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# Clinical and Translational Science Award

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July 2007

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*The*  
**UNIVERSITY**  
*of* **VERMONT**

# CTSA: PURPOSE

- To assist institutions to transform their approaches to clinical and translational research to promote an integrated academic home, to:
  - ❑ Capitalize, advance and nurture well-trained multidisciplinary investigators.
  - ❑ Create an incubator for novel ideas and approaches.
  - ❑ Synergize multi- and inter-disciplinary clinical and translational research to catalyze application of new technologies to front lines of patient care

# CTSA: DEFINITIONS

## ■ Clinical Research

### □ NIH defines human clinical research as:

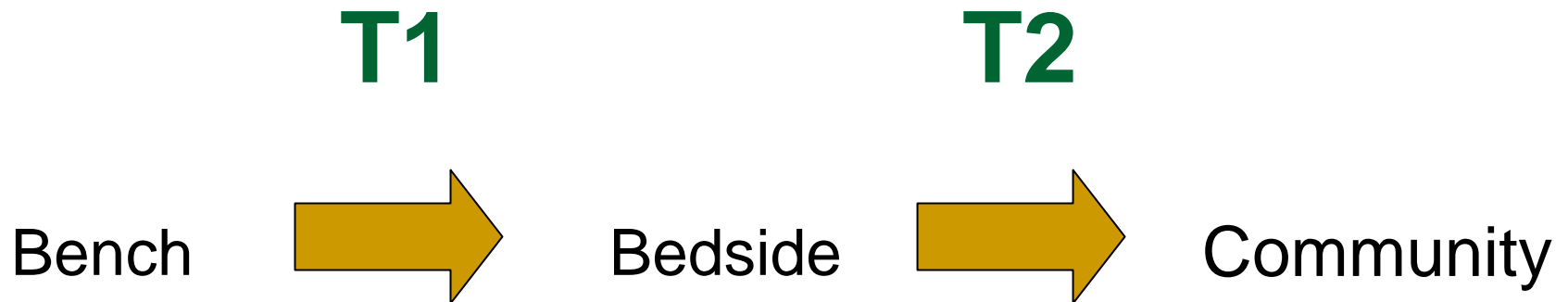
- Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.
- Epidemiologic and behavioral studies.
- Outcomes research and health services research.



# CTSA: DEFINITIONS

- Translational Research
  - ❑ Application of discoveries generated by laboratory research and pre-clinical studies to trials and studies in humans.
  - ❑ Enhancing the adaptation of best practices in the community.

# TRANSLATIONAL RESEARCH



# CTSA: ELEMENTS

- Institutional Support
- Major Administrative Entity
  - Center / Department / Institute
- Authority (Probably Joint) For Space, Resources, Faculty, Time And Promotion
- Establishment Of Clinical And Translational Research As An Academic Discipline



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# CTSA: ELIGIBILITY

- Organization that can confer higher degrees (MS or PhD) in clinical research or related fields (Nursing, Pharmacology, Public Health).
- Partnerships with schools of medicine, nursing, public health, dentistry, engineering, etc. strongly encouraged.
- Organizations that conduct clinical and translational research.

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# CTSA: COMPONENTS

- Research Education, Training and Career Development.
- Facilities, cores and expertise to carry out and refine clinical and translational research.

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# CTSA: RESEARCH EDUCATION, TRAINING & CAREER DEVELOPMENT

- Integrated “career path” of education and training (U54 Cooperative Agreement).
- Research Components
  - Research education
    - Didactic courses
    - Short term research experiences
    - Interdisciplinary
    - For MDs, nurses, PhDs, coordinators, etc.

# CTSA: RESEARCH EDUCATION, TRAINING & CAREER DEVELOPMENT

- Research Components (cont)
  - Postdoctoral Research Training (T32)
    - Leads to PhD (not MS) or MD/PhD.
    - Clinical and translational sciences.
    - 3-year (minimum) full-time training.
    - Pays for stipends and tuition.
    - At least 4 trainees
  
  - Medical Career Development (K12)
    - For those completing sub-specialty training
    - To bridge training and independence
    - 2-5 years at 75% effort (50% if justified)
    - Supports salary, fringe and research costs
    - Established mentors



# SUCCESSFUL CTSA APPLICATIONS

Mayo Clinic College of Medicine	University of Pittsburgh
University of Texas Health Science Center at Houston and MD Anderson Cancer Center	Columbia University Health Sciences
University of California, Davis	University of Rochester
Rockefeller University	Duke
Oregon Health & Science University	University of California – San Francisco
University of Pennsylvania	Yale University

# SUMMARY OF FINANCIAL PROJECTIONS

## CURRENT 5-YR FUNDING

GCRC	\$12.1 million
K30	\$ 1.5 million

**Current 5-year Total**                      **\$13.6 million**

## FUTURE 5-YR FUNDING

With a CTSA		Without a CTSA	\$0
GCRC	\$12.1 million		
K30	\$ 1.5 million		
<u>CTSA Increment</u>	<u>\$30.0 million</u>		
	\$43.6 million		
Less Institutional Costs	\$ 4.0 million		
<b>Total</b>	<b>\$39.6 million</b>		

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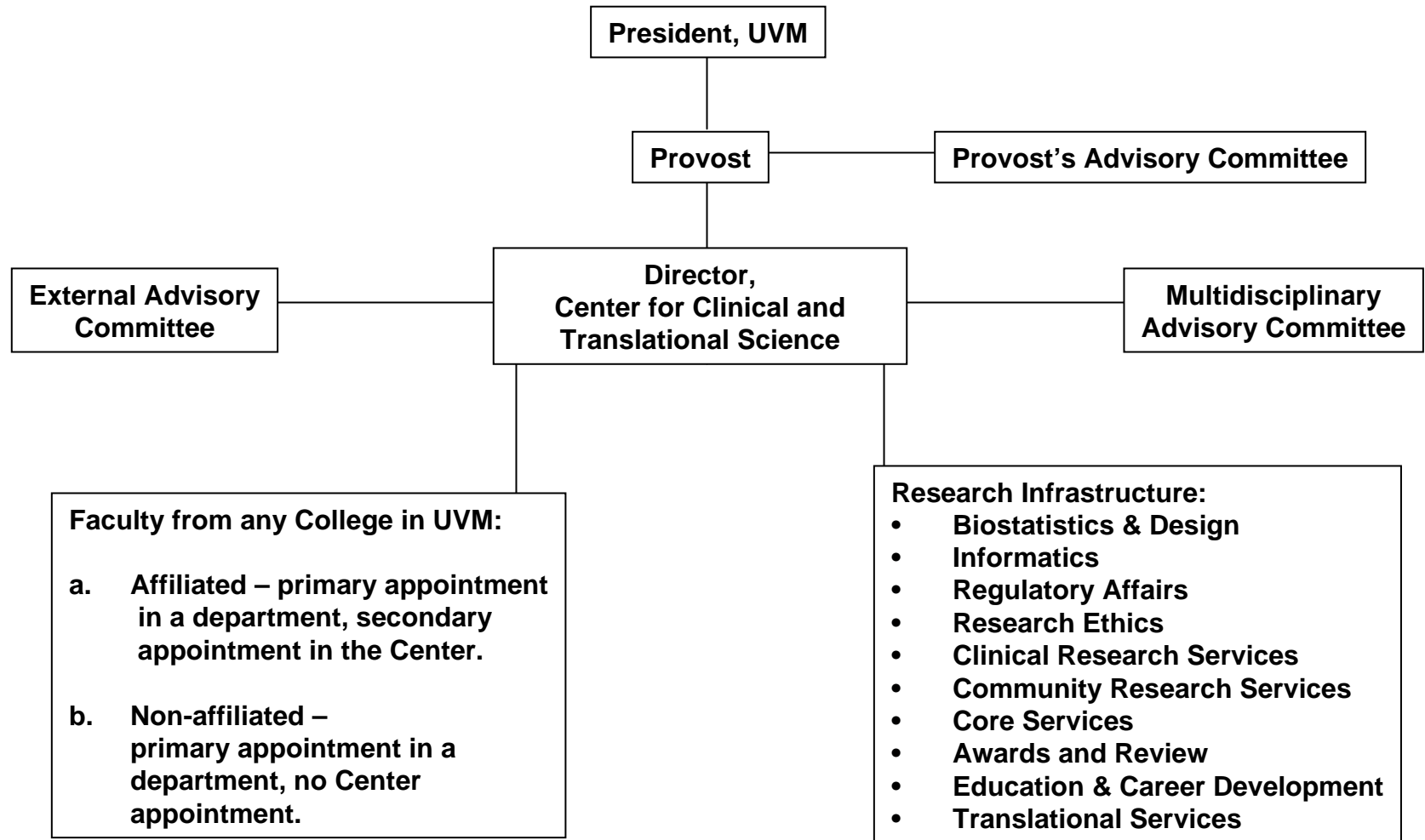
# TIMELINE

- UVM Application: March 2006
- Summary Statement: August 2006

# FEEDBACK and RESPONSE

- Lack of clarity in the governance structure
  - Previous
    - Department in the College of Medicine
    - Director reporting to the Dean
  - Current
    - Created Matrix Center
    - Designated Center for Clinical and Translational Science as a Matrix Center
    - Director reporting to the Provost

# The UVM Center for Clinical and Translational Science Organizational Chart



# FEEDBACK and RESPONSE

- Lack of tangible evidence of multidisciplinary
  - Previous
    - Focused in College of Medicine
    - Little outreach to other Colleges and Schools
  - Current
    - New Center Structure
    - Transcollegial CTSA Committee

# FEEDBACK and RESPONSE

- Educational programs are not particularly innovative.
  - Previous
    - Description of Planned Programs
  - Current
    - Programs under review by Graduate Executive Committee
    - Certificate in CTS
    - Masters of Science in CTS
    - Doctor of Philosophy in CTS
    - Certification for research nurses and coordinators



# FEEDBACK and RESPONSE

- Lack of a Director of Informatics.
  - Previous
    - TBA
  - Current
    - National search underway for an academic bioinformaticist
    - Opportunity with new Electronic Medical Record at FAHC
    - Two candidates have visited campus

# FEEDBACK and RESPONSE

## ■ CTSA Space

### □ Previous

- Described plans

### □ Current

#### ■ Clinical:

- Reconfiguration of GCRC on Baird 7 in FAHC
- Move mass spectrometers
- Maximize outpatient facilities
- Satellite at Timberlane

#### ■ Academic/Service:

- Commitment to space in the Given Courtyard infill
- To Trustees in June



# FEEDBACK and RESPONSE

- “Clinical and translational research at UVM appears to be fragmented and not integrated with multiple competing divisions.”
  - Previous
    - No clarity concerning interactions of GCRC, OCTR, VCC
  - Current
    - Ongoing discussions of representatives of CCTS, GCRC, OCTR, VCC, OSP
    - Division of issues into:
      - Mandatory elements: regulatory, financial, liability, training
      - Non-mandatory elements: services such as nursing and coordinators
    - Overall goal – one “front door” to the clinical research enterprise

# CTSA Advisory Committee

- Taka Ashikaga, Ph.D., Biometry, COM
- Ira Bernstein, M.D., Obstetrics & Gynecology, COM
- Naomi Fukagawa, M.D., Ph.D., Medicine, COM
- Brian Flynn, Ph.D., Health Promotion Research, COM
- Richard Galbraith, M.D., Ph.D., Patient Oriented Research, COM
- Benjamin Littenberg, M.D., Internal Medicine/Primary Care, COM
- Mark Phillippe, M.D., Obstetrics & Gynecology, COM
- Russell Tracy, Ph.D., Dean's Office, COM

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# BIOSTATISTICS COMMITTEE

- Richard Albertini, M.D., Ph.D., Pathology, COM
- Taka Ashikaga, Ph.D., Biometry, COM
- Jan Bunn, Ph.D., Biometry, COM
- Peter Callas, Ph.D., Biometry, COM
- Dryver Huston, Ph.D., Mechanical Engineering, CEMS
- Pamela Vacek, Ph.D., Biometry, COM



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# BIOINFORMATICS COMMITTEE

- Jeffery Bond, Ph.D., Director of Bioinformatics, COM
- Marianne Burke, MLS, Director, Dana Library, COM
- Frank Harris, Chief Information Officer, FAHC
- Diantha Howard, M.S., Informatics, GCRC
- Jill Jemison, B.A., Education and Training, COM
- Christopher Allen, Ph.D., Advanced Computing Center, CAS
- Charles MacLean, M.D., Primary Care/Internal Medicine, COM
- David Todd, Ph.D., Chief Information Officer, UVM
- Xindong Wu, Computer Science, CEMS



# REGULATORY AFFAIRS COMMITTEE

- Ruth Farrell, Associate Vice-President, Office of Sponsored Programs, UVM.
- Michael Hawkins, J.D., Risk Manager, FAHC.
- Alan Homans, M.D., Pediatrics and Chair of the IRBs.
- Charles Jefferis, Associate Vice-President, Risk Assessment and Institutional Compliance Officer, UVM.
- Kimberly Luebbbers, RN, BSN, OCN, ASCP (MT), Director of the Office of Clinical Trials, UVM
- David McGarry, R.Ph., Investigational Pharmacy, FAHC.
- Donna Silver, Assistant Program Director, Research Protections Office, UVM.
- Nancy Stalnaker, Program Director, Research Protections Office, UVM.

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# RESEARCH ETHICS COMMITTEE

- Tyler Doggett, Ph.D., Philosophy, CAS
- Robert Macauley, MSt., M.Div., M.D., Pediatrics and Director of the Department of Clinical Ethics at FAHC
- Rae Nishi, Ph.D., Anatomy and Neurobiology, COM
- Betty Rambur, DNSc., RN, Dean, College of Nursing and Health Sciences
- Markus Thali, Ph.D., Microbiology and Molecular Genetics, COM

# CLINICAL RESEARCH SERVICES COMMITTEE

- Philip Ades, M.D., Medicine, COM
- Ira Bernstein M.D., Obstetrics & Gynecology, COM
- Laurie Lester Ph.D., Administrative Director, GCRC.
- Kimberly Luebbers RN, BSN, OCN, ASCP (MT), Clinical Trials Research
- Hollister McFadden, Vermont Cancer Center
- Anthony Minichiello RN, Nurse Manager, GCRC
- Hyman Muss M.D., Hematology/Oncology, COM
- Richard Pratley M.D., Diabetes & Metabolism Translational Medicine Unit, COM
- Richard Wasserman M.D. MPH., Pediatrics, COM, and Director, Pediatric Research in Office Settings, American Academy of Pediatrics

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# COMMUNITY RESEARCH COMMITTEE

- Brian Flynn, Sc.D., Office of Health Promotion Research, COM
- Mary Canales, RN, Ph.D., Nursing, CNHS
- Nick Danigelis, Ph.D., Sociology, CAS
- Berta Geller, Ph.D., Family Medicine and Radiology, COM
- Jean Harvey-Berino, Ph.D., Nutrition & Food Science, CALS
- John Helzer, M.D., Psychiatry, COM
- Sharon Henry, Ph.D., Rehabilitation & Movement Science, CNHS
- Benjamin Littenberg, M.D., Medicine, COM
- Charles Maclean, M.D., Medicine, COM
- Ted Marcy, M.D., Medicine, COM
- Judy Shaw, R.N., Pediatrics, COM
- Craig Trumbo, Ph.D., Family Medicine, COM

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# EDUCATION & CAREER DEVELOPMENT COMMITTEE

- Jason Bates, Ph.D., Medicine, COM
- Rickard Galbraith, M.D. Ph.D., Medicine, COM
- Steve Lidofsky, M.D., Medicine, COM
- Ben Littenberg, M.D., Primary Care/Internal Medicine, COM
- Mark Nelson, Ph.D., Pharmacology, COM
- Rae Nishi, Ph.D., Anatomy and Neurobiology, COM
- Alan Rubin, M.D., Primary Care/Internal Medicine, COM

# COM CORE SERVICES

- Jeffrey P. Bond, PhD, Director of Bioinformatics
- Ralph Budd, M.D., Director, Flow Cytometry Core
- Mark Evans, Ph.D., Scientific Director, The Experimental Pathology Translational Research Core
- Tim Hunter, Manager, DNA Analysis Core and Manager, Microarray Facility Core
- Dwight Matthews, Ph.D., Director, Biomedical Mass Spectrometry Core
- Paul Newhouse, M.D., Director, Functional Brain Imaging Core
- Douglas J. Taatjes, Ph.D., Director, Microscopy Imaging Center (MIC) Core
- Russell Tracy, Ph.D., Director, Biochemical Analysis and Biorepository Core.



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# CTSA AWARDS & REVIEW

- Taka Ashikaga, Ph.D., Mathematics and Statistics, CEMS
- Mary Canales, Ph.D., R.N., Nursing, CNHS
- Naomi K. Fukagawa, M.D., Ph.D., Medicine, COM
- James Hudziak, M.D. , Psychiatry, COM
- James Iatrides, Ph.D., Mechanical Engineering, CEMS
- Larry Kien, M.D. Ph.D., Pediatrics, COM
- David Krag, M.D., Surgery, COM
- Benjamin Littenberg, M.D., Medicine and Nursing, COM & CNHS
- Richard Pratley, M.D. , Medicine, COM
- David Schneider, M.D. Medicine, COM
- Judy Shaw, R.N., M.P.H., Pediatrics, COM
- The Research Ethicist from the Department of Clinical and Translational Science (TBD)

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# EVALUATION COMMITTEE

- Peter Callas, PhD, Mathematics and Statistics, CEMS
- William Cats-Baril, PhD, School of Business Administration
- Brian Flynn, Sc.D., Health Promotion Research, COM
- Jill Jemison, Education & Training, COM
- Karen Richardson-Nassif, PhD, Medical Education Evaluation, COM
- Janice Yanushka Bunn, PhD, Mathematics and Statistics, CEMS

# CTSA Transcollegial Committee

- Mark Bouton, Ph.D., Psychology, College of Arts & Sciences
- William Cats-Baril, Ph.D., School of Business
- Susan Comerford, Social Work, College of Education and Social Services
- Nick Danigelis, Ph.D., Sociology, College of Arts & Sciences
- Catherine Donnelly, Ph.D., Nutrition & Food Sciences, College of Agriculture & Life Sciences
- Yves Dubief, Ph.D., Engineering, College of Engineering and Mathematical Sciences
- Richard Galbraith, M.D., Ph.D., Patient Oriented Research, College of Medicine
- Sharon Henry, Ph.D., Rehabilitation & Movement Science, College of Nursing & Health Science
- James Iatridis, Ph.D., Engineering, College of Engineering and Mathematical Sciences
- Jane Kolodinsky, Ph.D., Community Development & Applied Economics, College of Agriculture & Life Sciences
- Marcia Ring, Nursing, College of Nursing & Health Sciences
- Susan.Ryan, Center on Disability & Community, College of Education and Social Services
- Austin Troy, Ph.D., Rubenstein School of Environment & Natural Resources

# CTSA/OCTR/VCC/GCRC Integration Committee

- Ira Bernstein, M.D., Department of Obstetrics & Gynecology, COM
- Brian Cote, Associate Dean for Finance and Administration, COM
- Richard Galbraith, M.D., Ph.D., Associate Dean, Patient Oriented Research, COM
- Barbara Guerard, Executive Director, Medical Group Management, FAHC
- Kim Luebbers, Office of Clinical Trials Research, COM
- David McFadden, M.D., Surgery, COM
- Hollister McFadden, Vermont Cancer Center, COM
- Polly Parsons, M.D., Medicine, COM
- Mark Phillippe, M.D., Obstetrics & Gynecology, COM
- Robert Schapiro, M.D., Neurology, COM
- Paul Taheri, M.D., President of the Faculty Practice, FAHC
- Russell Tracy, Ph.D., Senior Associate Dean for Research & Academic Affairs, COM

# PERSONNEL AND SERVICES FOR CLINICAL RESEARCH

	<u>OCTR</u>	<u>GCRC</u>	<u>VCC</u>	<u>TOTAL</u>
<b>Administration (FTEs)</b>	2.25?	2.4	4.5?	9.15
<b>Nursing</b>	6	6	0	12
<b>Coordinators</b>	4	0	8	12
<b>Review Functions</b>	Contracting & Budgets	SAC (Science, Safety & Resource Utilization)	PRC (Science)	
<b>Cores</b>	0	Physiology (1) Mass Spec (2) Biochemistry (2) Nutrition (3)	DNA (3) Microarray (2) Molecular Diagnostics (1)	14
<b>Biostatistics</b>	0	0.25	0	0.25
<b>Informatics</b>	2	1	1	4
<b>Technicians</b>	0	5	10	15
<b>Regulatory</b>	2	0.5	1	3.5
<b>Education</b>	?	0.5	0	0.5

# CTSA Web Site

- <http://www.med.uvm.edu/research/TB1+I+C+RL.asp?SiteAreaID=579>