Clinical and translational science is essential to the mission of this institution and to improving the health of society. For such important work to continue to grow and expand, it is necessary to continue to improve the quality, and efficiency of the regulatory support structure that is an integral component of this research enterprise. We are a major research institution with an outstanding reputation for research and research with human subjects is a critical part of our research portfolio. As such, it is important that we have an outstanding, efficient, accredited human research protection program.

The University of Colorado Denver | Anschutz Medical Campus has committed to integrating existing systems whenever possible and eliminating redundancy. Such process changes can only be made with the full support and collaboration of our Affiliate Hospital Partners for whom our human research protection program is integral. This report serves to provide objective data concerning the status of our current system, and detail initiatives that are now underway to improve the system.

This report is designed to be transparent and provide objective data on the status of the essential research administration infrastructure at University of Colorado Denver | Anschutz Medical Campus. It also serves as a platform to continue to monitor progress towards the goals of efficiency and effectiveness that have been outlined in the institutions’ 5 year quality improvement plan as a priority to the institution. To improve communication with the clinical and translational research community, this report will be updated and published annually to detail the level of progress made and facilitate discussion concerning other potential initiatives.

I hope that you will find this report helpful and use it to become engaged in helping us to find solutions to some of the hurdles to successful clinical and translational science at University of Colorado Denver | Anschutz Medical Campus.

RJ Traystman
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## Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CCTSI</td>
<td>Colorado Clinical &amp; Translational Sciences Institute</td>
</tr>
<tr>
<td>CHCO</td>
<td>Children’s Hospital Colorado</td>
</tr>
<tr>
<td>COI</td>
<td>Conflict of Interest</td>
</tr>
<tr>
<td>COMIRB</td>
<td>Colorado Multiple Institutional Review Board</td>
</tr>
<tr>
<td>CRC</td>
<td>Clinical Research Coordinator</td>
</tr>
<tr>
<td>CRSC</td>
<td>Clinical Research Support Center</td>
</tr>
<tr>
<td>CTO</td>
<td>Clinical Trial Office</td>
</tr>
<tr>
<td>CTRC</td>
<td>Clinical Translational Research Center</td>
</tr>
<tr>
<td>CTSA</td>
<td>Clinical Translational Science Award</td>
</tr>
<tr>
<td>DHHA</td>
<td>Denver Health &amp; Hospital Authority</td>
</tr>
<tr>
<td>DSMB</td>
<td>Data Safety and Monitoring Board</td>
</tr>
<tr>
<td>DVAMC</td>
<td>Denver Veterans Administration Medical Center</td>
</tr>
<tr>
<td>ERA</td>
<td>Electronic Research Administration (InfoED)</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FTE</td>
<td>Full Time Employee</td>
</tr>
<tr>
<td>FY</td>
<td>Fiscal year (July 1– June 30)</td>
</tr>
<tr>
<td>GCP</td>
<td>Good Clinical Practice</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice</td>
</tr>
<tr>
<td>HIPAA</td>
<td>Health Insurance Portability and Accountability Act</td>
</tr>
<tr>
<td>HRPP</td>
<td>Human Research Protection Program</td>
</tr>
<tr>
<td>HRRC</td>
<td>Hospital Research Review Committee (UCH only)</td>
</tr>
<tr>
<td>IBC</td>
<td>Institutional Biosafety Committee</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>OGC</td>
<td>Office of Grants and Contracts</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>PRA</td>
<td>Professional Research Assistant</td>
</tr>
<tr>
<td>RAC</td>
<td>Research Advisory Committee</td>
</tr>
<tr>
<td>RDRC</td>
<td>Radioactive Drug Review Committee</td>
</tr>
<tr>
<td>SARC</td>
<td>Scientific Advisory Review Committee</td>
</tr>
<tr>
<td>UCH</td>
<td>University of Colorado Hospital</td>
</tr>
<tr>
<td>UPI</td>
<td>University Physicians Incorporated</td>
</tr>
<tr>
<td>WIRB</td>
<td>Western Institutional Review Board</td>
</tr>
<tr>
<td>YTD</td>
<td>Year To Date</td>
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</table>
INTRODUCTION
A quality improvement plan was developed for the University of Colorado Denver | Anschutz Medical Campus Human Research Protection Program (HRPP) in February 2012. The aim of this plan is to outline a five year plan to improve the effectiveness, quality and efficiency of the university’s HRPP in collaboration with the HRPP’s of our affiliate hospitals.

The full plan can be reviewed at: http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/UCD-Human-Research-Protection-Program-Policies-.aspx

- For 2012 - Goal 1: Increase the effectiveness of the regulatory approval processes and support.
- For 2013 - Goal 2: Improve the quality of protocols submitted for regulatory support.
- For 2015 - Goal 3: Increase the efficiency of the regulatory approval process.

The aim of this report is to provide a baseline status of the regulatory approval processes and metrics. This report details the current regulatory approval processes; it provides historic and current metrics for human subject protocol approval; and highlights some of the initiatives that are underway to meet Goal 1, with the understanding that progress on one goal is designed to impact each of the goals outlined.

Moving forward, the Vice Chancellor for Research will publish a report each year to document the progress made to meet these goals, challenges still to be addressed and new initiatives using objective metrics. The aim is to be much more transparent about the compliance enterprise at the University of Colorado Denver | Anschutz Medical Campus and facilitate on-going dialogue with the research community to continue to improve the overall program.

Your feedback on this report and any of the initiatives outlined in this report are welcome and should be directed to:

Alison Lakin
Assistant Vice Chancellor for Regulatory Compliance
Alison.Lakin@UCDenver.edu

or via the Regulatory Compliance web site at:
http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/Regulatory-Compliance.aspx
Currently the process is largely sequential and not transparent.
CCTSI Needs Assessment

The Evaluation and Tracking component of the Colorado Clinical and Translational Science Institute (CCTSI) administered an online survey in March 2011 to assess the research needs of CCTSI members and non-members at the University of Colorado Denver | Anschutz Medical Campus and affiliate organizations. A major theme that emerged from this needs assessment concerned regulatory issues. For example, one item on the needs assessment presented a list of 10 specific types of research services and supports; respondents were given 10 points to allocate as they wished across these items to establish relative priorities. Regulatory-related issues emerged as the top three priorities when the points allocated by respondents were aggregated / summed. Specifically, investigators expressed a need for more streamlined regulatory processes and reduced cycle times, as well as for personnel that investigators can approach for information or assistance in complying with regulatory requirements.

Priority ranking of general research needs (total points allocated; (n= 456)

<p>| | |</p>
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<td>a</td>
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<td>c</td>
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<td>e</td>
<td>f</td>
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<td>g</td>
<td>h</td>
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<td>i</td>
<td>j</td>
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<tr>
<td>k</td>
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<tr>
<th>a.</th>
<th>b.</th>
<th>c.</th>
<th>d.</th>
<th>e.</th>
<th>f.</th>
<th>g.</th>
<th>h.</th>
<th>i.</th>
<th>j.</th>
<th>k.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduced time to protocol approval (e.g., parallel regulatory review/approval rather than serial review across SARC and COMIRB)</td>
<td>Resources and assistance to support research study recruitment and retention</td>
<td>Improved information about, and access to, CCTSI resources (e.g., developed novel methodologies, community liaisons)</td>
<td>Specialized IRB review panels (e.g., community engagement, behavioral research)</td>
<td>Budget development and implementation training / assistance</td>
<td>Document translation and in-person translators (e.g., Spanish to English)</td>
<td>Good laboratory practice (GLP) facility integrating existing campus entities (e.g., CU Tech Transfer Office, Bioscience Park)</td>
<td>Regulatory documentation assistance (e.g., case report forms, regulatory binders, AE reporting)</td>
<td>Increased educational offerings focusing on community engagement and/or community-based participatory research</td>
<td>Increased IRB educational offerings</td>
<td>CCTSI/University/CTSA consortium Data Safety Monitoring Boards (DSMBs)</td>
</tr>
</tbody>
</table>
Work Flow Analysis

From November 2011 through June 2012, the University of Colorado Evaluation Center undertook two comprehensive workflow analyses: one focused on investigator-initiated studies and the other on industry-sponsored studies. The goals of these workflow analyses were to gain an in-depth understanding of: 1) what each regulatory entity was gatekeeping, and 2) the flow of documents and information within and between them.

The following investigator or research study coordinator needs emerged, specifically during the workflow interviews:

- The need to understand (demystify) the regulatory review process (where and how to enter the process, the role of each entity, what forms were needed by whom, and what were the responsibilities of investigators and their support staff versus those of the regulatory entities in terms of moving documents through the process).

- The need to improve communication with investigators and their research coordinators so they have a better sense of where their protocol is in the process, how long things are taking and if any documentation is missing that could delay the process.

- Enhance the capacity of research study coordinators to prepare study protocols, budgets, consent forms and other regulatory documents and respond appropriately to reviewer feedback; additional recommendations included:
  » Professionalize the role (hire professionals that are: 1) more credentialed, 2) have more directly relevant on-the-job training and experience, 3) who intend to pursue role as a career).
  » Invest in research study coordinator career development by providing more on-the-job training and mentoring.
  » Make training a mandatory requirement of all research study coordinators across the institution.
  » Create more accountability for the professional fulfillment of role; establish job performance benchmarks (e.g., that their protocols/documents require fewer cycles of re-review).

- Make a concerted institutional effort to promote recruitment, enrollment and retention of diverse human subjects to build a reputation with industry and improve feasibility/success of participating in multi-site clinical trials.
  » Undertake a public relations campaign that highlights the cutting-edge research happening at the Institution.
  » Build informatics capacity to identify eligible patients from electronic medical records.

- Streamline the process of regulatory review so that the university and its investigators are not losing out on opportunities to participate in industry-sponsored studies.
Scientific Advisory Review Committee Days to provisional approval for studies utilizing the Adult UCH Clinical Translational Research Center 2011-2012

*Note: these data include time to respond by the research team
COMIRB Initial Protocol Distribution

2010
732 Approvals
2011
1,237 Approvals

- Full Board
- Expedited
- Exempt/Not Human Subject Research

Protocol Volume Per Panel

Panel A: Primarily PI Initiated Trials
- 2010: 57
- 2011: 65

Panel B: Primarily PI Initiated Trials
- 2010: 45
- 2011: 44

Panel C: Both PI Initiated and Multi-site Trials
- 2010: 86
- 2011: 58

Panel D: Primarily Multi-site Trials
- 2010: 42
- 2011: 65

*Note: these data include time to respond by the research team
*Note: these data include time to respond by the research team

Other significant Data

- Protocols approved on first review – 25% (Panel D – 80%)
- Percent of Protocols given minor modifications – 44.86%
- Percent of protocols requiring more than one full board review – 30.14%
Subanalysis of approval timelines for multi-site federally funded studies using COMIRB

<table>
<thead>
<tr>
<th>Year</th>
<th>COMIRB</th>
<th>HRRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>26</td>
<td>19</td>
</tr>
<tr>
<td>2010</td>
<td>49</td>
<td>30</td>
</tr>
<tr>
<td>2009</td>
<td>73</td>
<td>37</td>
</tr>
</tbody>
</table>

Subanalysis of approval timelines for multi-site industry sponsored studies using WIRB

<table>
<thead>
<tr>
<th>Year</th>
<th>WIRB</th>
<th>HRRC</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>21</td>
<td>16</td>
</tr>
<tr>
<td>2010</td>
<td>40</td>
<td>32</td>
</tr>
<tr>
<td>2009</td>
<td>35</td>
<td>21</td>
</tr>
</tbody>
</table>
Surveys

COMIRB Website Survey

The COMIRB website was updated in April 2012 based on the feedback received from an initial survey. Data analysis from March 2011- March 2012 identified concerns with the available information and usability of the website. New survey results (July 2012) shown below indicate increased user satisfaction (n=40). COMIRB has a feedback survey link on its website as part of its quality improvement program.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>The website enhanced my understanding of what IRB-related resources are available</td>
<td>0.0%</td>
<td>4.5%</td>
<td>31.8%</td>
<td>54.5%</td>
<td>9.1%</td>
<td>44</td>
</tr>
<tr>
<td>The website enhanced my access to needed resources</td>
<td>0.0%</td>
<td>7.7%</td>
<td>23.1%</td>
<td>59.0%</td>
<td>10.3%</td>
<td>39</td>
</tr>
<tr>
<td>IRB policies and procedures are easy to find on the site</td>
<td>2.3%</td>
<td>25.6%</td>
<td>18.6%</td>
<td>39.5%</td>
<td>14.0%</td>
<td>43</td>
</tr>
<tr>
<td>The forms I need are easy to access on the website</td>
<td>0.0%</td>
<td>12.2%</td>
<td>9.8%</td>
<td>48.8%</td>
<td>29.3%</td>
<td>41</td>
</tr>
<tr>
<td>The “Frequently Asked Questions” section of the website is informative</td>
<td>4.9%</td>
<td>4.9%</td>
<td>41.5%</td>
<td>43.9%</td>
<td>4.9%</td>
<td>41</td>
</tr>
<tr>
<td>Overall, I feel the IRB website is a useful resource to those responsible for developing and submitting human subjects protocols</td>
<td>2.5%</td>
<td>2.5%</td>
<td>17.5%</td>
<td>62.5%</td>
<td>15.0%</td>
<td>40</td>
</tr>
</tbody>
</table>
COMIRB satisfaction survey

A COMIRB satisfaction survey was offered to all recipients of the 6,500 approval letters sent from March 2011 through March 2012; of these 29 investigators responded. Constructive feedback is essential for COMIRB to improve services and provide directed customer service. For your convenience, a survey link is listed at the end of every COMIRB approval and feedback letter.

Please indicate the extent to which you agree with the following statements about the IRB review process.

The IRB review process...

<table>
<thead>
<tr>
<th>Question</th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neither Agree nor Disagree</th>
<th>Agree</th>
<th>Strongly Agree</th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provided written feedback that was clear (i.e., easy to follow/understand)</td>
<td>3.4%</td>
<td>13.8%</td>
<td>6.9%</td>
<td>58.6%</td>
<td>17.2%</td>
<td>29</td>
</tr>
<tr>
<td>Led to changes in the protocol and/or related documents that made sense to me</td>
<td>10.3%</td>
<td>13.8%</td>
<td>20.7%</td>
<td>48.3%</td>
<td>6.9%</td>
<td>29</td>
</tr>
<tr>
<td>Enhanced the integrity of my research study</td>
<td>10.3%</td>
<td>17.2%</td>
<td>44.8%</td>
<td>17.2%</td>
<td>10.3%</td>
<td>29</td>
</tr>
<tr>
<td>Increased my understanding of human research subject protections</td>
<td>13.8%</td>
<td>20.7%</td>
<td>34.5%</td>
<td>17.2%</td>
<td>13.8%</td>
<td>29</td>
</tr>
</tbody>
</table>

COMIRB Improvement Initiatives

- Ensure robust scientific review of protocols prior to IRB submission
- Conduct pre-review outside COMIRB
- Electronic submission of protocols
- COMIRB Office Hours
- Pre-submission meetings to assist investigators to develop complex protocols prior to submission
- Continue to improve website
The Office of Grants and Contracts (OGC) negotiates and manages an approximate $142M portfolio of contracts each year on behalf of the faculty of the University of Colorado Denver I Anschutz Medical Campus. The demand for research-related contracts has increased significantly with the concomitant need for efficient operations to support this growing area at the University of Colorado Denver I Anschutz Medical Campus. The number of fully executed contracts has grown from 971 in FY 2009 to 1,143 in FY 2011 and is projected to remain approximately the same in FY 2012. These numbers do not include the negotiation of subcontracts to other institutions, which is approximately 500-600 per year. Despite the increased volume, the average number of business days in contracts which were under negotiation dropped 46% between Fiscal Year 2009 and 2012 YTD.

The OGC Contracting Office is supported by 2.5 FTE contract attorneys. During FY 2011, they each negotiated an average of 457 contracts. In comparison, the average contract workload among federal agencies during this time period ranged from 142 to 154 per FTE (January 2012 Library of Congress OIG, Report No. 2011-SP-105).

Over the past four years OGC identified and pursued a number of goals to improve contract negotiations:

1. Change in expertise of the contracting staff from generalists to attorneys.
2. Development of a closer working relationship with the Office of University Counsel and refining negotiation of required university legalize into University of Colorado Denver I Anschutz Medical Campus contracts.
3. Implement campus-wide procedures requiring complete routing/electronic versions of proposed contracts to be submitted to an electronic e-mail portal prior to commencing negotiations.
4. Implement tracking and management of proposed contracts in ERA (InfoEd).
5. Establish goals for negotiation time frames for final execution of contracts.

The results associated with these goals have produced improved contract negotiations and turn-around. Of note are additional responsibilities assigned to OGC during this period of time – consolidation of sponsored research administration from the Downtown Campus and negotiation of approximately 240 Confidentiality Disclosure Agreements annually that were formerly negotiated by the CU Technology Transfer Office (TTO).
Business Days in Contract Negotiation FY 2009 thru FY 2012 YTD

<table>
<thead>
<tr>
<th>Test</th>
<th>FY 2009*</th>
<th>FY 2010</th>
<th>FY 2011</th>
<th>FY 2012 YTD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>24</td>
<td>16</td>
<td>16</td>
<td>13</td>
</tr>
<tr>
<td>Mode</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Median</td>
<td>6</td>
<td>5</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>40</td>
<td>28</td>
<td>27</td>
<td>19</td>
</tr>
</tbody>
</table>

Notes:

* CU Denver Research Consolidation – OGC took over management of the Downtown Campus Sponsored Projects

* OGC was given the responsibility of negotiating University of Colorado Denver I Anschutz Medical Campus Confidential Disclosure Agreements from CU TTO

Business Days = ((Total Number of Days from Receipt of Routing-Contract to University of Colorado Denver I Anschutz Medical Campus Signature)/7)*5

Contract Negotiation Turn-Around

Office of Grants and Contracts

University of Colorado Denver | Anschutz Medical Campus FY 2009
Applications and proposals submitted for sponsored program funding over 11 year comparison
Anschutz Medical Camps

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Number</th>
<th>Total Amount</th>
<th>Research Number</th>
<th>Research Amount</th>
<th>Training Number</th>
<th>Training Amount</th>
<th>Service &amp; Other Number</th>
<th>Service &amp; Other Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002-2003</td>
<td>2,442</td>
<td>481,301,721</td>
<td>1,861</td>
<td>408,901,179</td>
<td>335</td>
<td>38,525,285</td>
<td>246</td>
<td>33,875,25</td>
</tr>
<tr>
<td>2003-2004</td>
<td>2,640</td>
<td>518,693,231</td>
<td>2,046</td>
<td>454,310,945</td>
<td>325</td>
<td>33,033,160</td>
<td>269</td>
<td>31,349,12</td>
</tr>
<tr>
<td>2007-2008</td>
<td>2,755</td>
<td>556,259,923</td>
<td>2,209</td>
<td>482,634,903</td>
<td>277</td>
<td>27,235,794</td>
<td>269</td>
<td>46,389,22</td>
</tr>
<tr>
<td>2008-2009</td>
<td>4,103</td>
<td>850,182,718</td>
<td>3,482</td>
<td>728,595,063</td>
<td>331</td>
<td>39,210,179</td>
<td>290</td>
<td>82,377,47</td>
</tr>
<tr>
<td>2009-2010</td>
<td>3,872</td>
<td>721,061,598</td>
<td>3,120</td>
<td>644,414,749</td>
<td>507</td>
<td>12,580,963</td>
<td>245</td>
<td>64,065,88</td>
</tr>
<tr>
<td>2010-2011</td>
<td>3,809</td>
<td>661,967,224</td>
<td>3,192</td>
<td>586,742,890</td>
<td>378</td>
<td>48,250,107</td>
<td>239</td>
<td>26,974,22</td>
</tr>
</tbody>
</table>

Future Initiatives in the Office of Grants and Contracts to support Research Contracting:

- Migration of University of Colorado Denver I Anschutz Medical Campus Subcontracts into InfoEd
- Phase II Implementation of InfoEd Grant Module – Electronic Proposal Routing and Proposal Development
- Implementation of a Central Information Warehouse for sponsored program and contracting analytics
University and Affiliate Human Subject Related Publications

Total Publication numbers based on Pubmed Search of (“University of Colorado” OR “Anschutz Medical Campus” OR “Denver Health” OR “The Children’s Hospital” or “Children’s Hospital Colorado” OR “80218” OR “80045” OR “80206” OR “80204” NOT “80309”) AND date range, select ‘species’ = ‘human’.

![Bar Chart](chart.png)
INITIATIVES
Building a protocol approval tracking database

Why do we need accurate data?
- To really understand where we are – locally and nationally
- To better understand the current system of review and to prioritize change
- To accurately see the result of any change across the system
- To attract sponsors – both NIH and Industry want to see data
- To be transparent to faculty
- To meet national expectation that system data is available – for CTSA grant, AAHRPP accreditation

What data is currently available?
- Each entity within the system maintains its own data in its own database
- Currently there is no way to aggregate across the system
- Little data is published for investigators
- Process evaluation is based on anecdotal experiences
- Process changes cannot be evaluated systematically
- Downstream effects of any changes cannot be evaluated

Protocol Tracking Database
The plan is to build a protocol tracking database to accurately track individual protocols through the approval process. Wherever possible data will be pulled from primary source databases but other data points will be entered manually.

Implementation will occur in three phases:
1. Investigator initiated and grant funded protocols to approval
2. Industry sponsored protocols to approval
3. The life cycle of the human subject protocol

The infrastructure for the database is nearly complete. Data input for phase I will begin in September with 2011 data being entered to serve as a baseline to compare to 2012 data. The plan is to make aggregate data on cycle times across the system available to faculty every 6 months.
The scientific advisory research committee (SARC) now meets every two weeks to review pediatric and adult protocols. To improve efficiency, SARC will only review the protocol, budget and resource requests. Once the protocol has been approved by SARC the Research Subject Advocate and Navigator on the CTRC will work with the investigator to finalize the IRB submission packet prior to submission to COMIRB and facilitate review by the applicable affiliate(s). The aim is to limit redundancy and improve the cycle time by reducing the deferral rate at the IRB. Currently there are insufficient data to evaluate if these changes (instituted in January 2012) have improved timelines but anecdotal feedback is in support of these changes.
Investigator initiated and Grant Funded Non CTRC or CTO Protocol Approval Flow (non WIRB)

The aim is to develop a similar approval process for investigator-initiated research to match what is currently in place under the revised CTRC approval process. Each division/department or school (depending on protocol volume) will be asked to identify faculty to review the investigator-initiated protocol and concur that the science is appropriate. (Funded grants and similar peer-review protocols will be able to circumvent the previous step.)

The University of Colorado Denver | Anschutz Medical Campus has established resources in the form of protocol specialists and facilitators to be housed in the newly formed Clinical Research Support Center to help the investigator navigate the system and complete the necessary documents for approval.
Adult CTO/UCH/WIRB process

The Adult CTO that is based at UCH has been approved by WIRB to utilize their fast-track panel. WIRB commits to reviewing the protocol in 5 days, thereby streamlining the approval process for the CTO, UCH and University of Colorado Denver I Anschutz Medical Campus. The plan is to have regulatory approvals within 15 days.

This process will be beta-tested within the next few months before being made available to any industry funded research that intends to use the Adult CTO.

![Flowchart of Adult CTO/UCH/WIRB process]

Total = 15 days
Electronic Research Administration

The University of Colorado invested in an electronic system to facilitate the submission and review of projects through various compliance committees.

In late 2008, the Office of Grants and Contracts and COMIRB conducted a database conversion and both offices have been using the system for office processing since that time. OGC successfully completed beta-testing of the electronic grants submission process using the Boettcher awards in 2012 and continues to move forward to expand its electronic capabilities.

COMIRB has been accepting electronic submission for exempt and expedited protocols since September 2011. The plan is to begin full board electronic submissions by the end of the year.

The Office of Conflict of Interest and Commitment has been using this system to collect financial disclosures since 2010. The system is now being integrated with OGC and COMIRB to facilitate the identification of potential overlaps that may be a financial conflict of interest. This integration will enhance University of Colorado Denver I Anschutz Medical Campus’ ability to identify potential overlap between research projects and significant financial interests in a timely and compliant manner.
CLINICAL RESEARCH SUPPORT CENTER
Founded in Spring 2012, with resources provided by the Chancellor and Deans at Anschutz Medical Campus.

The goals are to:

1. Improve protocol opening timelines
2. Improve IRB efficiency
3. Increase departmental and PI protocol accountability
4. Ensure protocol scientific integrity and vetting
5. Improve compliance through clinical research education, training, and monitoring
The ultimate goal of the CRSC is to streamline clinical research protocols through institutional systems while maintaining compliance within the Human Research Protection Program (HRPP).

The CRSC consists of specialized, but integrated, expert teams that focus on the entire clinical trial process:

**Protocol Specialist team** to guide investigators and their research team in:
- COMIRB pre-review to ensure quality and accurate submissions; compliance with applicable local and federal regulations as they relate to the specifics and nuances of both adult and pediatric clinical research.
- Regulatory guidance and direction in order to ensure compliance with all internal, external and federal policies.

**FDA Coordinating Center to:**
- Facilitate FDA IND/IDE submissions, communication, maintenance, follow-up, and compliance.
- Provide Clinical Trials.gov training, maintenance and compliance.

**Study Support Resources (post-approval) to:**
- Conduct quality assurance and quality improvement reviews of individual departments and/or individual investigators.
- Budget Specialist to assist in the development of the clinical trial budget to ensure all research expenses are included and site-specific requirements are met.
- Provide periodic oversight of on-going studies to ensure compliance.

**Augment existing Training and Education programs:**
Building upon the core clinical trials curriculum developed by the CCTSI, the Education Team provides on-going and innovative educational opportunities to clinical research professionals across the University of Colorado Denver I Anschutz Medical Campus and its affiliates.

**Clinical Research Forum (CRF):**
A monthly gathering of clinical research professionals: investigators, coordinators, regulatory affairs coordinators, data managers and administrators. The purpose is to network with peers, exchange pertinent knowledge and improve standardized practices across our research community.
Clinical Research Professional Lecture Series:
A one-hour lecture held monthly and presented by experts in a variety of fields. The topics provide clinical research professionals with an opportunity to learn about the various treatment and research programs on campus and in the community.

Clinical research training core curriculum courses:
- Intro to Clinical Trials and Good Clinical Practice
- Overview of Human Subject Regulations
- Trial Design
- COMIRB Submissions
- Writing Informed Consents
- IRB Responsibilities after Approval
- Recruitment for Clinical Trials
- Clinical Trial Start Up
- Clinical Trial Maintenance
- Clinical Trial Close Out
- Export control
- Responsible Conduct of Research (for Investigators)
- How the FDA and COMIRB Interact
- Preparing for FDA Audits
- Budgeting for Clinical Trials
- Research Billing Compliance
- Human Gene Transfer: Submitting to the Institutional Biosafety Committee
- HITECH HIPAA Training
- Conflict of Interest
- Introduction to Responsible Conduct of Research (for CRCs)

In 2011, a subset of 107 clinical research professionals attending 10 of the CCTSI clinical trial training for investigators and coordinators (87% of the total attendees) completed course satisfaction surveys. The figure below details the demographic of these attendees.
In the figure below, results show that 81% of respondents felt that the courses were applicable to their current position and that after training; they are better prepared to perform their required clinical research duties.

**Satisfaction Survey Results (n=107), 87% Response Rate**

- I’m better prepared to run a clinical trial (write an ICF, submit to COMIRB/IBC, etc)
- I will be able to apply what I learned today back to my actual job
Clinical Research Support Center Staff

<table>
<thead>
<tr>
<th>Role</th>
<th>Name</th>
<th>Email</th>
<th>Phone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director</td>
<td>Bernadette Pistone, RN, PhD</td>
<td><a href="mailto:Bernie.Pistone@UCDenver.edu">Bernie.Pistone@UCDenver.edu</a></td>
<td>303-724-1065</td>
</tr>
<tr>
<td>Senior FDA/Quality Improvement Specialist</td>
<td>Andrea Buchmeier, CCRC</td>
<td><a href="mailto:Andrea.Buchmeier@UCDenver.edu">Andrea.Buchmeier@UCDenver.edu</a></td>
<td>720-848-7173</td>
</tr>
<tr>
<td>Senior Education/ Quality Assurance Specialist</td>
<td>Jennifer Maitlen, RN, BSN, CCRP</td>
<td><a href="mailto:Jennifer.Maitlen@UCDenver.edu">Jennifer.Maitlen@UCDenver.edu</a></td>
<td>720-848-7174</td>
</tr>
<tr>
<td>Facilitator</td>
<td>Molly Van Rheen, MS</td>
<td><a href="mailto:Molly.VanRheen@UCDenver.edu">Molly.VanRheen@UCDenver.edu</a></td>
<td>720-848-8594</td>
</tr>
</tbody>
</table>
Affiliates

University of Colorado Hospital
The Clinical Research Advisory Committee (RAC) was formed in the summer of 2011 at the request of Dean Richard Krugman and UCH President Bruce Schroffel, with the mission of advising the School of Medicine and University Hospital on how to expand, streamline, and improve clinical research activities. The RAC’s goals are to provide a voice for clinical investigators and coordinators, develop solutions to issues challenging the clinical investigative community, improve collaboration between the research community and UCH, and to utilize the limited resources in an efficient and productive manner.

The committee’s membership is broadly representative, with the intent to be inclusive. Five working groups have been formed, addressing:

- Protocol Approval Streamlining
- Enhancing UCH structural support for clinical research
- Improving EPIC implementation to facilitate research needs
- Improving recruitment and retention for research subjects
- Facilitating the use of medical imaging for research purposes

Each of the above areas of are very much a “work in progress”, and continued collaboration and commitment will be necessary going forward to bring these efforts to fruition.

Children’s Hospital Colorado
Children’s Hospital Colorado is in the process of re-structuring its Research Institute, CTO and CTRC into an integrated, coordinated system. This transition is being done in collaboration with University of Colorado Denver I Anschutz Medical Campus to ensure a seamless connection is developed with the newly established CRSC.

Denver Veterans Administration Medical Center
The VA is currently in the process of establishing a VA liaison position. This position will focus on improving connection points between the VA and University of Colorado Denver I Anschutz Medical Campus HRPP to facilitate human subject research collaborations between the two institutions.

Denver Health & Hospital Authority
Denver Health continues to collaborate with University of Colorado Denver I Anschutz Medical Campus to improve communication between the two institutions and integrate education programs.
Progress has been made to streamline processes within University of Colorado Denver I Anschutz Medical Campus but most of these changes are currently being beta tested so it is premature to evaluate them.

University of Colorado Denver I Anschutz Medical Campus, UCH and CHCO have significant initiatives currently in development. It will be important for the research enterprise to ensure that these initiatives are carefully integrated so that there is an effective and efficient process as well as a compliant process.

Significant work remains to be completed if this task is to be achieved by the end of 2012.

The tracking database is an essential tool to objectively evaluate progress to streamline the process and identify efficiencies in cycle times. Current data is fragmented and is inconsistently collected.

The next report (Spring 2013) will provide more consistent data to evaluate the initiatives that are currently underway.
CONTACT INFORMATION

Colorado Clinical Translational Science Institute (CCTSI)
720-848-7100
CCTSI@UCDenver.edu

Colorado Multiple Institutional Review Board (COMIRB)
303-724-1055
COMIRB@UCDenver.edu

Clinical Research Support Center
720-848-7173
ClinicalResearchSupportCenter@UCDenver.edu

Environmental Health and Safety
303-724-0345
Reg.Compliance@UCDenver.edu

Grants and Contracts
303-724-0090
GrantsAndContracts@UCDenver.edu

Institutional Biosafety Committee (IBC)
303-724-5541
IBC@UCDenver.edu

Radioactive Drug Research Committee (RDRC)
303-724-1057
RDRC@UCDenver.edu

Regulatory Compliance
303-724-1010
Reg.Compliance@UCDenver.edu
Conflict of Interest (COI)
Export Control
HIPAA/Privacy
Responsible Conduct of Research (RCR)