Quality Improvement Plan for the UCD Human Research Protection Program

**Situation Statement:** The UCD HRPP is intimately connected to the HRPP’s of the affiliate hospitals. The effectiveness, quality and efficiency of each HRPP is dependent on a streamlined, integrated model that builds on the responsibilities and strengths of each institution to establish a delineated, integrated system of protection for human subject research.

### Inputs
- Affiliate organizations have regulatory leadership with enduring histories, deep expertise
- Funds/resources for new Research Support Center
- Funds/resources for the development of a centralized institutional database to support tracking cycle times across the entirety of the review process
- Newly-hired regulatory navigators
- QA program
- Core director who embraces innovation
- CTTIC courses
- Evaluative expertise of TEC

### Outputs
- Establish Research Support Cntr
- Provide training, mentoring, TA
- Develop interactive Web site
- Establish consolidated forms with templated language
- Establish a federated IRB, standardized agreements that span affiliates
- Integrate a coordinated feasibility assessment (includes detailed budgetary review) at the front-end of the review process
- Establish a mechanism for pre-review
- Establish infrastructure to conduct formative, process and summative evaluation and utilize information to inform ongoing quality improvement
- Establish institutional database to track cycle times
- Investigators
- Research Study Coordinators
- Fellows/trainees
- (Potential) research study subjects
- Review committee members and others who participate in the review process
- Administrators
- Partners in the conduct of clinical trials (other institutional partners in multi-site trials, industry partners, etc.)

### Activities (What we will do)

<table>
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<tr>
<th>Activities</th>
<th>Outputs</th>
<th>Participation</th>
<th>Results: Outcomes – Impact</th>
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<td>(Who we will impact)</td>
<td>Short Term</td>
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<td>Investigators/study coordinators report high satisfaction with support (including training) and process changes</td>
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<td>Diverse perspectives inform human subjects protection</td>
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<td>A positive dose-response is detectable between CTTIC training and cycle times, as well as number of resubmissions</td>
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### Assumptions
- NIH directives (the CTSA renewal effort, specifically) will garner the institutional support and political will necessary to achieve broad-based initiatives, including the establishment of unified IRB options
- The Front-Range Health Care Consortium will be another impetus for streamlining regulatory review-approval processes (to facilitate the consortium’s engagement, for example, in industry-sponsored drug trials and other multi-center studies)
- Local stakeholders will be motivated to collaborate effectively to achieve bold initiatives

### External Factors (that may shape program over time)
- The federal and state regulatory environment(s)
- Increased emphasis on industry-sponsored studies and clinical trials
- Increased scrutiny of budgets

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1 Logic model format from: [http://www.uwex.edu/ces/pdande/evaluation/evallogicmodelworksheets.html](http://www.uwex.edu/ces/pdande/evaluation/evallogicmodelworksheets.html)
<table>
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<tr>
<th>Goal</th>
<th>Indicator (from logic model above)</th>
<th>Metrics</th>
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| **Goal 1:** Increase the effectiveness of the regulatory approval processes and support (2012) | **Indicator 1:** Existing services are centralized and expanded to facilitate the preparation and maintenance of regulatory and administrative requirements | • Establish a Research Support Center (includes that establishment of a centralized FDA oversight office that will track INDs, IDEs, and address FDA annual reporting requirements)  
  o Reduce cycle times (comparative analysis utilizing data from centralized, institutional database):  
    o Investigators who utilize services (especially preview) versus comparable investigators who do not  
    o CTRC protocols versus comparable protocols that do not require SARC review  
  o Enhanced investigator satisfaction with accessibility and support available to address regulatory requirements (satisfaction survey data: CTRC investigators; those who utilize the Research Support Center; CCTSI needs assessment data: 2014 and 2010 results compared)  
  • Develop interactive website (Web traffic metrics for new Reg Knowledge site, existing CTRC site)  
  • Improved communication, coordination between entities  
    o Communication logs (adopt system currently utilized by Cancer Center to track investigator and Support Center staff responsiveness, amount and type of technical assistance provided, etc.)  
    o Annual workflow analysis of investigator-initiated studies (to be expanded to include COI, Institutional Biosafety Committee and Radioactive Drug Research Committee)  
    o Annual workflow analysis of industry-sponsored studies (WIRB, CTOs, Office of Grants and Contracts and affiliates) |
| **Indicator 2:** Increased human resource capacity exists to support investigators (e.g., through pre-review, education and training of research study coordinators, navigators) | • # of new hires and total FTE for mission-critical aspects of the Research Support Center and Regulatory Knowledge and Support Core (CCTSI)  
  • Communication logs (responsiveness, amount and type of technical assistance provided, etc.)  
  • Adjustments made to personnel and FTE based on demand for services/support (evidence collected through feedback loop established between external evaluation team and RKSC leadership)  
  • Study coordinators who have participated in CTTIC training report higher job satisfaction, self-efficacy to respond effectively to regulatory requirements, require fewer resubmissions, and are more likely to be retained (thus enhancing human resource capacity) |
| **Indicator 3:** Investigators/study coordinators report high satisfaction with support and process changes | • Satisfaction survey results (surveys tailored for investigators and study coordinators; CTRC investigators; reviewers; Web site users; evaluation feedback following internal audits, those who utilize the Research Support Center)  
  • Comprehensive CCTSI needs assessment results (2014 results compared with 2010)  
  • CTTIC course evaluations |
| **Indicator 4:** All relevant input (that is critical to the scientific integrity, feasibility and regulatory aspects of a given protocol) is provided in a consolidated (streamlined) manner and informs pre-review | • Reduction in time from submission to board review from 60 to 30 working days by March 2013  
  • Annual workflow analysis of investigator-initiated studies (to be expanded to include COI, Institutional Biosafety Committee and Radioactive Drug Research Committee)  
  • Annual workflow analysis of industry-sponsored studies (WIRB, CTOs, Office of Grants and Contracts and affiliates)  
    • Compare CTRC, Research Support Center protocols and those touched by both, not touched by either  
    • Eliminate cycles of re-review (stemming from investigators receiving reviews in tandem rather than as a coordinated process involving all relevant review entities) |
| **Indicator 5:** A positive dose-response is detectable between CTTIC training and cycle times, as well as number of resubmissions | • Study coordinators who have participated in CTTIC training report higher job satisfaction, self-efficacy to respond effectively to regulatory requirements, require fewer resubmissions, and are more likely to be retained (thus enhancing human resource capacity)  
  • Research study teams demonstrate fewer deviations and lower rates of non-compliance following internal audits – another education/training mechanism |

2 Historical trends will be examined annually (with reports published in April).
### Goal 2: Improve the quality of protocols submitted for regulatory approval

**Indicator 1: Reduced number of protocols are deferred**
- Deferral Rate will be reduced to 10% in 3 years
- Historical trends:
  - % of all new submissions that are approved on first submission
  - % of all new submissions that require only minor modifications
  - % and type of protocols requiring multiple reviews by full committee

**Indicator 2: Increased number of protocols require only minor modifications**
- See above

**Indicator 3: Services and processes undergo continuous quality improvement, informed by external evaluation**
- All evaluation systems, tools, and processes (designed to assess the metrics identified in this plan) will be developed by August 2012; the timing of implementation will be aligned with the timeframes specified in this plan for the development and implementation of program components
- Evaluation feedback mechanisms will be established through monthly meetings with key stakeholders (monthly meeting schedule has been established and will continue in an ongoing fashion)
- Utilization of evaluation data will support continuous quality improvement with specific examples available to highlight in the CCTSI renewal application (currently in place and will be ongoing)

**Indicator 4: Increased demand and ability to participate in multi-site and industry-sponsored clinical trials**
- Historical trends in number of industry-sponsored and multi-site clinical trials
- Research productivity of these trials:
  - Recruitment and retention rates
  - Accrual of human subjects compared to proposed accrual schedules
  - Advancement through phased trials (and associated funding) and tech transfer process (and associated funding) (data available from Technology Transfer Office and Corporate Alliance Office)
  - Publications

**Indicator 5: Reviewers indicate that submitted protocols and review processes/procedures are high quality (and implemented with fidelity, as per check lists)**
- Deferral Rate will be reduced to 10% in 3 years (centralized institutional database and review committee meeting documentation)
- # of hours spent reviewing and preparing each week by members and reviewers (trends on annually-administered reviewer satisfaction survey)
- # of protocols reviewed each meeting and length of review committee meeting (panel meeting minutes)
- Evidence of reviewer perspectives regarding the quality of materials and processes (reviewer mandatory self-assessments and reviewer satisfaction surveys, administered by phone by external evaluation team)

### Goal 3: Increase the efficiency of the regulatory approval process

**Indicator 1: Improved cycle times**
- Historical trends in cycle times by panel (reduce by 25% within one year of full implementation of electronic submission)
- # of hours spent reviewing and preparing each week by members and reviewers (trends on annually-administered reviewer satisfaction survey)
- # of protocols reviewed each meeting and length of review committee meeting (panel meeting minutes)

**Indicator 2: The need for, and burden associated with, establishing subcontracts is obsolete**
- # of new hires and total FTE (i.e., increased human resource capacity) in Office of Grants and Contracts for subcontracting
- Historical trends in cycle times by affiliate organization(s) (Office of Grants and Contracts)
- Standardized agreements have been established for all CCTSI affiliates (monthly meetings with RKSC and CCTSI Executive Committee meeting documentation)

**Indicator 3: Review process is no longer viewed as a significant rate-limiting step in translational research**
- Historical trends in cycle times by panel (reduce by 25% within one year of full implementation of electronic submission)
- Deferral rate will be reduced to 10% in 3 years
- Historical trends:
  - % of all new submissions that are approved on first submission
  - % of all new submissions that require only minor modifications
  - % and type of protocols requiring multiple reviews by full committee
Comprehensive CCTSI needs assessment results (2014 results compared with 2010)
Perceptions of CCTSI External Advisory Committee members

- Deferral rate will be reduced to 10% in 3 years
- Historical trends:
  - % of all new submissions that are approved on first submission
  - % of all new submissions that require only minor modifications
  - % and type of protocols requiring multiple reviews by full committee
- Comprehensive CCTSI needs assessment results (2014 results compared with 2010)
- Annual workflow analysis of investigator-initiated studies
- Annual workflow analysis of industry-sponsored studies

Indicator 4: Investigator/research study coordinator interactions with regulatory agencies are streamlined

- Historical trends:
  - % of all new submissions that are approved on first submission
  - % of all new submissions that require only minor modifications
  - % and type of protocols requiring multiple reviews by full committee

- Comprehensive CCTSI needs assessment results (2014 results compared with 2010)
- Annual workflow analysis of investigator-initiated studies
- Annual workflow analysis of industry-sponsored studies

Indicator 5: Increased research productivity (particularly clinical trials)

- Historical trends in number of industry-sponsored and multi-site clinical trials
- Research productivity of these trials:
  - Recruitment and retention rates
  - Accrual of human subjects compared to proposed accrual schedule
  - Advancement through phased trials (and associated funding) and tech transfer process (and associated funding) (data available from Technology Transfer Office and Corporate Alliance Office)
  - Publications

Indicator 6: Greater agility to respond to Just-in-Time solicitations

- Historical trends in number of Just-In-Time submissions (adjusted for number of opportunities available over time) (data source: CTRCs)
- Comprehensive CCTSI needs assessment results (2014 results compared with 2010)
- Investigator satisfaction survey (add item about just-in-time solicitations to investigator survey administered at approval)

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