

University of Florida Clinical and Translational Science Institute External Advisory Committee Report

March 9, 2010

The External Advisory Committee to the University of Florida CTSI completed the 2010 site visit on February 15-18, 2010.

Members present: Tesheia Johnson, Thomas Pearson, Ted Shortliffe, Dennis Bier, Debra Haire-Joshu, Lisa Lavange and Alastair Wood (by telephone). Regrets R. Filart (NCRR) due to weather related flight cancellation.

The visit began with a dinner on Feb 10, 2010 which included UF leadership and the site visitors. Dr. Guzick and others conveyed the news that Dr. Stacpoole would be stepping down as P.I. in order to return to his laboratory research program. He will continue to serve until a replacement is identified and in place. The EAC was assured that the CTSI would continue to receive strong oversight and support in the transition.

February 11, 2010: With minor modifications, the attached agenda (Attachment B) was presented by the CTSI investigators who made themselves available for questions and discussion. Following the formal presentations, the EAB met with Drs. Guzick, Philips and others to provide comments and responses to the day's events. A detailed list of topics discussed is presented in Attachment A.

Overview: The EAC was disappointed to hear that Dr. Stacpoole was stepping down but were greatly reassured by the very strong commitment, vision and support provided by the University leaders in the program and the commitment to expeditiously identify a successor. The strengths of the program designed by Dr. Stacpoole included informatics, nurturing environment for young and established investigators, a strong educational program, community engagement and outreach and a well functioning PCIR (CRU). Some of the weaknesses identified included the need for a stronger and more streamlined governance structure along with appropriate operational and administrative support at all levels, evaluation and tracking of programs, information about pilot program support/success, lack of clear organizational approach to biospecimen collection, storage and retrieval, very little information regarding programs for pediatrics. An opportunity was noted in the plans for the Comprehensive Drug Development Program (CDDP) (including GMP facility) but there several concerns expressed about the financial and scientific viability of such a program. Threats to the program included the remote possibility of a prolonged search for a new leader for the CTSI and the need for more comprehensive functional metrics.

Summary of Committee Key Recommendations:

1. A replacement for Dr. Stacpoole should be identified as soon as possible. The committee further recommends that the institutionally leaders remain engaged after the new PI is identified to ensure a smooth transition.
2. The governance structure be re-examined to determine the most efficient and effective structure for the organization to facilitate achieving programmatic goals
3. The operational and administrative structure should be examined to determine if the current level of support is sufficient to meet the needs of the program. Most CTSA PIs have found a need for very senior level operational, grants management, financial, and HR support with the appropriate level of clerical and accounting support to be a key requirement for a well-functioning program.
4. The programs evaluations system and base line metrics much be established immediately. The committee felt strongly that without reliable baseline data the UF program will be quite disadvantaged at renewal as there would be no sound method of evaluation progress towards improvement.
5. At future meetings, the EAC would like to hear about what has been transformed as a result of the CTSA award. The meetings should also include a presentation of CTSA key functions which will allow the committee to provide feedback on the UF's progress towards achieving CTSA awards programmatic goals.

Attachment A:

Summary of points raised in open and executive session of the EAB

Strengths

- Institutional commitment is strong
- Embraced by Leadership (including culture)
- Excellent environment for transformation
- Connections to community are formidable
- Education resources are strong
- Strong 2nd grant submission
 - Biomedical Informatics (BMI) and Electronic Medical Record much stronger
 - Impressed by progress
- BMI, Biostatistics, Epidemiology and Health Policy Research
 - New Division of BMI
 - All join cross College of Medicine department
- Many developments to support clinical research
 - Regulatory Knowledge and Research Support (RKRS) is strong
 - REDCap and Scientific Advisory Committee process
 - Closer to action than most organizations
- Participant and Clinical Interaction Program- PCIP (CRUs) - Also strong
- Cores will be strong if brought together (of those we heard about)
 - Biobehavioral Core – rather ordinary. Need to link more to TTRP
 - Metabolomics is strong
- PCIP-CRU's is challenging
 - How to tie together and become cohesive
 - Missing some depth
 - Working to bring together clinical trials units – thereby increasing efficiency
 - Organize all clinical trial units in CTSI
 - Combined with RKRS improvements, good opportunity for organization to grow and advance (including financially)
- VIVO
 - National Consortium wants to do
 - Great opportunities for UF CTSI
- Community Engagement and Research Program (CERP)
 - Many opportunities developed
 - Institute of Food and Agricultural Sciences (IFAS) in all counties (67)
 - Challenge working with so many units

- CTSI approach is new to IFAS
- CTSI will need to put deliverables in place (IFAS)
- New opportunities for IFAS Extension service
- UF could be very competitive
- Help to move Extension Service into electronic age
- CERP- not well integrated yet

Weaknesses

- Need Governance Structure
- Administrative Support- need more structure and senior administrators
- Communications: unclear if the various parts of the CTSA Program had been convened before.
- Steering and Planning Committee: Many members and % effort. More appropriate to serve in advisory capacity and meet perhaps yearly. Motivation for attendance should be access to research opportunities rather than payment
- Did not hear about Pilot Programs (impacted by Governance)
 - Need to tie in other goals to Pilot Programs/RFA
- Not Addressed
 - Evaluation and Tracking
 - Governance
 - Pilot Project Program
 - Clinical and Research Ethics Program
 - Novel Methodologies
 - Research Design and Analysis Program
 - Public-Private Partnerships
 - Comparative effectiveness research
- Also need to hear in the future
 - What has been transformed?
 - Existing expertise became part of CTSI- but has it overall grown/transformed?
- Explore membership model
- What projects should be included in /count as CTSI? Or using CTSI services?
- Evaluation is driving Organization - not what we want to become
- Need to hear more about Implementation Plan
- Need Evaluation and Tracking baseline data now
- Need cohesive Administrative Structure
 - Need different level of management (than former GCRC for example)
 - Too many advisory committees

- Challenge to Culture
 - Change how we think
 - Become known entity that organization knows and wants to participate
- Biorepository Bank
 - All CTSA's are struggling with this
 - Too many types of specimens
 - No administrative process for dealing with requests for tissues
 - Be careful before committing to too much (scope can be too large)
 - Planning, SOP's, etc are complicated
- Pediatrics?
- RKRS- proposed RPM approach could become expensive. Will all researchers work with a RPM? Not scalable.
- Scientific Advisory Committee (SAC) Review Process
 - Which protocols to review?
 - Generalized from GCRC
 - Make it a service?
 - PI, Chairs and Departments need role ****
 - Optional for younger investigators
 - Option: Studio approach? Bring together group of experts as needed
 - Review those funded by CTSI and those who want it?
 - Or those who are getting kicked back (from IRB) frequently
 - Include in metrics
- Do not bring in something to fix processes/units that are already working and break it.
- Careful to assess projects that need RPM and SAC review
- Careful in expecting cores to become self sufficient before able/ready
 - Recognize need to invest - but expect reasonable return (increase external funding)
 - Trainees use Pilot Program Awards to pay for Core services
 - Cores - base fiscal planning on growth model
 - Also consider outsourcing

Opportunities

- Comprehensive Drug Development Program (GMP) could work if has capacity/maturity to be a service provider. Example- serve multi-center studies
 - Can you justify financially?
 - Can you justify investment – will it result in growth?
 - Is there need nationally?

- Do not have critical mass of research needs?
- Issue – Managing Intellectual Property
- Looks very risky
- Have necessary expertise?
- Should it be part of CTSI?
- Does need exist?
- If already existed and thriving - would be different
- Very expensive core
- Training and Education
 - Many colleges- take advantage of multidisciplinary Advisory Committee
 - Work through trainees to drive transformation
- Report what we have done for individual Departments (including training)
 - May be way to achieve buy-in
 - Becomes recruitment tool
- Mid-level Researchers
 - Salary cap is an issue
 - Could use reward/endowment to fill gap

Threats

- Comprehensive Drug Development Program (CDPP)
- Interim leadership gap during formative time
- Need strong team around PI including KFC Directors
 - Co-PI's/Leadership Team is possible model
 - Strong Administrative support is important
- Careful regarding 'no carry forward' of grant funds from year to year
- Evaluation and Tracking Program not activated
- Need functional metrics

Attachment B:

Agenda for the CTSI Annual Retreat and NCRR Review

Thursday, February 11th

- 7:30 – 8:00 a.m. **Registration and Continental Breakfast**
Hilton University of Florida Conference Center
- 8:00 – 8:05 a.m. **Peter Stacpoole, Ph.D, M.D.**
Professor, Department of Medicine, Biochemistry and Molecular Biology
Associate Dean for Clinical Research and Training
College of Medicine
Principal Investigator, CTSA
Director, UF CTSI
“Welcome”
- 8:05 – 8:30 a.m. **Winfred Phillips, Ph.D.**
UF Vice President for Research
- David Guzick, M.D., Ph.D.**
Senior Vice President for Health Affairs and
President of the UF & Shands Healthcare System
- 9:30 – 10:00 a.m. **David Nelson, M.D.**
Professor, Division of Gastroenterology, Hepatology, and Nutrition
College of Medicine
Director of the Regulatory Knowledge & Research
Support Program, UF CTSI
CTSA SG #1: Building CTR Capability
“Building Clinical and Translational Research Capability at UF”
- 10:00 – 10:30 a.m. **Carl Pepine, M.D., M.A.C.C.**
Professor, Division of Cardiovascular Medicine
College of Medicine
Director, Participant and Clinical Interactions Program
“Resources for Patient-Oriented Research”
- 10:30 – 10:45 a.m. Break
- 10:45 – 11:15 a.m. **Marco Pahor, M.D.**
Professor and Chair, Department of Aging and Geriatric Research
Director, KL2 Program, UF CTSI
*“University of Florida Institute on Aging Claude D. Pepper Older
Americans Independence Center: CTSI Clinical Research Unit”*
- 11:15 -11:45 a.m. **Marian Limacher, M.D., FACC**
Professor of Medicine, Division of Cardiovascular Medicine
Director, Advanced Postgraduate Program in Clinical Investigation
Director of Training and Professional Development, UF CTSI

CTSA SG #2: Education and Career Development
"Training and Professional Development"

- 11:45 – 12:15 p.m. **Thomas Beaver, M.D., M.P.H.**
Associate Professor, Department of Surgery
Director Minimally Invasive Cardiac Surgery
"Translational Research in Cardiovascular Surgery"
- 12:15 – 1:00 p.m. Lunch
- 1:00 – 2:00 p.m. **Michael Conlon, Ph.D.**
Research Associate Professor, Department of Epidemiology and Health
Policy Research
College of Medicine
Interim Director, Biomedical Informatics Program, UF CTSI
CTSA SG #3: Biomedical Informatics & Consortium-Wide Collaborations
"Creating Biomedical Informatics at the University of Florida"
- 2:00 – 2:45 p.m. **Elizabeth Shenkman, Ph.D.**
Professor and Chair, Department of Epidemiology and Health Policy
Research
College of Medicine
Co-Director, Community Engagement and Research Program, UF CTSI
CTSA SG #4: Improving Community Health
"The Community Engagement and Research Program (CERP)"
- 2:45 – 3:00 p.m. Break
- 3:00 – 3:30 p.m. **Henrietta Logan, D.D.S.**
Professor, Department of Community Dentistry and Behavioral Science
College of Dentistry
Department of Community Dentistry and Behavioral Science
"Building Community Engagement"
- 3:30 – 3:50 p.m. **Jesse Gregory, Ph.D.**
Professor, Department of Food Science and Human Nutrition
Institute of Food and Agricultural Sciences (IFAS)
College of Agricultural and Life Sciences
Director, Translational Technologies and Resources Program, UF CTSI
CTSA SG #5: Advancing T1 Research
*"Advancing T1 Research: UF's CTSI Translational Technologies and
Resources Program"*
- 3:50 – 4:10 p.m. **David Powell, Ph.D.**
Department of Chemistry
Director, Metabolomics Core, UF CTSI
"UF CTSI Metabolomics Core"
- 4:10 – 4:30 p.m. **Sara Jo Nixon, Ph.D.**
Professor and Chief, Division of Addiction Research

Department of Psychiatry
Director, Biobehavioral Core, UF CTSI
"Comprehensive Biobehavioral Core"

4:30 – 4:50 p.m.

Nicholas Bodor, Ph.D., D.Sc.

Executive Director, Center for Drug Discovery
Graduate Research Professor, Department of Pharmaceutics
College of Pharmacy
Director, Comprehensive Drug Development Program, UF CTSI
"Center for Drug Discovery"

4:50 – 5:00 p.m.

Peter Stacpoole, Ph.D, M.D.

Concluding Remarks