfsutrac1.med.utah.edu/utrac](https://hfsutrac1.med.utah.edu/utrac)

- Account requestor screenshot assistance document
  [medicine.utah.edu/crce/images/Requesting_utrac_logins.pdf](medicine.utah.edu/crce/images/Requesting_utrac_logins.pdf)

- Request a uTRAC account, managers only
  [http://uuhsc.utah.edu/manager/](http://uuhsc.utah.edu/manager/)

Important Dates

- uTRAC question will appear in IRB: 08Sept09
  - only new studies can be entered
  - logic is predetermined in ERICA application

- All studies required to use uTRAC: 10Nov09
  - Including new, continuing review and amended studies
  - Required to build a PBG and budget in uTRAC (submit to MCA review)

- EPIC integration Nov2010
  By Sept2010 all IRB approved studies enrolling participants will need to have departmental approval in uTRAC
Please contact:

Johanna Wolff, CRC
Clinical Research Compliance Officer
Johanna.wolff@hsc.utah.edu
801-213-3604
Setting-Up a New Industry Clinical Trial at the University of Utah
Idea to Grant Submission Process
Flow Chart
Idea to Grant Submission

Health Sciences

Total Time elapsed: 10 wks @ 40 hrs/wk

ID which part staff might be able to do? HCl, Pediatrics
IRB Approval Process Flow Chart
COI disclosures

Begin IRB Process
Log into ERICA
New user?
Create profile
IRB Studies page
Need new study?
New Studies Application
Submit to IRB
IRB Approved?

- Unit required
- Takes 5 minutes
- Contact Info.
- Data base of medical studies
- Information on IRB Website
  - Smart form (will prompt with all questions)
  - Can stop/resume at any point
  - It prepared it will take 30 minutes for Retrospective Chart Review and 2 hours for multicenter trials
  - Notes: SAEs
    - CIR Registration
    - Amend Application
    - Report Form
    - Final IRB Report

- Must be approved by all subcommittees, this might take more than 3 months. No over 30 days. The IRB being the final approval. All subcommittees are automatically contacted when the applications is submitted.
- IRB review response is typically within 2 weeks.
- Common approval delays are incomprehensive application, information and wrong answers.
- The back and forth for approval of a new study may take several non-linear time, will take approximately 4-6 weeks.
- Annual renewal takes approximately 30 minutes to prepare and 45 days for approval.
- Approval period is actually less than a full year due to federal guidelines requirements.

Fall and Spring Classes: "How to complete your ERICA Application?"
OSP Process – Pre-Award Grant Process
Flow Chart
A viable administrative research infrastructure that can support and enhance clinical trials is the essential core of a high-performing, successful research enterprise. The Forum on Regulation of the Association of Academic Health Centers (AAHC) created a new management tool, the *Clinical Trials Functional Process Map*, to assist academic health center leaders in building, improving, and evaluating infrastructure that both sustains the research mission and responds to the regulatory environment.

The *Clinical Trials Functional Process Map* is a systems tool that permits academic health center leaders to take account of the full spectrum of administrative functions associated with clinical trials when examining operations, reengineering structures, assessing resources, or allocating funds to support the research mission. Additionally, the tool provides institutional leaders a new capability to evaluate the nature and scope of activities related to clinical trials, to judge efficiency and effectiveness in operations, and to improve investigator, staff, and patient satisfaction.

Designed by chief compliance officers from academic health centers nationwide, the *Clinical Trials Functional Process Map* is based on existing structures and activities found within these institutions along with data from AAHC institutional profiles of compliance functions. Processes related to budgeting and billing for clinical trials and compliance with the national coverage decision and local coverage rules were especially considered when outlining activities and developing the three phases of clinical research. To ensure that the tool illustrated the broadest spectrum of clinical research activities, research was defined as all research protocols, regardless of funding type, involving human subjects and clinical services.

**TOOL DESIGN**

The resulting functional process map reflects the administrative infrastructure for clinical research
as well as the budgeting and billing processes for clinical trials found in academic health centers throughout the nation. The various institutional processes are categorized into three phases of clinical research: (1) research study design, (2) patient management, and (3) research study close out. These three phases are then broken down into the operational activities, which are further broken down into tasks that must take place to ensure completion of each activity. For all three phases, 45 tasks were identified.

**UNDERSTANDING THE PHASES**

Phase I: study design, comprises "behind the scenes" activities or operations associated with the conceptualization of the study and the processes needed to apply for and receive grants to conduct clinical trials. The four component activities are:
- Study design/protocol development and scientific feasibility;
- Budget development;
- Clinical trials agreement and/or award; and

"The Clinical Trials Functional Process Map is significant for highlighting the interrelated activities and the connectivity that must exist across the research enterprise."
Phase II, patient management, comprises activities related to encounters with patients and delivery of services. The three component activities are:
- Participant screening, enrollment, and registration;
- Scheduling services; and
- Services provided and charges generated.

Phase III, study close out, comprises activities related to financial and patient management at the end of the trial, including accounting and reconciliation of bills. The two component activities are:
- Payment reconciliation; and
- Study close.

SIGNIFICANT TO PERFORMANCE

The Clinical Trials Functional Process Map is significant for highlighting the interrelated activities and the connectivity that must exist across the research enterprise. Leaders of academic health centers, whether chancellors, vice presidents for health affairs, department chairpersons, vice presidents for research, or chief compliance officers, will be able to address optimal performance within each phase, activity, or task and look for innovative ways to approach infrastructure issues and the integration of operations.

ASSESSING AND EVALUATING OPERATIONAL READINESS, EFFECTIVENESS, AND EFFICIENCY

One of the most effective uses of the Clinical Trials Functional Process Map is to assess and evaluate operational readiness for clinical trial activities from an administrative and management perspective. Effectiveness and efficiency can then be assessed by examining the allocation of resources, particularly the magnitude and influence of personnel involved in all activities related to clinical trials billing.

To accomplish this goal, the Forum on Regulation identified eight major personnel categories, called stakeholder groups, which are representative of the types of individuals involved in the nine activity areas identified on the map. It should be noted that each stakeholder group comprises a wide variety of individuals who possess multiple skill sets and competencies within a broad range of job responsibilities.

The eight stakeholder groups are:
1. pre-award (IRB/central institutional review board/contract administration/financial administration/legal counsel);
2. audit;
3. research team;
4. research participants (patients/subjects);
5. compliance;
6. sponsors;
7. post-award (grants accounting/medical records/coding); and
8. providers.

Chief compliance officers from academic health centers used the Clinical Trials Functional Process Map to chart stakeholder involvement through all activity areas related to clinical trial billing at their respective institutions. Each time a stakeholder was involved in a task, it was noted. A table shows the compiled results from a sampling of institutions (see Table 1).

Little uniformity regarding stakeholder involvement was revealed, except for the research team stakeholder group. The research team stakeholder had by far the most touch points in the entire clinical trials billing process, highlighting the complex, and sometimes burdensome administrative duties researchers must perform. Interestingly, the compliance stakeholder was not identified throughout the activities, although monitoring of activities is an ongoing process.

On average, institutions identified four of the eight stakeholder groups within each activity. Seven stakeholder groups were recorded in Activity 4 (IRB processes) and Activity 9 (study close). Given the multifaceted labor-intensive functions performed within these activities, it was not surprising to find involvement by multiple stakeholder groups. However, identification of a large number of stakeholders could indicate too many overlapping responsibilities or bottle-necking within the system.

Only three stakeholder groups, the fewest recorded in any activity, were noted in Activity 1
(study design and protocol development) where the pre-award, research team, and sponsor stakeholders were consistently identified. This could suggest that institutional processes may be well-defined or regulated at this point.

Some of the institutions did not identify any stakeholder group in several tasks: Activity 3 (clinical trials agreement and/or award); Activity 5 (participant screening, enrollment, and registration); Activity 7 (services provided and charges generated); and Activity 9 (study close), which suggests that the function was performed as part of a related task at the reporting institution.

Further examination of institutional processes will be necessary to determine what accounts for the variability among institutions in these activities. The lack of uniformity in participation by the various stakeholder groups also indicates that further review is necessary to define the tasks and functions performed by individuals within each stakeholder group. Assessing current skill and competency requirements is essential to understanding operational efficiency and effectiveness. This assessment can also assist institutional leaders in developing an established set of skills and competencies that support and sustain a high-quality, productive research infrastructure.

CONCLUSION

All academic health center leaders are encouraged to use the Clinical Trials Functional Process Map to examine current organizational and management structures for clinical research, particularly with regards to billing and budgeting for clinical trials. Using this tool, leaders can assess the allocation of personnel and costs related to clinical trial activities, analyze work flow across functions and departments, evaluate best practices, identify gaps in management and control of the administrative functions, and determine educational and communication needs. Thus, this valuable new tool provides multiple ways to strengthen the research infrastructure and enhance the research mission.

The authors:

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VISION
To advance the nation’s well-being through the vigorous leadership of academic health centers.

MISSION
To improve the nation’s health care system by mobilizing and enhancing the strengths and resources of the academic health center enterprise in health professions education, patient care, and research.

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AAHC – Investing in Clinical Trial Compliance
The number of clinical trials is rapidly increasing both in the U.S. and throughout the world given the need for new treatments and cures for disease and disability. Simultaneous expansion of regulations governing such trials is placing tremendous strain on the administration and management of clinical trials and their associated compliance functions within academic health centers. Academic health centers must allocate increasing amounts of funds in the areas of infrastructure, personnel, and IT systems, as well as in strategic planning and other operations, to ensure a safe and effective clinical trial process.

WHAT ARE CLINICAL TRIALS?

Clinical trials, the backbone of the nation’s efforts to bring new drugs and technologies to market, are essential to the research mission of academic health centers nationwide. Clinical trials advance scientific knowledge and promote discoveries to treat and cure illness and disease. They serve to increase the quality of life and longevity of countless people in this nation and around the world. During a trial, researchers gain important information and understanding about an experimental treatment, including its risks, benefits, and efficacy.

After researchers test new therapies or procedures in the laboratory and in animal studies, those experimental treatments with the most promising results are moved into clinical trials under strict scientific guidelines. The trials are carefully designed and carried out with human volunteers under the highest ethical standards, including the informed consent of participating human subjects and the approval of the institutional review board. Every clinical trial is closely supervised by the appropriate authorities within an institution and follows all strict state and/or federal regulatory standards. Participants in
a clinical trial follow a specific protocol while being seen regularly by the physician and research staff to monitor their health and safety.

WHO SPONSORS CLINICAL TRIALS?

Clinical trials are sponsored or funded by a variety of organizations or individuals in addition to federal agencies such as the National Institutes of Health (NIH), the Department of Defense (DOD), and the Department of Veterans Affairs (VA). Other sponsors might include medical institutions, foundations, voluntary groups, and pharmaceutical companies. Trials can take place in a variety of locations, including academic health centers, hospitals, doctors’ offices, and community clinics.

WHY SHOULD ACADEMIC HEALTH CENTERS PERFORM CLINICAL TRIALS?

Academic health centers, the leading institutions that serve society through research and education, must conduct clinical trials as part of their core mission to improve the nation’s health and well-being. Researchers in academic health centers generate the ideas that eventually need to be tested in clinical trials. New approaches to treatment must be evaluated on large numbers of carefully selected patients in trials conducted by investigators who can interpret sophisticated data and determine whether a treatment should be released to market. These competencies and skills, as well as the necessary research infrastructure to conduct such trials, are found largely within academic health centers.

THE HIGH COST OF COMPLIANCE

Federal oversight of the academic health center research enterprise has expanded in recent years, in part, as a response to some well-publicized incidents in research involving human subjects. Regulations cover an increasingly broad spectrum of research operations and touch all research processes from human subjects to budgeting, billing, and reimbursement. There are no signs that the intensity of the regulatory environment is abating. Rather, governmental rules and regulations are multiplying with their impact spreading across the institution.

Establishing an effective and efficient process for clinical trials billing can be particularly costly given the large number of individuals, the number of sites involved, and the IT integration that is necessary. The IT industry has not kept pace with clinical trial operations and the demand for services, often forcing academic health centers to turn to homegrown IT solutions or to purchase IT software from multiple vendors, thus increasing expenditures. In addition, hospitals affiliated with academic health centers may not invest sufficiently in clinical trial billing operations in part because the benefits of having clinical trials within their institutions may not be fully recognized. As a result, academic health centers may find it difficult to partner on clinical trial IT investments.

Thus, academic health centers are faced with a growing number of requirements that must be met with limited and strained resources. The costs of compliance are skyrocketing; for a one-year period, some institutions reported increases as high as 70%, according to a 2005 report by the Association of Academic Health Centers. Expenditures are required to create and staff the systems needed to increase efficiency and effectiveness. Of note, the personnel with the required skills and competencies to manage the complex and technical aspects of clinical trial processes are hard to find and in high demand throughout the country. Compliance is now considered to be the most commonly expanded academic health center function today.

ACADEMIC HEALTH CENTERS TRANSFORM COMPLIANCE

The heightened concern over accountability, along with the regulatory environment, has changed
the way academic health centers approach compliance, with the result that the organization, management, and funding of compliance has become a top priority for academic health center leaders. Academic health center leaders view compliance as an ongoing and evolving function, with a continuing need to improve processes and structures to respond to changing priorities or focus areas. As a result, the oversight and management of compliance within academic health centers, particularly with regard to clinical trials, is being transformed. Compliance programs for clinical trials comprise multiple elements that include budgeting and billing, training, auditing, and monitoring. One of the most critical areas of concern in clinical trials compliance is the billing of services for subjects in clinical trials, which is complex and involves multiple stakeholders from principal investigators to hospital and physician office billing clerks. In response, academic health centers have created new infrastructure, changed policies and procedures, and implemented new systems that include educational programs and auditing and monitoring activities.

A significant move toward consolidation of compliance functions is underway in academic health centers across the nation as existing decentralized organizational structures may not be able to accommodate new legal and regulatory environments. Research administrators are acquiring additional responsibilities and new administrative offices are being established for oversight. Changes in organizational structure are occurring, resulting in enlarged compliance structures at the institutional, school, and/or departmental level, adding to institutional expenditures on needed infrastructure.

"Ultimately, the public's trust in the institution must be the guiding force in all aspects of clinical trials compliance and the issue against which all expenditures of effort and finances should be judged."
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Pediatrics Research Process Flow Sheets
(Draft)
Step 1: Study Feasibility and Budget Process

1.1: Obtain Confidentiality Agreement (CDA)
   Send to OSP for review and signatures

1.2: Determine Protocol Feasibility
   (ethical, practical and scientific review)

1.3: Determine study procedures.
   Begin completion of the Protocol Billing Grid (PBG)

1.4: Contact PCTO

1.5: CTO Will Assist With:
   Completion of MCA and NCD questions
   Obtaining procedure prices (University and PCMC)
   Completion and PCMC Approval of the PBG
   Budget Preparation

1.6: Obtain Initial Budget with Sponsor

1.7: Contact Financial Analyst
   (Rebecca Dunn)

1.8: CTO Will Assist With:
   Preparation of Sponsor Budget
   Department Approval of Sponsor Budget
   Negotiation of Sponsor Budget (if applicable)

1.9: Negotiate and Finalize Budget with Sponsor

Go to Pre-Study Process
Step 2: Pre-Study Process
Clinical Trials New Hire Checklist
Clinical Research New Hire Orientation Checklist

DEPARTMENT: _______________________
Manager: ______________________________
Employee’s University ID#: _____________________

Departmental Set-Up Actions (Pre employee arrival)

__________ Confidentiality & Information Security Agreement
http://www.compliance.utah.edu/forms/1.1A%20Form%20-%20Confidentiality%20and%20Information%20Security%20Agreement.pdf

__________ Complete University ID number request form: Personnel Action Notification
http://www.hr.utah.edu/hris/pan/

__________ Set up Computer Access: Power chart and other applicable computer programs for new employee (Takes 24-48 hours)
http://uuhsc.utah.edu/manager/

__________ Telephone request
http://www.it.utah.edu/services/phones/index.html

__________ Complete required Human Resources paperwork
http://uuhsc.utah.edu/manager/

FIRST DAY (Employee actions/responsibilities)

__________ Tour of relevant buildings/resources (keys, pager, phone)

__________ UUHSC, PCMC and/or VA (if required)

__________ Campus Information System for e-mail account activity
https://gate.acs.utah.edu/psp/plpr/EMPLOYEE/EMPL/h/?tab=PAPP_GUEST

__________ Activate outlook e-mail account
http://email.uuhsc.utah.edu

__________ Obtain a history of vaccines
http://www.hr.utah.edu/hsc/imm/

__________ Parking permit(s)

FIRST WEEK

__________ Reporting process in case of accident
http://web.utah.edu/risk_management/insurance/html/incident_accident_info.htm

__________ Disaster Training
http://www.ehs.utah.edu/Disaster.html

__________ Defensive driving video (if required by department, offered at orientation)

__________ Hepatitis vaccine and TB test** (UUHSC Occupational Health)
http://uuhsc.utah.edu/hospepi/employee/

__________ Discuss and review confidentiality procedures

__________ HIPAA Training
http://hipaatrain.pointecast.com/lms/login/

__________ Work instructions for first day/week

__________ Review initial job responsibilities

__________ Kronos (Time and Attendance)
https://www.kronos.utah.edu/wfc/applications/wtk/html/ess/logon.jsp

**If patient contact
FIRST MONTH

- Division goals, mission and values
- U of U Ethical Standards and Code of Conduct
  www.hr.utah.edu/ethicalstandards/index.php
- Bloodborne Pathogens Training (if required)
  www.ehs.utah.edu
- Phlebotomy Certification (if required)
- Sign up for ‘New Coordinator Orientation’ through the University of Utah
  http://education.research.utah.edu/
- CITI Training  (I thought this was going under first month)
  http://www.research.utah.edu/irb/training/citi_training.html
- CPR (I would put this under first month- if required)
  http://www.health.utah.edu/healthpromotion/cep/classes/cpr.html

Clinical Trials at the University of Utah

- Clinical Trials Management Website and Study Start up Checklist
  (http://uuhsc.utah.edu/clinicaltrials/)
- Contact Office of Sponsored Projects (OSP)
  http://www.osp.utah.edu/
  http://education.research.utah.edu/detail.cfm?class=58
- Review information and register for Research Administration Training
  Classes (RATS)
  http://education.research.utah.edu/

Ongoing

- University CRC monthly meetings
  http://uuhsc.utah.edu/clinicalTrials/training/crc-mtgs.html
- Departmental Staff meetings
- HIPAA (renewed annually)
- CITI (renewed every 5 years)
- CPR (renewed every 2 years)
- Continuing Education Credits: Association of Clinical Research
  Professions (ACRP re-certification every 2 years, membership annually) or
  Society of Clinical Research Associates (SoCRA re-certification every
  3 years, membership annually)

University of Utah basic contact information:

University Hospital: 581-2121
Main campus: 581-7200
UUHSC Occupational Health: 581-2227
Information Technology: 587-6000
Netcom (Telephone requests): 581-4000
University of Utah contact information continued:

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**Conflict of Interest Office**
John Barlow- Director  
801-581-6351  
Jahn.barlow@hsc.utah.edu

**Environmental Health and Safety**
Marty Shaub- Director  
801-581-6590

**HIPAA Privacy Office**
801-587-9241

**Institutional Review Board**
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801-581-3655  
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