Enhanced Research Environment

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Assistant Vice Chancellor for Regulatory Compliance, UC Denver
Specific Aims

1. Promote a responsible and safe research environment
2. Across the lifespan of each study
   AND
3. Improve the research enterprise to ensure an
   • Ethical
   • Efficient
   • Cost-Effective system
1. Promote a Responsible and Safe Research Environment

- Expand role of SARC
- Integrate Research Bioethics consultation
- Integrate with community via the PACT-Ethics Committee
- Facilitation committee
- Expand training to research coordinators and PIs including responsible conduct of research
- Site initiation and auditing
2. Across the lifespan of the study

- Implementation of OnCore (CTMS) as the backbone infrastructure
- Study Monitoring Committee
  - currently for CHCO, UCH, Boulder and NJ CTRC
  - plan to expand to include all research at Anschutz Medical Campus

Goal - To identify and assist failing studies
3. Improve the Research Enterprise

- Single central Web Portal for protocol submission and review
- Centralized IRB and expanded use of various IRB models
- Centralized Clinical Research Support Center
- OnCore: Clinical Trial Management System
- Process Improvement (QPIP)
Single Research Web Portal: UCDenver.edu/Research

- Centralized resource for all Research related information on the UCDenver website
- 4 tiles to guide general audience type
- Research events Calendar
  - Pulled from events where ‘researcher’ is checked under ‘intended audience’ field
- Research Participants Page - Good place to send participants looking for studies
- 23rd most visited page on UCDenver.edu
Centralized IRB

The University of Colorado Denver – Anschutz Medical Campus
IRB Structure & Collaborations

The Colorado Multiple Institutional Review Board (COMIRB)

The Children's Hospital of Denver
FWA00004730

Colorado Prevention Center
FWA00004778

Denver Health Medical Center
FWA00004689

University of Colorado Hospital
FWA 00004686

Veteran's Affairs Medical Center
FWA00001681

National Cancer Center Institutional Review Board Initiative
(facilitated review)
FWA00000778

National Jewish Medical and Research Center Institutional Review Board (reciprocity)
FWA00000778

Western Institutional Review Board (serves as additional panels)

Utilize Institutional Review Board Authorization Agreements for Collaborations (various roles)

COMIRB Panel A (Adult General Panel)

COMIRB Panel B (Adult General Panel)

COMIRB Panel C (Pediatric Panel)

COMIRB Panel D (Adult Specialty Panel)

Expedited/Exempt Track

COMIRB Panel S (Social and Behavioral Panel)

Formal Affiliations
UCD
Established With Affiliated Hospitals or Research Centers

COMIRB
Established with external IRB’s

Formal Relationships

The University of Colorado Denver – Anschutz Medical Campus
IRB Structure & Collaborations

The Colorado Multiple Institutional Review Board (COMIRB)
Other Central IRB mechanisms used:

- NCI CIRB
- NeuroNEXT
- CASBG
- Collaborative Pediatric Critical Care Research Network (pending)
- Master Common Reciprocal IRB Agreement
Centralized Clinical Research Support Center

Regulatory Development
- FDA Assistance
- IND/IDE Application
- FDA Annual Reports
- ClinicalTrials.gov

Pre-Review
- Human Research Portal
- Pre-Review of Submissions
- Consent writing assistance

Education
- Clinical Trials training courses
- Responsible Conduct of Research
- Post approval study start-up assistance

Study Monitoring
- Audits by request from study team
- For cause audits
- Study monitoring Committee

SUPPORT ACROSS THE LIFETIME OF A PROTOCOL

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Clinical Research Support Center Metrics

Customer Tickets by type

Audits

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Studies</td>
<td>25</td>
</tr>
<tr>
<td>COMIRB</td>
<td>0</td>
</tr>
<tr>
<td>Radioactive Drug Committee Studies</td>
<td>3</td>
</tr>
<tr>
<td>FDA Submissions</td>
<td></td>
</tr>
<tr>
<td>IND Submissions (incl. in progress)</td>
<td>5</td>
</tr>
<tr>
<td>IND – Single Patient and Compassionate Use</td>
<td>2</td>
</tr>
<tr>
<td>IDE Submission (inc. in progress)</td>
<td>2</td>
</tr>
<tr>
<td>ClinicalTrials.gov</td>
<td></td>
</tr>
<tr>
<td>Records</td>
<td>455</td>
</tr>
<tr>
<td>FDAAA Applicable</td>
<td>88</td>
</tr>
<tr>
<td>% of active studies updates in 2014</td>
<td>98%</td>
</tr>
</tbody>
</table>

*Portal implemented August 4, 2014
OnCore Implementation:
Collaboration between CU AMC and UCHealth

- Clinical Trial Management System (CTMS) funded in November 2013
  - Currently in planning phase
- Proposed early adopters
  - Department of Orthopedics
  - Division of Renal Diseases and Hypertension
  - Cancer Center
- 2015: Expanded roll-out
Efficiency

• Expansion of the Clinical Research Support Center
• Process improvement through collaboration with hospital affiliates
• Clinical Trials Management System (OnCore)
Process Improvement Initiative with QPIP: Protocol Review

- Submission Documents sent to Sharepoint Mailbox - Feasibility Form - Budget - Protocol
- Approvals needed triage
- SARC Review
- CHCO
- CTRC
- UCHealth
- E-Review
- Concurrent Document Preparation Assistance
- Post-Revision Document Preparation Assistance
- Consolidated Feedback to PI
**Portal Data**

- 25 Instructor led training sessions
- Average days from Submission to Approval: 30.38
- 24 Protocols have received scientific review by the Scientific Review Advisory Committee
  - 9 were not using CTRC resources
Colorado Multiple Institutional Review Board

IRB TIMELINE

<table>
<thead>
<tr>
<th>Year</th>
<th>Committee Duration</th>
<th>PI Duration</th>
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<tbody>
<tr>
<td>2014</td>
<td>19</td>
<td>8</td>
</tr>
<tr>
<td>2013</td>
<td>21.02</td>
<td>15.07</td>
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<tr>
<td>2012</td>
<td>22.37</td>
<td>22.87</td>
</tr>
<tr>
<td>2011</td>
<td>26</td>
<td></td>
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</tbody>
</table>

IRB Volume

Number of Reviews to Approval

<table>
<thead>
<tr>
<th>Year</th>
<th>1 review</th>
<th>2 reviews</th>
<th>3 reviews</th>
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</thead>
<tbody>
<tr>
<td>2012</td>
<td>27</td>
<td>65</td>
<td>8</td>
</tr>
<tr>
<td>2013</td>
<td>46</td>
<td>44</td>
<td>11</td>
</tr>
<tr>
<td>2014</td>
<td>33</td>
<td>44</td>
<td>23</td>
</tr>
</tbody>
</table>

2012: 1290
2013: 1359
2014: 1400
# Office of Grants and Contracts

## 2014 Fiscal Year

- **4,485 Proposals**
- **2,337 Awards**

### Departments
- **Pre Award / Contracting**
  - 14 FTE
- **Post Award / Accounting**
  - 26 FTE
- **Electronic Research Administration**
  - 5 FTE

## Proposal Review, Project Setup, Contract Negotiation, Subcontract Negotiation

<table>
<thead>
<tr>
<th>Year</th>
<th>Proposal Review</th>
<th>Project Setup</th>
<th>Contract Negotiation</th>
<th>Subcontract Negotiation</th>
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</thead>
<tbody>
<tr>
<td>2013</td>
<td>1</td>
<td>13</td>
<td>37</td>
<td>52.4</td>
</tr>
<tr>
<td>2014</td>
<td>4.2</td>
<td>4.3</td>
<td>38.9</td>
<td>41.7</td>
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</table>

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## Technology Transfer Office Metrics

<table>
<thead>
<tr>
<th>Fiscal year</th>
<th>New Patent Filings</th>
<th>US Patents granted</th>
<th>Commercial IP licenses in force</th>
<th>Startup Companies from CU IP</th>
<th>Revenue</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013 - 2014</td>
<td>90</td>
<td>51</td>
<td>377</td>
<td>9</td>
<td>$4.3M</td>
</tr>
<tr>
<td>2012 - 2013</td>
<td>115</td>
<td>37</td>
<td>348</td>
<td>8</td>
<td>$16.5M</td>
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<tr>
<td>2011 - 2012</td>
<td>116</td>
<td>41</td>
<td>399</td>
<td>10</td>
<td>$32.8M</td>
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<tr>
<td>2010 - 2011</td>
<td>126</td>
<td>39</td>
<td>374</td>
<td>11</td>
<td>$3.9M</td>
</tr>
</tbody>
</table>
Cost-effective

• Collaboration with Affiliates to avoid duplication of resources
• Key partnership with DOM
• Process improvement with assistance from QPIP
Ethical component

• Integrate the Ethics Core into the Support Center
• Utilize the PACT-Ethics Committee
Research Ethics

- **Research Ethics Consultations 2014:**
  - 6 Consults
  - 1 publication:

- **Hospital Wide Ethics Grand Rounds:**
  - Ethics on the Borderland: Research or QI?

- **Responsible Conduct of Research Class**
5th Annual Research Ethics Conference

- Title: Protecting Research Participants’ Privacy: Is It Possible? Should We Care?
- Date: October 9, 2014
- Time: 10-2
- Attendees: 60
- Evaluations Summary:
  - 11 Questions:
    - Mean= 3.8 - 4.6
    - Example: “Attending conference was a valuable use of my time,” mean=4.6.
PACT ETHICS COMMITTEE
Partnership of Academicians and Communities for Translation

Mission:
To cultivate awareness among academicians and communities in Colorado of ethical issues related to community engaged medical research; to develop tools for addressing such issues; to disseminate these tools; and to support use of the tools as well as relationships among the users.
PACT ETHICS COMMITTEE

Composition:

• 3 Community members
• 3 PACT Council members
• 4 PACT community engagement representatives
• 2 University bioethicists
• 1 Central Administration
• 4 PACT scientific staff
Initial issues being considered:

• Community fatigue in research

• Role of the PACT-Ethics committee to facilitate and/or review community consultation plans for protocols involving waiver of consent in emergency settings

• Subject recruitment
National CTSA Consortium Involvement

Our program is involved in the national CTSA Consortium Working Group for:

- GCP training and competencies
- Contract templates
- IRB Reciprocity

DSMB Affinity Group is also still active
Questions for EAC

• Tracking data across the various institutions is difficult to obtain to really address quality improvement further.

• Need fully operational CTMS to track protocols through the lifespan – 3 to 5 years away depending on implementation resources – this makes addressing failing studies difficult.

• How best to facilitate recruitment in a decentralized environment is unclear.

• Suggestions?