



# UNIVERSITY OF FLORIDA

Office of the Provost  
and Senior Vice President

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October 14, 2004

MEMORANDUM:

TO: Dr. Debra Austin, Chancellor  
FROM: David R. Colburn *DR*  
SUBJECT: Response on the Y-Axis

Attached are the documents requested by your office regarding the Strategic Planning Process. We have also attached a copy of our Legislative Budget Request to the Board of Governors so that members of the BOG and the Strategic Planning/Educational Policy Committee can see how they relate.

Please do not hesitate to call me if you have any questions.

Cc: President J. Bernard Machen

**BOARD OF GOVERNORS  
STRATEGIC PLANNING/EDUCATIONAL POLICY COMMITTEE**

**Strategic Planning for the State University System  
Y-Axis**

Goals and Objectives	2002-03 (or as indicated)	2008-09	2012-13
<b>II. Constituent University Goals</b>			
<b>A. Access to and Production of Degrees</b>			
1. Bachelor	7,975	8,936	9,088
2. Master's	2,889	4,134	5,169
3. Doctoral*	591	1,080	1,455
4. Professional	941	1,128	1,202
<b>TOTAL</b>	<b>12,396</b>	<b>15,278</b>	<b>16,914</b>
5. Access/Diversity: Minority Representation in SUS Graduates as Percentage of Expected Representation	16%		
a. Bachelor	17%	17%	17%
b. Master	14%	14%	14%
c. Doctoral	11%	11%	11%
d. Professional	17%	17%	17%
<b>B. Meeting statewide professional and workforce needs (details to support I.A.)</b>			
<b>TOTAL Degrees</b>	<b>12,396</b>	<b>15,278</b>	<b>16,914</b>
<b>TOTAL Degrees in Targeted Programs</b>	<b>5,053</b>	<b>6,292</b>	<b>7,194</b>
<b>Targeted Program Degrees as % of All Degrees</b>	<b>41%</b>	<b>41%</b>	<b>43%</b>
1. Critical Needs: Education	136	173	202
2. Critical Needs: Health Professions	762	850	970
3. Economic Development: Emerging Technologies	2,717	3,563	4,051
a. Mechanical Science and Manufacturing	981	1,388	1,587
b. Natural Science and Technology	725	926	1,056
c. Medical Science and Health Care	402	499	585
d. Computer Science and Information Technology	427	495	535
e. Design and Construction	172	229	262
f. Electronic Media and Simulation	11	26	26
4. Economic Development: High-wage/high-demand jobs	1,438	1,706	1,971
5. Educated citizenry/workforce (not specifically targeted)	7,344	8,986	9,720
<b>C. Building world-class academic programs and research capacity</b>			
<b>1. Research Expenditures</b>			
a. Total Research Expenditures per full-time faculty	165,375	290,500	353,105
b. Federal Research Expenditures per full-time faculty	71,536	130,725	158,897
c. Research expenditures - Contracts and Grants (Constant dollars)	506,435,909	678,607,963	824,852,220
2. U.S. Patents Issued per 1000 full-time faculty	26.5	42.8	64.2
3. National Research Council rankings (Number of ranked programs and, of those, number in top 25% nationally)	32 progs ranked (6 in top 25%)	65 progs ranked (16 in top 25%)	65 progs ranked (16 in top 25%)
4. Center of Excellence for Regenerative Health Biotechnology	See Attached		
5. Doctoral degrees per 1000 full-time faculty	253	462	623
<b>6. Other Forms of National Recognition for Institutions' Academic and Research Programs</b>			
a. Number of Faculty who are Members of the National Academies (NAS, IOM, NAE)	16	18	18
b. Number of Faculty receiving major national honors & awards	19	24	28
<b>D. Meeting community needs and fulfilling unique institutional responsibilities</b>			
See Attached Narrative, Position, and Fiscal Summary for UF's Regional Network for VA-based Medical Education.			

Total SUS Academic R&D Expenditures for FY2002

Source: Webcaspar NSF Survey of R&D Expenditures at Universities and Colleges

Year: 2002

Academic Institution (standardized)	Total Academic R&D Expenditures
Florida Agricultural and Mechanical University	\$31,147
Florida Atlantic University	\$23,995
Florida International University	\$47,654
Florida State University	\$134,351
New College of the University of South Florida	\$132
University of Central Florida	\$66,351
University of Florida	\$386,316
University of North Florida	\$2,061
University of South Florida	\$197,894
University of West Florida	\$8,652
Total Academic Institution (standardized)	\$898,553

NOTE: All dollars are in thousands.

Source: Webcaspar

Total SUS Federally Funded Academic R&D Expenditures for FY2002  
Source: Webcaspar NSF Survey of R&D Expenditures at Universities and Colleges

Year: 2002

<b>Academic Institution (standardized)</b>	<b><u>Federally Financed Academic R&amp;D</u> <u>Expenditures</u></b>
<b>Florida Agricultural and Mechanical University</b>	\$21,592
<b>Florida Atlantic University</b>	\$15,566
<b>Florida International University</b>	\$32,057
<b>Florida State University</b>	\$70,456
<b>New College of the University of South Florida</b>	\$55
<b>University of Central Florida</b>	\$29,929
<b>University of Florida</b>	\$167,108
<b>University of North Florida</b>	\$1,397
<b>University of South Florida</b>	\$84,108
<b>University of West Florida</b>	\$5,315
<b>Total Academic Institution (standardized)</b>	<b>\$427,583</b>

NOTE: All dollars are in thousands.

Total Full Time Faculty  
Source: IPEDS Fall Staff Survey 2001

UnitID	Institution Name	Grand total men(S2001_F, 1_F, Total full-time faculty (Instruction/research/public service))	Grand total women(S2001_F, 1_F, Total full-time faculty (Instruction/research/public service))	Total
134130	UNIVERSITY OF FLORIDA	2,477	1,034	3,511
132903	UNIVERSITY OF CENTRAL FLORIDA	620	356	976
133650	FLORIDA AGRICULTURAL AND MECHANICAL UNIVERSITY	320	192	512
133669	FLORIDA ATLANTIC UNIVERSITY-BOCA RATON	466	294	760
133951	FLORIDA INTERNATIONAL UNIVERSITY	528	264	792
134097	FLORIDA STATE UNIVERSITY	845	398	1,243
136172	UNIVERSITY OF NORTH FLORIDA	243	142	385
137351	UNIVERSITY OF SOUTH FLORIDA	1,103	806	1,909
138354	THE UNIVERSITY OF WEST FLORIDA	158	90	248
433660	FLORIDA GULF COAST UNIVERSITY	76	85	161
262129	NEW COLLEGE OF FLORIDA	33	30	63
	<b>TOTAL</b>	<b>6,869</b>	<b>3,691</b>	<b>10,560</b>

NOTE: These figures were not used in full time calculations  
Instead, non-tenuring earning headcount was removed

# Degrees Granted by Level for Groupings in Y-Axis

Degree Level		2002-03 Degrees	2008-09 Degrees	2012-13 Degrees
<b>Critical Needs in Education</b>				
Bachelor	13.1001-Special Ed	31	41	41
Master	13.1001-Special Ed	61	61	74
Doctorate	13.1001-Special Ed	2	6	10
Bachelor	13.1306-Foreign Languages Teacher Ed.	0	0	0
Master	13.1306-Foreign Languages Teacher Ed.	3	0	0
Doctorate	13.1306-Foreign Languages Teacher Ed.	0	0	0
Bachelor	13.1311-Mathematics Teacher Ed.	0	0	0
Master	13.1311-Mathematics Teacher Ed.	5	15	15
Doctorate	13.1311-Mathematics Teacher Ed.	0	0	0
Master	13.1315-Reading Teacher Ed.	2	3	3
Doctorate	13.1315-Reading Teacher Ed.	0	0	0
Bachelor	13.1316-Science Teacher Ed.	0	0	0
Master	13.1316-Science Teacher Ed.	10	20	24
Doctorate	13.1316-Science Teacher Ed.	0	0	0
Master	42.1701-School Psychology	17	18	22
Doctorate	42.1701-School Psychology	5	9	13
<b>TOTAL</b>		<b>136</b>	<b>173</b>	<b>202</b>

## Critical Needs in Health Professions

Bachelor	51.0701-Health Services Administration	0	0	0
Master	51.0701-Health Services Administration	30	41	52
Doctorate	51.0701-Health Services Administration	0	5	9
Master	51.0807-Physician Assistant (51.0912)	60	75	94
Bachelor	51.1601-Nursing	167	167	167
Master	51.1601-Nursing	68	74	93
Doctorate	51.1601-Nursing	7	0	0
Pharmacy	51.2001-Pharmacy	254	422	472
Master	51.2308-Physical Therapy	15	32	40
Bachelor	51.2306-Occupational Therapy	54	0	0
Master	51.2306-Occupational Therapy	8	34	43
Bachelor	51.2795-Health Science	99	0	0
Master	51.2795-Health Science	0	0	0
<b>TOTAL</b>		<b>762</b>	<b>850</b>	<b>970</b>

## Emerging Technologies in Mechanical Science and Manufacturing

Bachelor	14.0101-Engineering	0	0	0
Bachelor	14.0201-Aerospace Engineering	24	29	29
Master	14.0201-Aerospace Engineering	16	37	45
Doctorate	14.0201-Aerospace Engineering	6	11	15
Bachelor	14.0701-Chemical Engineering	71	74	74
Master	14.0701-Chemical Engineering	14	14	18
Doctorate	14.0701-Chemical Engineering	10	11	15
Bachelor	14.1001-Electrical Engineering	138	183	183
Master	14.1001-Electrical Engineering	138	248	303

# Degrees Granted by Level for Groupings in Y-Axis

Degree Level		2002-03 Degrees	2008-09 Degrees	2012-13 Degrees
Doctorate	14.1001-Electrical Engineering	17	20	28
Bachelor	14.1301-Engineering Science	20	21	21
Master	14.1101-Engineering Mechanics	0	36	36
Doctorate	14.1101-Engineering Mechanics	2	8	12
Bachelor	14.1801-Materials Engineering	60	101	101
Master	14.1801-Materials Engineering	47	103	127
Doctorate	14.1801-Materials Engineering	16	46	58
Bachelor	14.1901-Mechanical Engineering	89	0	0
Master	14.1901-Mechanical Engineering	36	69	85
Doctorate	14.1901-Mechanical Engineering	16	10	14
Master	14.2301-Nuclear Engineering	4	16	20
Doctorate	14.2301-Nuclear Engineering	3	8	12
Bachelor	14.2701-Industrial & Systems Engineering	64	102	102
Master	14.2701-Industrial & Systems Engineering	92	102	126
Doctorate	14.2701-Industrial & Systems Engineering	3	12	16
Bachelor	27.0101-Mathematics	51	55	55
Master	27.0101-Mathematics	11	18	22
Doctorate	27.0101-Mathematics	2	6	10
Bachelor	27.0501-Statistics	7.5	11	11
Master	27.0501-Statistics	22	29	37
Doctorate	27.0501-Statistics	1	8	12
<b>TOTAL</b>		<b>980.5</b>	<b>1388</b>	<b>1587</b>

## Emerging Technologies in Natural Science and Technology

Bachelor	02.0401-Plant Science	8	19	23
Bachelor	03.0102-Environmental Science	41	35	35
Master	03.0102-Environmental Science	0	0	0
Bachelor	14.0301-Agricultural Engineering	35.5	52	52
Master	14.0301-Agricultural Engineering	4	17	21
Doctorate	14.0301-Agricultural Engineering	4	14	18
Bachelor	14.1401-Environmental Health Engineering	27	52	52
Master	14.1401-Environmental Health Engineering	22	43	55
Doctorate	14.1401-Environmental Health Engineering	3	13	17
Bachelor	14.2301-Nuclear Engineering	9	8	8
Bachelor	14.2401-Coastal Engineering	0	0	0
Master	14.2401-Coastal Engineering	11	19	23
Doctorate	14.2401-Coastal Engineering	4	6	10
Bachelor	26.0202-Biochemistry	0	0	0
Doctorate	26.0202-Biochemistry	4	14	18
Bachelor	26.0301-Botany	13	5	5
Master	26.0301-Botany	4	23	35
Doctorate	26.0301-Botany	0	8	12
Master	26.0305-Plant Pathology	3	0	0
Doctorate	26.0305-Plant Pathology	1	10	14
Master	26.0495-Plant Molecular & Cellular Biology	0	0	0
Doctorate	26.0495-Plant Molecular & Cellular Biology	1	0	0
Bachelor	26.0501-Microbiology (26.0503)	195	196	196

# Degrees Granted by Level for Groupings in Y-Axis

Degree Level		2002-03 Degrees	2008-09 Degrees	2012-13 Degrees
Master	26.0501-Microbiology (26.0503)	3	12	16
Doctorate	26.0501-Microbiology (26.0503)	4	9	13
Bachelor	26.0603-Ecology (26.1301)	0	0	0
Master	26.0603-Ecology (26.1301)	13	18	23
Bachelor	26.0701-Zoology	109	86	86
Master	26.0701-Zoology	7	40	52
Doctorate	26.0701-Zoology	6	11	15
Bachelor	26.0702-Entomology	14.5	0	0
Master	26.0702-Entomology	10	0	0
Doctorate	26.0702-Entomology	3	13	17
Bachelor	40.0501-Chemistry	61	56	56
Master	40.0501-Chemistry	5	21	29
Doctorate	40.0501-Chemistry	38	52	64
Bachelor	40.0601-Geology	9	11	11
Master	40.0601-Geology	8	15	21
Doctorate	40.0601-Geology	1	5	9
Bachelor	40.0801-Physics	27	21	21
Master	40.0801-Physics	14	22	29
Doctorate	40.0801-Physics	3	0	0
<b>TOTAL</b>		<b>725</b>	<b>926</b>	<b>1056</b>

## Emerging Technologies in Medical Science and Health Care

Bachelor	14.0501-Biomedical Engineering	0	0	0
Master	14.0501-Biomedical Engineering	17	21	29
Doctorate	14.0501-Biomedical Engineering	2	10	14
Dentistry	51.0401-Dentistry	80	80	80
Master	51.0501-Dental Science	6	18	23
M.D.	51.1201-Medicine (M.D.)	111	120	132
Master	51.1395-Medical Sciences (26.9999)	15	12	16
Doctorate	51.1395-Medical Sciences (26.9999)	30	47	59
Doctorate	51.2001-Pharmacy (51.2099)	6	16	21
Master	51.2201-Public Health	24	36	45
Doctorate	51.2201-Public Health	0	0	0
Veterinary	51.2401-Veterinary Medicine (D.V.M.)	82	86	98
Master	51.2501-Veterinary Medical Sciences	18	40	51
Doctorate	51.2501-Veterinary Medical Sciences	11	13	17
<b>TOTAL</b>		<b>402</b>	<b>499</b>	<b>585</b>

## Emerging Technologies in Computer Science and Information Technology

Bachelor	11.0101-Computer & Information Sciences	111.5	124	124
Master	11.0101-Computer & Information Sciences	25	27	35
Doctorate	11.0101-Computer & Information Sciences	0	0	0
Bachelor	14.0901-Computer Engineering	169	214	214
Master	14.0901-Computer Engineering	114	117	145
Doctorate	14.0901-Computer Engineering	7	13	17
<b>TOTAL</b>		<b>426.5</b>	<b>495</b>	<b>535</b>



Degrees Granted by Level for Groupings in Y-Axis

Degree Level	2002-03 Degrees	2008-09 Degrees	2012-13 Degrees
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**Emerging Technologies in Design and Construction**

Bachelor	04.0301-Urban & Regional Planning	0	0	0
Master	04.0301-Urban & Regional Planning	15	18	23
Bachelor	14.0801-Civil Engineering	87	100	100
Master	14.0801-Civil Engineering	63	99	123
Doctorate	14.0801-Civil Engineering	7	12	16
<b>TOTAL</b>		<b>172</b>	<b>229</b>	<b>262</b>

**Emerging Technologies in Electronic Media and Simulation**

Bachelor	50.0706-Digital Media	11	26	26
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**High-wage/high-demand jobs**

Bachelor	04.0201-Architecture	90	93	93
Specialist	13.0301-Curriculum & Instruction	38	43	55
Doctorate	13.0301-Curriculum & Instruction	8	17	21
Specialist	13.0401-Ed. Administration	35	31	39
Doctorate	13.0401-Ed. Administration	2	12	16
Master	13.0901-Social Foundations	2	0	0
Bachelor	13.1202-Elementary Education	178	161	161
Bachelor	13.1204-Early Childhood Education	0	0	0
Bachelor	13.1305-English Teacher Education	0	0	0
Bachelor	13.1312-Music Teacher Education	16	13	13
Bachelor	13.1317-Social Science Education	0	0	0
Bachelor	15.1001-Building Construction	112	124	124
Master	15.1001-Building Construction	24	27	38
Master	22.0104-Legal Specialization	84	93	115
Doctorate	51.0202-Audiology	154	218	266
Master	52.0201-Business Administration	523	711	867
Bachelor	52.0301-Accounting	169	163	163
Bachelor	52.0805-Insurance & Risk Mgmt.	2.5	0	0
<b>TOTAL</b>		<b>1437.5</b>	<b>1706</b>	<b>1971</b>

Academic R&D Expenditures per Full-Time Faculty  
Source: Webcaspar and IPEDS Fall Staff Survey

Type of Expenditure	2002-03			2008-09			2012-13		
	Amount	No. of Faculty	Expend per FT Fac	Amount	No. of Faculty	Expend per FT Fac	Amount	No. of Faculty	Expend per FT Fac
Academic R&D Expenditure	386,316,000	2,336	165,375	678,607,963	2,336	290,500	824,852,220	2,336	353,105
Federally Financed Academic R&D	167,108,000	2,336	71,536	305,373,583	2,336	130,725	371,183,499	2,336	158,897

Number of Patents Awarded per 1000 Full Time Faculty

Year	No. of Patents	No. of Faculty	Patents per 1000 FT Fac
2002-03	62	2,336	26.5
2008-09	100	2,336	42.8
2012-13	150	2,336	64.2

Number of Doctorates Awarded per 1000 Full Time Faculty

Year	No. of Doctorates	No. of FT Fac	Doctorates per 1000 FT Fac
2002-03	591	2,336	253.0
2008-09	1080	2,336	462.3
2012-13	1455	2,336	622.9

**Degrees Awarded by Race**  
Source: 2002-03 Student Data Course File

Race	Bach Degree	Mast Degree	Doct Degree	Prof Degree	Other Degree	Total
Asian	506	120	13	73	7	719
Black	508	118	23	71	6	726
Hispanic	812	182	23	82	6	1,105
Indian	33	9	3	4	0	49
N/A	47	29	11	4	0	91
Non-Res	119	541	141	8	2	811
White	5,950	1,798	377	699	71	8,895
<b>Total</b>	<b>7,975</b>	<b>2,797</b>	<b>591</b>	<b>941</b>	<b>92</b>	<b>12,396</b>
Minus N/A & Non-Res	7,809	2,227	439	929	90	11,494
Minority %	17.33%	13.85%	11.16%	16.90%		16.36%

## Faculty Honors & Awards Include:

Reported in 2005 Top  
American Research  
Universities Report,  
TheCenter

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American Council of Learned Societies (ACL:S)	1
Bechman Young Investigators	
Burroughs Wellcome Fund Career Awards	
Cottrell Scholars	
Fulbright Amercian Scholars	4
Getty Scholars in Residence	
Guggenheim Fellows	
Howard Hughes Medical Institute Investigators	
Lasker Medical Research Awards	
MacArthur Foundation Fellows	
Andrew W. Mellon Foundation Distinguished Achievement Awards	
National Endowment for the Humanities (NEH) Fellows	
National Humanities Center Fellows	
National Institutes of Health (NIH) MERIT (R37) and Outstanding Investigator (R35)	7
National Medal of Science and National Medal of Technology	
NSF CAREER Awards	1
Newberry Library Long-Time Fellows	
Pew Scholars in Biomedicine	
Presidential Early Career Awards for Scientists and Engineers (PECASE)	
Robert Wood Johnson Policy Fellows	
Searle Scholars	
Sloan Research Fellows	1
U.S. Secretary of Agriculture Honor Awards	2
Woodrow Wilson Fellows	
American Antiquarian Society Fellowships	3
TOTAL for 2005 Strategic Plan	19

## Educational and General Operating Budget Form I

University: University of Florida – Health Science Center

Issue: Regional Network for VA-based Medical Education

Priority Number: \_\_\_\_\_

Board of Governor's Goal and Objective: \_\_\_\_\_

### **Narrative:**

#### **Background**

In the state of Florida, the Veterans Administration Health System has six hospitals and a plethora of outpatient clinics. Three of the hospitals have affiliations with academic health centers. These include the Malcom Randall VA Hospital in Gainesville, the James Haley Veterans Hospital in Tampa, and the Miami Veterans Hospital in Miami. The three remaining hospitals are located in Lake City, West Palm Beach, and St. Petersburg. The three largest hospitals are those affiliated with the academic health centers in this state and are equipped to handle patients with high acuity illnesses. In contrast, the three hospitals that do not have academic affiliations are not well equipped either technically or with the appropriate staff to handle tertiary and quaternary medical problems and they do not participate in medical education.

The Bay Pines hospital in St. Petersburg has an extensive ambulatory care program that includes outpatient facilities in Naples, Ft. Myers, Port Charlotte, Sarasota, Ellenton, and Avon Park. Approximately 200 VA physicians staff the Bay Pines hospital and clinics. The Bay Pines hospital facility is located on 310 acres of beautiful property situated on Ciego Bay in south St. Petersburg. It is also the home of the VISN 8 director and his administrative staff.

The West Palm Beach VA hospital is located just off Interstate 95 at exit 76 in Palm Beach County. There would be ready access between the West Palm Beach VA hospital and the planned Scripps Florida Research Institute, which will be approximately 10 miles from the VA facility.

#### **Current Initiatives**

Orlando. Currently the College of Medicine utilizes the 600-bed Orlando Regional Medical Center (ORMC) for medical student training. Approximately 25 of UF's medical students/year spend a month or more on that medical campus taking electives that are offered by ORMC. ORMC has an active physician residency-training program that includes 185 individuals who are trained by 60 full-time physicians funded by ORMC. Many, but not all, of these individuals hold adjunct appointments with the University of Florida College of Medicine.

Preliminary discussions have been held between UF's College of Medicine and the ORMC staff to explore the feasibility of expanding the course offerings for medical students on that campus. As the class size increases in the College of Medicine, ORMC could become an important clinical training site for third and fourth year students. The patient population is varied socio-economically and manifests extensive tertiary and quaternary medical problems. There is a strong desire on the part of the ORMC officials to draw closer to the UF flag.

Orlando will be the site of a new VA hospital to be built in the next 5 years. There are several competing sites for the new hospital within the greater Orlando area. We have proposed to VA officials to locate this 150 bed hospital on the campus or adjacent to the campus of ORMC. This would allow us to develop a VA-based regional medical campus that could have expanded residency programs, medical student educational programs, and a faculty made up of UF physicians. A competing site is on existing VA property that was formally a naval air training station near Baldwin Lake in the northeast part of the city of Orlando. Currently, these facilities accommodate 320,000 outpatient visits each year. In addition to offering opportunities for medical student and residency education, research programs and expansion of the faculty of our College, Orlando represents a significant population base that would benefit by involvement with the University of Florida.

St. Petersburg. During the course of the Orlando discussions, the regional VA administrative leadership asked if we would consider developing an affiliation with the Bay Pines VA Hospital. We have met with Bay Pines officials to explore the feasibility of such a relationship. This visit included an extensive tour of the medical campus in St. Petersburg. Currently, the hospital serves over 100,000 patients, which includes all of the clinics mentioned earlier and the primary facility. There is a strong desire on the part of the VA leadership to form an affiliation with the University of Florida so that we could recruit faculty who could provide the expertise needed to care for patients with higher acuity illnesses and expand UF's medical education.

West Palm Beach. VA leadership has also identified the need for the West Palm Beach VA Hospital to upgrade its staff to handle the large number of more complicated patients they now must serve. That particular hospital was built in 1995 and is an outstanding 200-bed physical plant on a relatively small campus. Approximately 150 staff physicians serve the facility. Again, there is a strong desire on the part of the VA to develop an affiliation with the University of Florida.



An affiliation between UF and the West Palm Beach VA Hospital would provide an opportunity for UF to interact with Scripps Florida. To do so would require a rather modest investment when compared with the creation of an independent freestanding clinical entity for Scripps because the VA would provide the salaries and much of the support for many UF physicians and staff to be located at this site.

### *SUMMARY*

Collaborative partnerships between a University's academic health center and a regional VA medical facility are highly successful in facilitating quality medical education and in enhancing the quality of health care provided to veterans. A regional UF-VA network would include the relationships we already enjoy with the VA and expand upon them. An interesting picture evolves. UF would hold the primary affiliation and operational responsibility for the Malcom Randall VA Hospital in Gainesville, the Lake City VA hospital, the new 75,000 sq. ft. out-patient facility to be built in Jacksonville, the Bay Pines facility in St. Petersburg and its numerous clinics, the new VA hospital to be built in Orlando and the West Palm Beach VA Hospital. Half a million or more veterans and nearly 600 students in UF's College of Medicine would benefit from expanding this particular system for medical education and health care delivery.

# EDUCATIONAL AND GENERAL POSITION AND FISCAL SUMMARY

Operating Budget Form II

UNIVERSITY: University of Florida - Health Science Center  
 ISSUE TITLE: Regional Network for VA-based Medical Education

## POSITIONS

FACULTY	13.00
OTHER (A&P/USPS)	4.00
	<hr/>
TOTAL	17.00
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## SALARY RATE

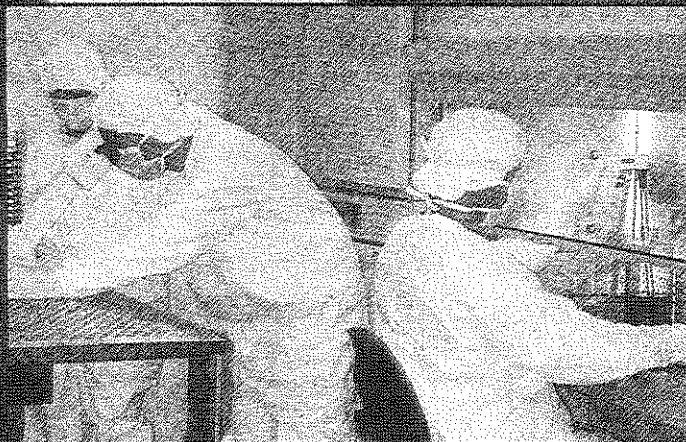
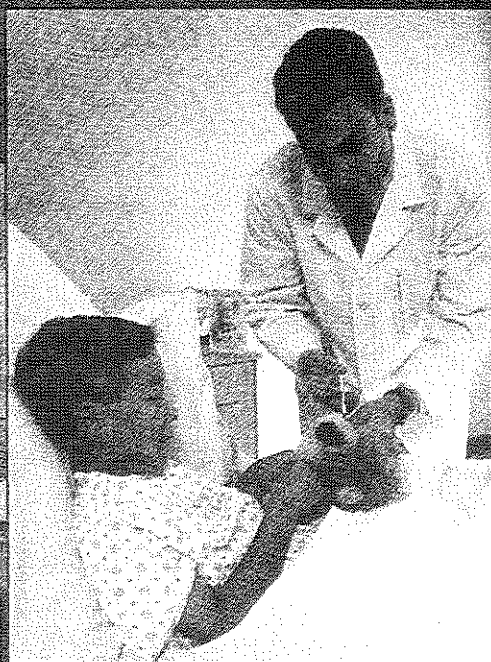
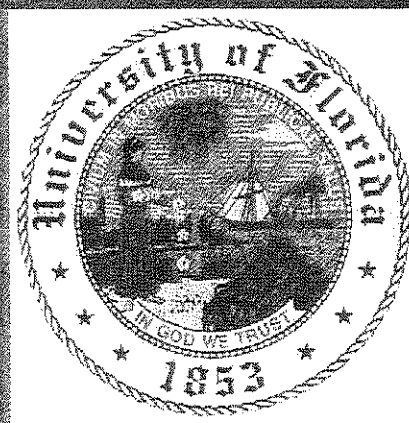
FACULTY	\$1,608,009
OTHER (A&P/USPS)	\$157,437
	<hr/>
TOTAL	\$1,765,446
	<hr/> <hr/>

SALARIES AND BENEFITS	\$2,160,000
OTHER PERSONAL SERVICES	
EXPENSES	\$20,000
OPERATING CAPITAL OUTLAY	
ELECTRONIC DATA PROCESSING	
SPECIAL CATEGORY (SPECIFIC)	
<hr/>	
<hr/>	
<hr/>	
	<hr/>
TOTAL ALL CATEGORIES	\$2,180,000
	<hr/> <hr/>

# ***Center of Excellence for Regenerative Health Biotechnology***

## **Quarterly Report**

**April 1 to June 30, 2004**



TO: Emerging Technology Commission

FROM: Richard O. Snyder, Ph.D., Director

DATE: July 8, 2004

RE: Quarterly Report for the Center of Excellence For Regenerative Health  
Biotechnology  
April 1, 2004 – June 30, 2004

This quarterly report covering Q2, 2004 for The University of Florida's Center of Excellence for Regenerative Health Biotechnology (CERHB) is presented to the Commission. In addition to the general and specific performance measures that we are required to report, below is a list of other activities conducted during this quarter:

- A presentation was made to Community College Teachers from around the State who attended a Biotechnology Workshop sponsored by Santa Fe Community College on May 13, 2004. There was significant interest in the joint CERHB-SFCC educational biotechnology laboratory and manufacturing skills program.
- A presentation on biologics manufacturing was made June 2, 2004 at the American Society for Gene Therapy.

**General Measurement Standards:**

1. Full financial disclosure of expenditures related to the cost proposal of the Center of Excellence.

APRIL 1, 2004-JUNE 30, 2004	CATEGORY	COE FUNDS	UF MATCHING	TOTAL
CERHB Equipment			\$ 28,113.00	
Design	OE (Expense)	\$ 15,000.00		
Renovation of the North Building		\$ 2,364,225.00		
Utility Service	OE (Expense)	\$ 24,993.00		
CERHB Progress Corp. Park Assessment Fee	OE (Expense)	\$ 1,190.00		
Operating Expenses	OE (Expense)	\$ 4,324.75		
Personnel	Salary	\$ 3,940.84		
Consultant and Professional Services	OPS	\$ 6,100.00		
<b>TOTAL THIS QUARTER</b>		<b>\$ 2,419,773.59</b>	<b>\$ 28,113.00</b>	<b>\$ 2,447,886.59</b>
<b>TOTAL SINCE INCEPTION</b>		<b>\$ 2,991,937.27</b>	<b>\$ 4,119,826.76</b>	<b>\$ 7,111,764.03</b>

**2. Effectiveness and success of the research being performed within the Center of Excellence.**

Nine peer-reviewed scientific publications were published by investigators who are members of CERHB partner organizations (Powell Gene Therapy Center, Center for Mammalian Genetics/Epigenetics, Adult Stem Cell Consortium) at UF.

**3. State of research collaboration with other universities or research entities as well as private industry.**

***Applied Genetics Technologies Corporation.*** The collaboration with the Powell Gene Therapy Center (a partner of CERHB) involves the development of gene therapies to treat genetic and acquired diseases including alpha-one anti-trypsin deficiency, blindness, and Muscular Dystrophy. The pre-clinical toxicology studies and manufacture of clinical grade vector for an alpha-one antitrypsin product are complete. The Investigational New Drug Application was submitted to the FDA and it was reviewed. The vector for the first cohort of patients was delivered to the Investigational Pharmacy, formulated, and injected by Dr. Flotte into the first patient on March 30, 2004. The entire first cohort has received the investigational product, and the first patient of the second cohort has received the next highest dose of the drug.

Testing of products for blindness and Muscular Dystrophy is in progress. A discussion between Dr. Hauswirth's group and the FDA was held on March 30, 2004 to discuss a clinical trial to treat blindness. Preparation for manufacturing another candidate product for alpha-one anti-trypsin deficiency is in progress.

***The Scripps Research Institute:*** As the Scripps Florida organization is established, UF CERHB will work with Scripps to map out a plan to assist the transition these bench discoveries into the clinic.

**4. State of personnel additions relative to the Center of Excellence and the core research being performed therein.**

UF's Division of Cellular and Molecular Therapy (DCMT) has hired two of five faculty members and their staff in Regenerative Medicine: Dr. Arun Srivastava as Division Chief and Dr. Kirsten Weigel-Kelley. These faculty members and staff have relocated from Indiana and have moved into the new CERHB Research facility. Three other faculty and their staff are being recruited. This will result in full occupancy of both of the buildings.

A search is underway for a Director of Operations who will oversee the day-to-day operations of the CERHB Biopharmaceutical Manufacturing Facility.

A coordinator of administrative services is being hired to manage the financial, personnel, and other administrative duties for the CERHB.

A manager of Quality Assurance is being hired to implement quality systems for the CERHB Biopharmaceutical Manufacturing Facility.

**5. Integration of the mission of the Center of Excellence with all levels of the K-20 education system.**

A new proposal to the National Science Foundation was submitted by UF CERHB and collaborators (The International Society for Pharmaceutical Engineering (ISPE), the University of Florida Center for Precollegiate Education and Training (UF

CPET), the Alachua County School Board, and Santa Fe Community College (SFCC)). This NSF funding will be used to implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry. We plan on partnering with school boards from the State of Florida to implement this curriculum at the high school level.

**6. Number of industry internships granted to graduate and post-doctorate students as a result of interaction with the Center of Excellence.**

None for this period because the CERHB facilities are under construction. However, we will have several biotechnology businesses as partners of the NSF training grant cited above in #5. Community College students taking the curriculum will be given the opportunity to intern at participating companies.

**7. Overall Economic Impact of the Center's Existence including number of inventions, number of patents, number of license technologies, and amount of revenue generated from royalties and licenses.**

None for this period because the CERHB facilities are under construction.

**8. Development of start-up businesses as a result of technology research being performed in the Center.**

None for this period because the CERHB facilities are under construction.

**9. Impact of the Center's relationship with out of state businesses.**

In conversations with business outside of Florida, CERHB actively promotes the increased biotechnology activity in the state (Scripps Florida, Center of Excellence, biotechnology company start-up support, venture capital funding, and university-based discovery and licensing). These companies remain in active contact with CERHB and UF OTL to monitor our progress and to stay informed about new activities in the State.

**10. Leveraging of financial resources including the obtaining of public and private matching funds as well as direct Federal grants or contract.**

The UF Department of Pediatric's new Division of Cellular and Molecular Therapy (DCMT) headed by Dr. Arun Srivastava as Division Chief, has hired Dr. Kirsten Weigel-Kelley, and will hire three more new faculty and a staff of up to 30 that will reside in the CERHB research facility. These investigators will bring up to \$10 million in new federal research dollars to UF. These investigators conduct research in various aspects of regenerative medicine. The Department of Pediatrics and the College of Medicine will fund approximately \$1million in renovation costs for laboratories in the CERHB facility. In two to three years this space will become available for new start up in conjunction with the Sid Martin Biotechnology Incubator.

Two "shared equipment" grant proposals were submitted to the National Institutes of Health on March 19, 2004. One of the grants is for an Amersham Biosciences Typhoon 9400 Variable Mode Imager and the other is for a FACSARIA<sup>®</sup> Flow Cytometer from Beckton Dickinson. The budgets submitted are \$140,655 and



\$445,750, respectively. These two instruments will support CERHB research activities in Gene Therapy and Adult Stem Cell biology. These proposals are under review.

As stated above, a new proposal to the National Science Foundation was submitted on May 17, 2004 by UF CERHB and collaborators. This NSF funding (\$600,000 over 3 years) will be used to implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry. 41 letters of support/participation were provided by Academic, State and Local Government, and Private Sector organizations. This proposal is under review.

A new proposal was submitted to the Gates Foundation (L. Chang, PI and R. Snyder, Co-PI) on June 20, 2004 for the development of a novel HIV vaccine and the manufacturing technology that would be required to manufacture the vaccine. Following the development, it is likely that the Vaccine would be manufactured in the CERHB Biopharmaceutical Manufacturing Facility.

**11. Interest of direct collaboration with Venture Capital entities.**

The UF office of Technology Licensing (OTL), a partner of the CERHB, has seen a jump in the interest by Venture Capital firms (InterSouth, InterWest) for local biotechnology start-ups housed at the UF Sid Martin Biotechnology Development Incubator. This increase in interest is a direct result of the Venture funding obtained by AGTC, and the statewide biotechnology initiatives.

**University of Florida Specific Standards:**

**1. Status of the purchase of the buildings to house the Center of Excellence.**

The University of Florida and Regeneration Technologies, Inc. executed the real estate transaction on October 31, 2003 for the purchase of two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities. The buildings are located at One and Two Innovation Drive in Alachua, FL in Progress Corporate Park, which is proximal to UF's Sid Martin Biotechnology Development Incubator.

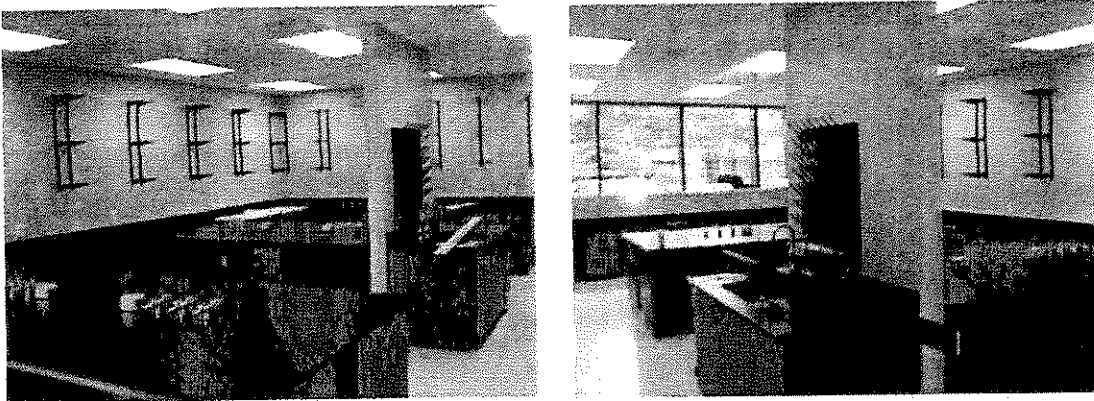
Operations management of both of these buildings has been integrated with the management of the Sid Martin Biotechnology Development Incubator, which has led to a significant reduction in the costs involved.

On July 1, 2004 these two buildings were accepted by the State of Florida.

**2. Status of the construction of the Vector Production facility, the microbial fermentation facility, and the cell culture facility.**

Two Innovation Drive will house the CERHB's training facility, the UF Powell Gene Therapy Center Vector Core, and 5 faculty members and their staff being hired in Regenerative Medicine by The Division of Cellular and Molecular Therapy (DCMT). We retained the services of Moses & Associates/PPI to design and renovate this building. The design phase and demolition of the interior are complete. Construction of one half of the building is complete and occupants (two faculty and

their staff) moved in June 26, 2004. Construction of the other half of the building (more research laboratories and the Education Center) is in progress and is expected to be complete in September 2004.



One Innovation Drive will house up to 15,000 square feet of class 10,000 and class 100,000 cleanrooms and supporting space for biopharmaceutical manufacturing. We retained the services of FLAD/AEI to write the building program, and the program is complete. Proposals were submitted for the program by 8 contractors and proposals were reviewed on June 23, 2004; the 5 selected contractors will be interviewed July 7, 2004. The construction is expected to last 18 months once it is initiated.

As part of the Commissioning Phase of the renovation for One Innovation Drive, construction validation services are required. A Request for Proposals is being drafted to solicit proposals for Validation Services.

In addition to increasing cGMP biopharmaceutical manufacturing capacity at One Innovation Drive, CERHB invested \$394,418 for improvements to the existing cleanrooms in the PGTC Human Applications Laboratory cGMP facility on the UF main campus in Gainesville, which is currently operating at capacity. The construction is complete, and equipment has been installed, calibrated, and validated. Operations have resumed.

**3. Status of the joint program with Santa Fe Community College related to the Biotech training program, the High-Tech training program, and the Regulatory Affairs training program.**

CERHB is working with SFCC to implement training programs to meet the demand for new high-tech jobs that will be created with 1) the opening of CERHB's Biopharmaceutical Manufacturing Facility in Alachua, 2) the maturation of existing start-up companies in the region, and 3) the establishment of new companies.

UF CERHB in partnership with SFCC will implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry. Design of this training facility for the building at Two Innovation Drive was completed in May 2004 with classrooms, conference areas, and wet labs outfitted with state-of-the-art equipment. Construction



is expected to be complete in September 2004. The education program will be housed in the CERHB Biotechnology Education Center so that students and potential employers can participate in joint activities such as internships and work-study programs. Local employers will play a major role in curriculum development to assure that the students are trained in suitable courses. The education center will serve a central role in providing opportunities for hands-on experience; this is an essential component of a successful training program and will produce graduates with not only theoretical knowledge, but also actual experience in manufacturing, regulatory, business, and legal activities.

UF CERHB and SFCC collaborated on a new proposal to the National Science Foundation to fund this initiative (see above). This proposal will be the foundation of the UF CERB-SFCC training initiative even if NSF does not fund our proposal.

UF serves on the executive committee of the Florida Consortium for Biotechnology Workforce Development (FCBWD). In September 2003, the Consortium received a \$1.25M Grant from Workforce Florida, Inc. to establish an on-line course for biotechnology training. The three principle participants are: Santa Fe Community College, Florida Community College at Jacksonville, and Hillsborough Community College. The on-line curricula will be a portal for students interested in biotechnology education to access the hands-on training offered by CERHB, and the CERHB hands-on curriculum will be complemented by these on-line courses. On-line modules are being drafted and will be reviewed in August 2004.

**4. Status of the joint program with the Florida Community College in Jacksonville in a course study in Bioinformatics.**

UF CERHB had a meeting with Dr. Linda Austin of FCCJ on February 6, 2004. Dr. Li Liu outlined the three-part skill set needed for a bioinformatics specialist: an understanding of biological systems, an understanding of computer science, and the ability to combine these two fields to facilitate molecular biology research. The current curriculum of FCCJ's bioinformatics program (4100 ATC) emphasizes the first two aspects, but does not include the third part, which may limit employment options for these students. UF proposed courses that would provide hands-on experience with real world academic/commercial projects to close this gap, and in turn increase student employability. UF's role would be to train FCCJ instructors and collaborate on curriculum development. FCCJ's curriculum committee is reviewing the proposed changes.

**5. Status of the development of an IDP track in Biotechnology in the UF College of Medicine.**

Preliminary conversations have begun regarding the implementation of an IDP track in biotechnology.

**6. Status of new companies plans to move into the new Center of Excellence.**

Recruitment literature was drafted and distributed to the candidate companies and CERHB has been in discussion with the following potential Contract Manufacturing partners: Cambrex, Cytovance Biologics, Inc., Genzyme, Goodwin Biotechnology, Inc., Johnson & Johnson, Lonza, Inc., Meridian Bioscience, Inc., and Origin Pharmaceutical Services. CERHB representatives visited Genzyme in Boston, MA

on January 22 and 23, 2004 to discuss Genzyme's interest in establishing a Gainesville operation. At this time (April 2004), none of these companies made a commitment to establish manufacturing operations in Gainesville.

UF CERHB will operate this facility and manufacture biopharmaceuticals for biotechnology companies and academic institutions located in Florida and throughout the United States. UF has a track record of managing these types of facilities and has manufactured material for clinical trials under contract with private companies and under other contracts. The Director of CERHB has extensive experience in establishing and administering similar biomanufacturing operations and facilities

## **Center of Excellence for Regenerative Health Biotechnology**

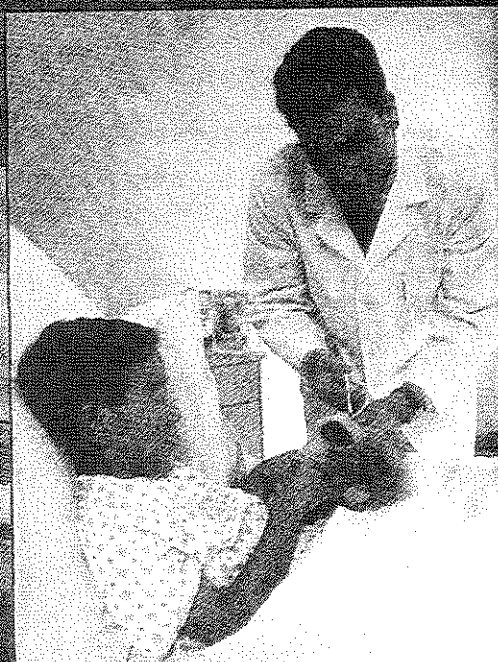
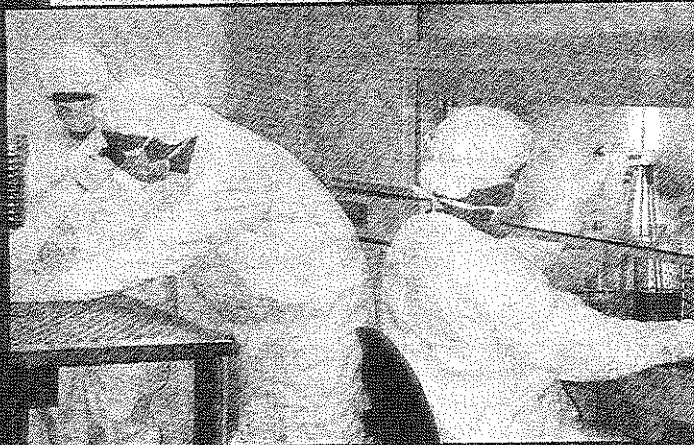
### **Summary of Activities April 1, 2004-June 30, 2004**

1. An application to the National Science Foundation was submitted on May 17, 2004 to develop hands-on curricula in Industrial Biotechnology at the College and High School levels. 41 letters of support/participation were provided by Academic, State and Local Government, and Private Sector organizations, including Scripps Florida.
2. The two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities have been designed. Renovations for half of the Research facilities are complete, and the occupants moved in June 26, 2004.
3. Human clinical trials began March 30, 2004 that utilized vector manufactured by the UF PGTC Human Applications Laboratory. The first cohort of patients have been treated and treatment of the second cohort of patients at the next highest dose has begun.
4. A new proposal was submitted to the Gates Foundation on June 20, 2004 for the development of a novel HIV vaccine and the manufacturing technology that would be required to manufacture the vaccine.
5. Searches have begun for CERHB administrative and Quality Systems personnel.
6. Proposals were submitted for the construction of the CERHB Biopharmaceutical Manufacturing Facility by 8 contractors and proposals were reviewed on June 23, 2004; 5 selected contractors were invited to present on July 7, 2004.
7. The Florida Consortium for Biotechnology Workforce Development (FCBWD) received a \$1.25M Grant from Workforce Florida, Inc. to establish an on-line course for biotechnology training. On-line modules are being drafted and will be reviewed in August 2004.

# *Center of Excellence for Regenerative Health Biotechnology*

## *Quarterly Report*

*January 1 to March 31, 2004*



TO: Emerging Technology Commission

FROM: Richard O. Snyder, Ph.D., Director

DATE: April 5, 2004

RE: Quarterly Report for the Center of Excellence For Regenerative Health  
Biotechnology  
January 1, 2004 – March 31, 2004

This quarterly report covering Q1, 2004 for The University of Florida's Center of Excellence for Regenerative Health Biotechnology (CERHB) is presented to the Commission. In addition to the general and specific performance measures that we are required to report, below is a list of other activities conducted during this quarter:

- On January 9, 2004, the Governor of Florida, Jeb Bush, visited the University of Florida's Center of Excellence for Regenerative Health Biotechnology to announce his expanded Centers of Excellence initiative. The Governor was given a tour of UF's PGTC Human Applications Laboratory.



- UF Sponsored a Florida Consortium for Biotechnology Workforce Development (FCBWD) focus group that took place February 6, 2004. This event provided an opportunity for North Florida biotech industry representatives to outline the employee skills that need to be taught. One of the outcomes of the meeting was unanimous support for web-based instruction that supplements laboratory and manufacturing skills that need to be taught in a hands-on environment.



### General Measurement Standards:

1. **Full financial disclosure of expenditures related to the cost proposal of the Center of Excellence.**

JANUARY 1, 2004-MARCH 31, 2004	CATEGORY	COE FUNDS	UF MATCHING	TOTAL
CERHB Equipment			\$ 208,801.76	
Design and Renovation	OE (Expense)	\$ 221,113.00		
CERHB(electric/PPD/gases	OE (Expense)	\$ 43,000.00		
Operating Expenses	OE (Expense)	\$ 5,639.44		
Personnel	Salary	\$ 3,139.68		
Consultant and Professional Services	OPS	\$ 7,950.00		
<b>TOTAL THIS QUARTER</b>		<b>\$ 280,842.12</b>	<b>\$ 208,801.76</b>	<b>\$ 489,643.88</b>
<b>TOTAL SINCE INCEPTION</b>		<b>\$ 572,163.68</b>	<b>\$ 4,091,713.76</b>	<b>\$ 4,663,877.44</b>

2. **Effectiveness and success of the research being performed within the Center of Excellence.**

Sixteen peer-reviewed scientific publications were published by investigators who are members of CERHB partner organizations (Powell Gene Therapy Center, Center for Mammalian Genetics/Epigenetics, Adult Stem Cell Consortium) at UF.

**Instrumentation for UF's Adult Stem Cell Consortium has been purchased that will enhance the analysis of cells and tissues.** The new confocal microscope has been installed. Two technicians have completed the basic training on the use of the machine and will assist researchers. The technicians are performing a series of trial images and are learning the basic software to become proficient with the fundamentals. In one month, a Leica trainer will return to answer any questions and teach them more advanced applications. An online sign-up process is being implemented to coordinate instrument usage.



**An Epigenetics seminar series began February 5, 2004 for the Spring semester that included researchers who are leaders in the field.** The topics presented include: Regulation of Imprinting, Control of Chromosome Replication, Meiotic RNA Silencing,

Chromosome Inactivation, Histone Modification, and Medical Applications of Epigenetics.

**3. State of research collaboration with other universities or research entities as well as private industry.**

*Applied Genetics Technologies Corporation.* The collaboration with the Powell Gene Therapy Center (a partner of CERHB) involves the development of gene therapies to treat genetic and acquired diseases including alpha-one anti-trypsin deficiency, blindness, and Muscular Dystrophy. The pre-clinical toxicology studies and manufacture of clinical grade vector for an alpha-one antitrypsin product are complete. The Investigational New Drug Application was submitted to the FDA and it was reviewed. The vector for the first cohort of patients was delivered to the Investigational Pharmacy, formulated, and injected by Dr. Flotte into the first patient on March 30, 2004.

Testing of products for blindness and Muscular Dystrophy is in progress. A discussion between Dr. Hauswirth's group and the FDA was held on March 30, 2004 to discuss a clinical trial to treat blindness. Preparation for manufacturing another candidate product for alpha-one anti-trypsin deficiency is in progress.

*The Scripps Research Institute:* UF CERHB met with representatives of Scripps on January 13, 2004 in Gainesville. Scripps will be a major source of new discoveries, many of which will be tested in the clinic. As the Scripps Florida organization is established, UF CERHB will work with Scripps to map out a plan to assist the transition these bench discoveries into the clinic.

**4. State of personnel additions relative to the Center of Excellence and the core research being performed therein.**

UF's Division of Cellular and Molecular Therapy (DCMT) has hired two of five faculty members and their staff in Regenerative Medicine: Dr. Arun Srivastava as Division Chief and Dr. Kirsten Weigel-Kelley. The faculty members and staff will reside in the CERHB Research facility after renovations (paid for by UF's Department of Pediatrics and College of Medicine) are complete. This will result in full occupancy of both of the buildings.

The Epigenetics faculty search is in progress. This hire would bridge UF's current efforts in Gene Therapy, Stem Cell Biology, and Materials Science. The Faculty research focus is in Epigenetic regulation of gene expression with an emphasis on histone biochemistry, establishing organ patterning, and or position effects

**5. Integration of the mission of the Center of Excellence with all levels of the K-20 education system.**

A new proposal to the National Science Foundation is being developed by UF CERHB and collaborators (The International Society for Pharmaceutical Engineering (ISPE), the University of Florida Center for Precollegiate Education and Training (UF CPET), the Alachua County School Board, and Santa Fe Community College (SFCC)). This NSF funding will be used to implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including

both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry. We plan on partnering with school boards from the State of Florida to implement this curriculum at the high school level.

**6. Number of industry internships granted to graduate and post-doctorate students as a result of interaction with the Center of Excellence.**

None for this period because the CERHB facilities are under construction. However, we will have several biotechnology businesses as partners of the NSF training grant cited above in #5. Community College students taking the curriculum will be given the opportunity to intern at participating companies.

**7. Overall Economic Impact of the Center's Existence including number of inventions, number of patents, number of license technologies, and amount of revenue generated from royalties and licenses.**

None for this period because the CERHB facilities are under construction.

**8. Development of start-up businesses as a result of technology research being performed in the Center.**

None for this period because the CERHB facilities are under construction.

**9. Impact of the Center's relationship with out of state businesses.**

In conversations with business outside of Florida, CERHB actively promotes the increased biotechnology activity in the state (Scripps Florida, Center of Excellence, biotechnology company start-up support, venture capital funding, and university-based discovery and licensing). These companies remain in active contact with CERHB and UF OTL to monitor our progress and to stay informed about new activities in the State.

**10. Leveraging of financial resources including the obtaining of public and private matching funds as well as direct Federal grants or contract.**

An application to the Economic Development Administration (EDA) for a \$2M Public Works Grant was submitted on January 14, 2004. The grant was awarded on February 24, 2004 and will aid the renovation of One Innovation Drive that will house the biopharmaceutical manufacturing facility. The fact that the initiative will provide significant employment to an economically distressed region qualified CERHB for the Federal Grant. The State funding that established CERHB made the proposal attractive to the EDA.





*Assistant Secretary of Commerce Dr. David A. Sampson awards \$2M check to UF*

The UF Department of Pediatric's new Division of Cellular and Molecular Therapy (DCMT) headed by Dr. Arun Srivastava as Division Chief, has hired Dr. Kirsten Weigel-Kelley, and will hire three more new faculty and a staff of up to 30 that will reside in the CERHB research facility. These investigators will bring up to \$10 million in new federal research dollars to UF. These investigators conduct research in various aspects of regenerative medicine. The Department of Pediatrics and the College of Medicine will fund approximately \$1 million in renovation costs for laboratories in the CERHB facility. In two to three years this space will become available for new start up in conjunction with the Sid Martin Biotechnology Incubator.

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As stated above, a new proposal to the National Science Foundation is being developed by UF CERHB and collaborators. This NSF funding (\$600,000 over 3 years) will be used to implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry.

#### **11. Interest of direct collaboration with Venture Capital entities.**

The UF office of Technology Licensing (OTL), a partner of the CERHB, has seen a jump in the interest by Venture Capital firms (InterSouth, InterWest) for local biotechnology start-ups housed at the UF Sid Martin Biotechnology Development Incubator. This increase in interest is a direct result of the Venture funding obtained by AGTC, and the statewide biotechnology initiatives.

## University of Florida Specific Standards:

### **1. Status of the purchase of the buildings to house the Center of Excellence.**

The University of Florida and Regeneration Technologies, Inc. executed the real estate transaction on October 31, 2003 for the purchase of two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities. The buildings are located at One and Two Innovation Drive in Alachua, FL in Progress Corporate Park, which is proximal to UF's Sid Martin Biotechnology Development Incubator.

Operations management of both of these buildings has been integrated with the management of the Sid Martin Biotechnology Development Incubator, which has led to a significant reduction in the costs involved.

### **2. Status of the construction of the Vector Production facility, the microbial fermentation facility, and the cell culture facility.**

Two Innovation Drive will house the CERHB's training facility, the UF Powell Gene Therapy Center Vector Core, and 5 faculty members and their staff being hired in Regenerative Medicine by The Division of Cellular and Molecular Therapy (DCMT). We retained the services of Moses & Associates to design and renovate this building. Both the design phase and demolition of the interior are complete. Construction is expected to be complete in July 2004.

One Innovation Drive will house up to 15,000 square feet of class 10,000 and class 100,000 cleanrooms and supporting space for biopharmaceutical manufacturing. We retained the services of FLAD/AEI to write the building program, and the program is complete. The bidding on the program by contractors and contractor interviews are planned to initiate in April 2004. The construction is expected to last 18 months once it is initiated.

In addition to increasing cGMP biopharmaceutical manufacturing capacity at One Innovation Drive, CERHB invested \$394,418 for improvements to the existing cleanrooms in the PGTC Human Applications Laboratory cGMP facility on the UF main campus in Gainesville, which is currently operating at capacity. The construction is complete, and equipment has been installed, calibrated, and validated.

### **3. Status of the joint program with Santa Fe Community College related to the Biotech training program, the High-Tech training program, and the Regulatory Affairs training program.**

CERHB is working with SFCC to implement training programs to meet the demand for new high-tech jobs that will be created with 1) the opening of CERHB's Biopharmaceutical Manufacturing Facility in Alachua, 2) the maturation of existing start-up companies in the region, and 3) the establishment of new companies.

UF CERHB in partnership with SFCC will implement a hands-on industrial biotechnology curriculum at community college and high-school levels (including both student and teacher training). The curriculum will be used to attract and train students for careers in the biotechnology industry. This training facility is currently

being designed for the building at Two Innovation Drive complete with classrooms, conference areas, and wet labs outfitted with state-of-the-art equipment. The education program will be housed in the CERHB Biotechnology Education Center so that students and potential employers can participate in joint activities such as internships and work-study programs. Local employers will play a major role in curriculum development to assure that the students are trained in suitable courses. The education center will serve a central role in providing opportunities for hands-on experience; this is an essential component of a successful training program and will produce graduates with not only theoretical knowledge, but also actual experience in manufacturing, regulatory, business, and legal activities.

UF CERHB and SFCC are collaborating on a new proposal to the National Science Foundation to fund this initiative (see above). This proposal will be the foundation of the UF CERB-SFCC training initiative even if NSF does not fund our proposal.

UF serves on the executive committee of the Florida Consortium for Biotechnology Workforce Development (FCBWD). In September 2003, the Consortium received a \$1.25M Grant from Workforce Florida, Inc. to establish an on-line course for biotechnology training. The three principle participants are: Santa Fe Community College, Florida Community College at Jacksonville, and Hillsborough Community College. The on-line curricula will be a portal for students interested in biotechnology education to access the hands-on training offered by CERHB, and the CERHB hands-on curriculum will be complemented by these on-line courses.

**4. Status of the joint program with the Florida Community College in Jacksonville in a course study in Bioinformatics.**

UF CERHB had a meeting with Dr. Linda Austin of FCCJ on February 6, 2004. Dr. Li Liu outlined the three-part skill set needed for a bioinformatics specialist: an understanding of biological systems, an understanding of computer science, and the ability to combine these two fields to facilitate molecular biology research. The current curriculum of FCCJ's bioinformatics program (4100 ATC) emphasizes the first two aspects, but does not include the third part, which may limit employment options for these students. UF proposed courses that would provide hands-on experience with real world academic/commercial projects to close this gap, and in turn increase student employability. UF's role would be to train FCCJ instructors and collaborate on curriculum development.

**5. Status of the development of an IDP track in Biotechnology in the UF College of Medicine.**

Preliminary conversations have begun regarding the implementation of an IDP track in biotechnology.

**6. Status of new companies plans to move into the new Center of Excellence.**

Recruitment literature was drafted and distributed to the candidate companies and CERHB has been in discussion with the following potential Contract Manufacturing partners: Cambrex, Cytovance Biologics, Inc., Genzyme, Goodwin Biotechnology, Inc., Johnson & Johnson, Lonza, Inc., Meridian Bioscience, Inc., and Origin Pharmaceutical Services. CERHB representatives visited Genzyme in Boston, MA

on January 22 and 23, 2004 to discuss Genzyme's interest in establishing a Gainesville operation. At this time (April 2004), none of these companies has made a commitment to establish manufacturing operations in Gainesville.

UF CERHB is prepared to operate this facility and manufacture biopharmaceuticals for biotechnology companies and academic institutions located in Florida and throughout the United States. UF has a track record of managing these types of facilities and has manufactured material for clinical trials under contract with private companies and under other contracts. The Director of CERHB has extensive experience in establishing and administering similar biomanufacturing operations and facilities

## **Center of Excellence for Regenerative Health Biotechnology**

### **Summary of Activities January 1, 2004-March 31, 2004**

1. Governor Jeb Bush visited the UF CERHB on January 9, 2004.
2. An application to the Economic Development Administration (EDA) for a \$2M Public Works Grant was submitted on January 14, 2004. The grant was awarded on February 24, 2004 and will be used to renovate the biopharmaceutical manufacturing facility.
3. The two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities have been designed and renovations for the Research and Educational facilities have begun.
4. CERHB representatives visited Genzyme in Boston, MA on January 22 and 23, 2004 to discuss Genzyme's interest in establishing a Gainesville operation.
5. UF CERHB met with representatives of Scripps on January 13, 2004 in Gainesville to discuss potential interactions.
6. Two grant applications for scientific instrumentation were submitted to the National Institutes of Health on March 19, 2004.
7. Work began on a new proposal to the National Science Foundation. This NSF funding will be used to implement a hands-on industrial biotechnology curriculum at community college and high-school levels.
8. Human clinical trials began March 30, 2004 that utilized vector manufactured by the UF PGTC Human Applications Laboratory.
9. UF Sponsored a Florida Consortium for Biotechnology Workforce Development (FCBWD) focus group that took place February 6, 2004.
10. Improvements for the UF Human Applications Laboratory are complete and new equipment has been installed, calibrated, and validated.
11. An Epigenetics seminar series began February 5, 2004 for the Spring semester
12. Instrumentation for UF's Adult Stem Cell Regenerative Medicine Program has been installed and technicians are being trained.

April 29, 2004

Email surveys@mit.edu  
Phone 617.253.8167**SURVEY PROPOSAL: 2004 Graduate and Professional Student Survey****Summary of Service**

The MIT Web Survey Service proposes to run a 2004 Graduate and Professional Student Survey for peer institutions. The proposal below covers the tentative schedule, development fees, and service fees.

Participating schools will provide MIT with local survey content (school logo, optional local questions) and student sample files including the following variables for cross institutional analysis and feed to data warehouse (for AAUDE schools only):

ID (unique id from institution)	Ethnicity (african american; asian	Age at time of survey (years)
Last Name	american hispanic; native	Degree objective (tbd)
First Name	american; white; international;	Entry date as graduate student
Middle Name	race/ethnicity unknown)	(dd/mm/yyyy)
Email address	Citizenship (citizen, permanent	Discipline (6-digit cip code)
Gender (male, female)	resident, international)	Final Term Flag (yes, no)

Participants may choose to send their own email, or have MIT send email invitations and reminders. Each email must be customized to include a student's unique survey URL. Interested participants will have until September 30, 2004 to sign up to participate for calendar year 2004.

**Tentative Schedule**

6 weeks before live	Notification to MIT of interest in survey participation
4 weeks before live	Final survey content to MIT (headers, welcome text, email letters etc)
2 weeks before live	Final list of students & email addresses to MIT
2 weeks after close	Survey data sent to participating school

**Development and Hosting Costs Fees**

Each participating school will be charged \$500 to participate. This participation fee will cover:

1. Customizing the survey with the school's custom header and footer
2. Adding one page of local questions (limited to 25 closed-ended and 5 open text; detail & samples on <http://web.mit.edu/surveys/grad2004/local.html>)
3. Hosting the survey on MIT web server, with download site for responder list.
4. Building student authentication with unique URLs.

**Service Fees**

In addition to the participation fee, schools will be charged for the number of students surveyed:

\$0.50 /student	Account / data management / support while survey live
\$0.50 /student	Email to individual students (launch email plus up to 3 reminders)
\$100 /instance	Student account additions after survey is live

*It is very difficult to add new students to the survey system once the survey is live.*

**Payment Schedule**

The Development and Hosting fees, as well as Service fees, will be invoiced while the survey is live, and due upon receipt of data.

**Team Members**

MIT's Web Survey Service is part of MIT's Information Services & Technology. The service is run by Jagruti S. Patel, Senior IT Consultant, and Jeffrey I. Schiller, Network Manager. Jag and Jeff will be the team members involved in this project. For questions or more information, please contact [surveys@mit.edu](mailto:surveys@mit.edu).

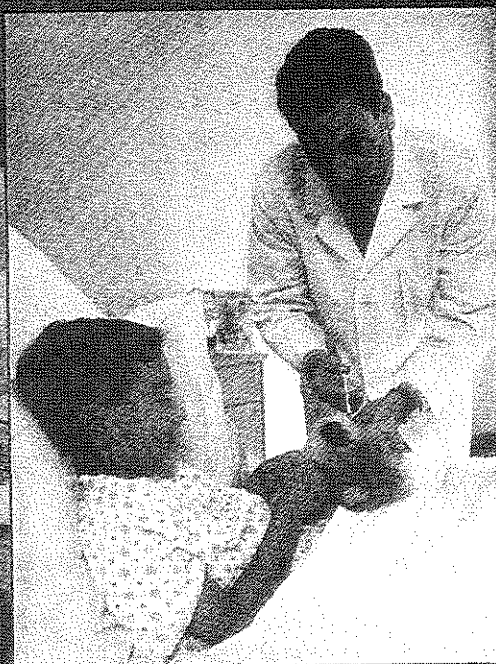




# *Center of Excellence for Regenerative Health Biotechnology*

## **Quarterly Report**

**October 1 to December 31, 2003**



TO: Emerging Technology Commission

FROM: Richard O. Snyder, Ph.D., Director

DATE: January 8, 2004

RE: Quarterly Report for the Center of Excellence For Regenerative Health  
Biotechnology  
October 1, 2003 – December 31, 2003

This quarterly report covering Q2, 2003 for The University of Florida's Center of Excellence for Regenerative Health Biotechnology (CERHB) is presented to the Commission. In addition to the general and specific performance measures that we are required to report, below is a list of other activities conducted during this quarter:

- A brochure was produced that is being distributed at meetings and press conferences.
- A presentation was made at the BioFlorida, Sixth Annual Conference. October 19-20, 2003, Orlando, FL.
- Sponsored a Florida Consortium for Biotechnology Workforce Development (FCBWD) meeting that took place December 12, 2003,
- Co-sponsor of a seminar series in Epigenetics for the Spring of 2004.

**General Measurement Standards:**

1. Full financial disclosure of expenditures related to the cost proposal of the Center of Excellence.

OCTOBER 1, 2003-DECEMBER 31, 2003	CATEGORY	COE FUNDS	UF MATCHING	TOTAL
Alachua Building purchase (44,500 SQFT)	OE(Expense)		\$ 3,121,721.00	
Confocal Microscope	OCO		\$ 476,000.00	
Lab Equipment	OCO		\$ 186,122.00	
Design and Renovation	OE(Expense)	\$161,078.00		
Utilities Blankets	OE(Expense)	\$ 43,000.00		
Operating Expenses	OE(Expense)	\$ 1,429.61		
Personnel	Salary	\$ 3,869.48	\$ 62,748.00	
<b>TOTAL THIS QUARTER</b>		<b>\$209,377.09</b>	<b>\$ 3,846,591.00</b>	<b>\$4,055,968.09</b>
<b>TOTAL SINCE INCEPTION</b>		<b>\$291,321.56</b>	<b>\$ 3,882,912.00</b>	<b>\$4,174,233.56</b>

2. Effectiveness and success of the research being performed within the Center of Excellence.



Eight peer-reviewed scientific publications were published by investigators who are members of CERHB partner organizations (Powell Gene Therapy Center, Center for Mammalian Genetics/Epigenetics, Adult Stem Cell Consortium) at UF.

Instrumentation for UF's Adult Stem Cell Consortium has been purchased that will enhance the analysis of cells and tissues.

**3. State of research collaboration with other universities or research entities as well as private industry.**

*Applied Genetics Technologies Corporation.* The collaboration with the Powell Gene Therapy Center (a partner of CERHB) involves the development of gene therapies to treat genetic diseases including alpha-one anti-trypsin deficiency, Leber's congenital Amerosis, and Limb Girdle Muscular Dystrophy. The pre-clinical toxicology studies are complete and manufacture of clinical grade vector for an alpha-one antitrypsin product is complete with clinical trials scheduled for Q1, 2004. Testing of products for Leber's Congenital Amerosis and Limb Girdle Muscular Dystrophy is in progress. Preparation for manufacturing another candidate product for alpha-one anti-trypsin deficiency is in progress.

*The Scripps Research Institute:* Establishing a research campus in Palm Beach County, Florida. Scripps has a track record of making significant discoveries in biotechnology. Scripps will be a major source of new discoveries, many of which will be tested in the clinic. The UF CERHB will work with Scripps to transition these bench discoveries to the clinical bedside.

**4. State of personnel additions relative to the Center of Excellence and the core research being performed therein.**

Stanley Stevens, Ph.D. an assistant scientist in Proteomics and Li Liu, MD a senior computer specialist in Bioinformatics have been hired for the UF Interdisciplinary Center for Biotechnology Research (ICBR). Their activities will support proteomics and bioinformatics activities for the entire UF campus, and they will interface with FCCJ faculty.

Established relationship with UF's Division of Cellular and Molecular Therapy (DCMT) resulting in five faculty members and their staff being hired in Regenerative Medicine. The faculty members and staff will reside in the CERHB Research facility after renovations (paid for by UF's Department of Pediatrics and College of Medicine) are complete. This will result in full occupancy of both of the buildings.

The Epigenetics faculty search is underway. This hire would bridge UF's current efforts in Gene Therapy, Stem Cell Biology, and Materials Science. The Faculty research focus is in Epigenetic regulation of gene expression with an emphasis on histone biochemistry, establishing organ patterning, and or position effects

**5. Integration of the mission of the Center of Excellence with all levels of the K-20 education system.**

A presentation was made to Marion County High School teachers who were invited by the University of Florida Center for Precollegiate Education and Training (UF CPET). Dr. Koroly is leading the effort to apply for NSF funding to implement a biotechnology curriculum at the high-school level (including both student and teacher training).

**6. Number of industry internships granted to graduate and post-doctorate students as a result of interaction with the Center of Excellence.**

None for this period

**7. Overall Economic Impact of the Center's Existence including number of inventions, number of patents, number of license technologies, and amount of revenue generated from royalties and licenses.**

None for this period

**8. Development of start-up businesses as a result of technology research being performed in the Center.**

Applied Genetic Technologies Corporation, a start-up company located at the Sid Martin Biotechnology Development Incubator received \$15M in B-round venture funding headed by premiere California-based Interwest Partners.

**9. Impact of the Center's relationship with out of state businesses.**

CERHB is in discussion with the following out of state potential Contract Manufacturing partners: Cambrex, Cytovance Biologics, Inc., Genzyme, Johnson & Johnson, Lonza, Inc., Meridian Bioscience, Inc., and Origin Pharmaceutical Services. In the course of these discussions, these companies have been made aware of the increased biotechnology activity in the state (Scripps Florida, Center of Excellence, biotechnology company start-up support, venture capital funding, and university-based discovery and licensing).

**10. Leveraging of financial resources including the obtaining of public and private matching funds as well as direct Federal grants or contract.**

A pre-application to the Economic Development Administration (EDA) for a \$2M Public Works Grant was submitted on Nov 11<sup>th</sup> 2003. This grant will aid the renovation of One Innovation Drive that will house the biopharmaceutical manufacturing facility. The fact that this initiative will provide significant employment to an economically distressed region qualifies CERHB for the Federal Grant. The State funding that established CERHB makes the proposal attractive to the EDA. Thirty letters of support for the CERHB biopharmaceutical expansion initiative were received from various local and state economic development agencies, state senators, the Scripps Research Institute, and local biotechnology companies. An estimated 265 jobs will be created in the local economy as a result of this initiative. Local companies also expect a total additional private sector investment of \$52.2M as their companies grow in parallel with the CERHB initiative. An invitation to submit an application was received by CERHB on December 9, 2003.

The UF Department of Pediatric's new Division of Cellular and Molecular Therapy (DCMT) headed by Dr. Arun Srivastava as Division Chief will bring 4 to 5 new faculty and staff of up to 30 to the CERHB research facility. These investigators work in areas such as sickle cell anemia, muscular dystrophy, and thalassemia, and will bring up to \$10 million in new federal research dollars to UF. These investigators conduct research in various aspects of regenerative medicine. The Department of Pediatrics and the College of Medicine will fund approximately \$1million in renovation costs for laboratories in the CERHB facility. In two to three years this space will become available for new start up in conjunction with the Sid Martin Biotechnology Incubator.

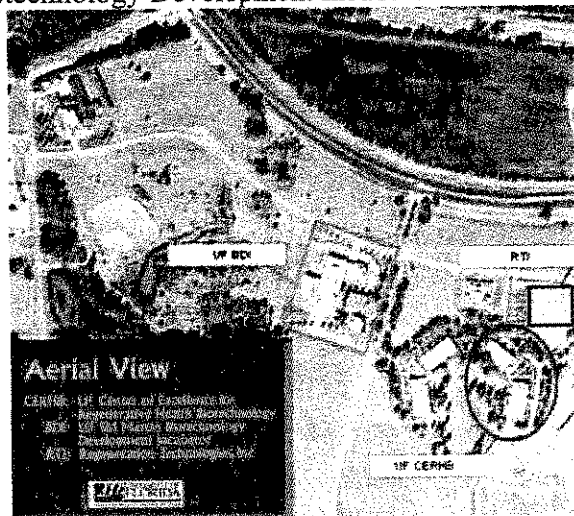
**11. Interest of direct collaboration with Venture Capital entities.**

The UF office of Technology Licensing (OTL), a partner of the CERHB, has seen a jump in the interest by Venture Capital firms (InterSouth, InterWest) for local biotechnology start-ups housed at the UF Sid Martin Biotechnology Development Incubator. This increase in interest is a direct result of the Venture funding obtained by AGTC, and the statewide biotechnology initiatives.

**University of Florida Specific Standards:**

**1. Status of the purchase of the buildings to house the Center of Excellence.**

The University of Florida and Regeneration Technologies, Inc. executed the real estate transaction on October 31, 2003 for the purchase of two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities. The buildings are located at One and Two Innovation Drive in Alachua, FL in Progress Corporate Park, which is proximal to UF's Sid Martin Biotechnology Development Incubator.





Operations management of both of these buildings has been integrated with the management of the Sid Martin Biotechnology Development Incubator, which has led to a significant reduction in the costs involved.

**2. Status of the construction of the Vector Production facility, the microbial fermentation facility, and the cell culture facility.**

Two Innovation Drive will house the CERHB's training facility, the UF Powell Gene Therapy Center Vector Core, and 5 faculty members and their staff being hired in Regenerative Medicine by The Division of Cellular and Molecular Therapy (DCMT). We have retained the services of Moses & Associates to design and renovate this building, and the design phase has been initiated.

One Innovation Drive will house up to 15,000 square feet of class 10,000 and class 100,000 cleanrooms and supporting space for biopharmaceutical manufacturing. We have retained the services of FLAD/AEI to write the building program, and the writing of the program has been initiated.

In addition to increasing cGMP biopharmaceutical manufacturing capacity at One Innovation Drive, CERHB has also invested approximately \$300,000 for improvements to the existing cleanrooms in the Human Applications Laboratory cGMP facility on the UF main campus in Gainesville, which is currently operating at capacity.

**3. Status of the joint program with Santa Fe Community College related to the Biotech training program, the High-Tech training program, and the Regulatory Affairs training program.**

CERHB is working with SFCC to implement training programs to meet the demand for new high-tech jobs that will be created with 1) the opening of CERHB's Biopharmaceutical Manufacturing Facility in Alachua, 2) the maturation of existing start-up companies in the region, and 3) the establishment of new companies.

On December 16, 2003, a meeting of CERHB and the Santa Fe Community College representatives, including SFCC President Dr. Jackson Sasser, was held to discuss the co-development of curriculum in bioprocess, quality systems, and regulatory affairs training that will take place in the new CERHB facility. This

training facility is currently being designed for the building at Two Innovation Drive complete with classrooms, conference areas, and wet labs outfitted with state-of-the-art equipment. The education program will be housed in the CERHB Biotechnology Education Center so that students and potential employers can participate in joint activities such as internships and work-study programs. Local employers will play a major role in curriculum development to assure that the students are trained in suitable courses. The education center will serve a central role in providing opportunities for hands-on experience; this is an essential component of a successful training program and will produce graduates with not only theoretical knowledge, but also actual experience in manufacturing, regulatory, business, and legal activities.

**4. Status of the joint program with the Florida Community College in Jacksonville in a course study in Bioinformatics.**

Two new UF faculty hires have been made in proteomics and bioinformatics. The planning of the joint program with FCCJ will initiate soon.

**5. Status of the development of an IDP track in Biotechnology in the UF College of Medicine.**

This has not yet been initiated.

**6. Status of new companies plans to move into the new Center of Excellence.**

Recruitment literature was drafted and distributed to the candidate companies and CERHB is in discussion with the following potential Contract Manufacturing partners: Cambrex, Cytovance Biologics, Inc., Genzyme, Goodwin Biotechnology, Inc., Johnson & Johnson, Lonza, Inc., Meridian Bioscience, Inc., and Origin Pharmaceutical Services.

# **Center of Excellence for Regenerative Health Biotechnology**

## **Summary of Activities**

October 1, 2003-December 31, 2003

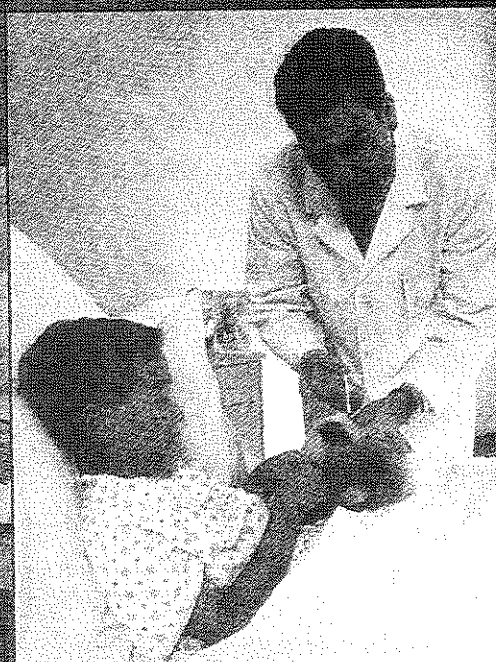
1. Purchased two buildings (22,500 ft<sup>2</sup> each) from Regeneration Technologies, Inc., that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities
2. Hired architect and engineering contractors to design and renovate both buildings
3. Currently in discussion with Contract Manufacturing companies for potential partnership.
4. Submitted a pre-application to the Economic Development Administration (US Dept of Commerce) for additional funds (\$2M) for the renovation of the building that will house the Biopharmaceutical Manufacturing Facility. Received an invitation to submit an application.
5. Established relationship with UF's Division of Cellular and Molecular Therapy (DCMT) resulting in five faculty members and their staff being hired in Regenerative Medicine. The faculty members and staff will reside in the CERHB Research facility after renovations (paid for by UF's Department of Pediatrics and College of Medicine) are complete. This will result in full occupancy of both of the buildings.
6. Hired Proteomics and Bioinformatics Staff for the UF Interdisciplinary Center for Biotechnology Research (ICBR)
7. Improvements for the UF Human Applications Laboratory are in progress
8. Purchased instrumentation for UF's Adult Stem Cell Regenerative Medicine Program
9. Made presentation at the BioFlorida, Sixth Annual Conference. October 19-20, 2003, Orlando, FL.



# *Center of Excellence for Regenerative Health Biotechnology*

**Quarterly Report**

**July 1 to September 30, 2003**



TO: Emerging Technology Commission

FROM: Richard O. Snyder, Ph.D., Director

DATE: January 8, 2004

RE: Quarterly Report for the Center of Excellence For Regenerative Health  
Biotechnology  
July 1, 2003 – September 30, 2003

This initial quarterly report covering Q1, 2003 for The University of Florida's Center of Excellence for Regenerative Health Biotechnology (CERHB) is presented to the Commission. In addition to the general and specific performance measures that we are required to report, below is a list of other activities conducted during this quarter:

- Mission – A Mission Statement for the Center was adopted:  
*To stimulate promising research and facilitate commercialization of technologies that will provide treatments and cures for human diseases, as well as create new companies and high-wage jobs for Florida.*
- A website has been established (<http://cerhb.rgp.ufl.edu/>) to provide public access to the current progress and activities, news, contacts, and mission related information.

#### **General Measurement Standards:**

1. **Full financial disclosure of expenditures related to the cost proposal of the Center of Excellence.**

JULY 1, 2003-SEPTEMBER 30, 2003	CATEGORY	COE FUNDS	UF MATCHING	TOTAL
Operating costs	OE(Expense)	\$ 18,593.12		
Renovation GMP Facility	OE(Expense)	\$ 61,686.00		
Personnel	Salary	\$ 1,665.35	\$ 36,321.00	
<b>TOTAL SINCE INCEPTION</b>		<b>\$ 81,944.47</b>	<b>\$ 36,321.00</b>	<b>\$ 118,265.47</b>

2. **Effectiveness and success of the research being performed within the Center of Excellence.**

Twelve peer-reviewed scientific publications were published by investigators who are members of CERHB partner organizations (Powell Gene Therapy Center, Center for Mammalian Genetics/Epigenetics, Adult Stem Cell Consortium) at UF.

3. **State of research collaboration with other universities or research entities as well as private industry.**

*Applied Genetics Technologies Corporation.* The collaboration with the Powell Gene Therapy Center (a partner of CERHB) involves the



development of gene therapies to treat genetic diseases including alpha-one anti-trypsin deficiency, Leber's congenital Amaurosis, and Limb Girdle Muscular Dystrophy. The pre-clinical toxicology studies are complete and manufacture of clinical grade vector is in progress for an alpha-one antitrypsin product.

***The Southeastern Regional Center of Excellence for Emerging Infections and Biodefense:*** Will begin the development of vaccines, diagnostic tests and treatments for potential bioterrorism agents and emerging infectious diseases. These candidate vaccines and treatments will need to be made in facilities like CERHB for testing in human clinical trials. A consortium of investigators from six universities including Duke University, University of North Carolina, Emory University, University of Alabama, Vanderbilt University and University of Florida were chosen to be part of this new biodefense initiative. Out of the total \$45M grant, UF will receive \$4M. CERHB facilities will be utilized by this consortium.

**4. State of personnel additions relative to the Center of Excellence and the core research being performed therein.**

**M. Peter Pevonka, MS, RPh,** (Assistant Vice President, Office for Research and Graduate Programs and Senior Associate Dean for Research Affairs, College of Medicine), was assigned general administrative oversight of the CERHB upon receipt of the State grant.

**Richard O. Snyder, Ph.D.** was hired as the Director and PI of the CERHB. Dr. Snyder is also the Director of the Human Applications Laboratory and Vector Core in the Powell Gene Therapy Center.

**David L. Day,** Director of the Office of Technology Licensing and Director of the Sid Martin Biotechnology Incubator, is the third member of the executive leadership group.

Administrative support has been consolidated with the UF Biotechnology Program.

In September, 2003 a search committee was formed that began recruitment of Epigenetics faculty. The committee members are: Edward Scott, Ph.D., Thomas Yang, Ph.D., Terence Flotte, MD, Kenneth Berns, MD, Ph.D., and Richard Snyder, Ph.D.

**5. Integration of the mission of the Center of Excellence with all levels of the K-20 education system.**

CERHB together with Dr. Mary Jo Karoly of the University of Florida Center for Precollegiate Education and Training (UF CPET), are formulating a plan for curriculum development and the means to effectively deliver this training curriculum to students and teachers in these communities to interest and train them in biotech-related college courses and careers.

**6. Number of industry internships granted to graduate and post-doctorate students as a result of interaction with the Center of Excellence.**

None for this period

7. **Overall Economic Impact of the Center's Existence including number of inventions, number of patents, number of license technologies, and amount of revenue generated from royalties and licenses.**

None for this period

8. **Development of start-up businesses as a result of technology research being performed in the Center.**

The UF Sid Martin Biotechnology Development Incubator is nearly at 100% occupancy with approximately 30 biotech start-up companies residing at this address. Of these companies, the following are making plans (increasing staff, obtaining financing) that depend on the establishment of the CERHB's biomanufacturing facility.

- A. ***Ixion Biotechnology, Inc:*** Anaerobic scale up fermentation of *Oxalobacter formigines*, for the prevention and treatment of primary hyperoxaluria and kidney stone formation. In addition, Ixion will need a facility for production of its pancreatic stem cell product for the treatment of Diabetes.
- B. ***Pasteuria Bioscience:*** Need for immediate scale up of two potential products for field-testing as replacements for pesticides and methyl bromide.
- C. ***AGTC:*** Immediate need for scale up and purification of viral gene therapy vectors for treatments of several human diseases.
- D. ***RegenMed, Inc:*** Immediate need for production facilities for adult stem cells for the treatment of a variety of liver, blood and neurological diseases.
- E. ***OraGenics, Inc.:*** Immediate need for the scale-up and purification of the genetically modified microbe for use in dental replacement therapy which is likely to prevent tooth decay permanently in both adults and children. In addition, they need a microbial fermentation facility capable of producing testable quantities of a new class of antibiotics for treatments for antibiotic resistant infections.
- F. ***Daimonion, LLC:*** Need for GMP manufacturing of monoclonal antibodies for developing In Vitro tests (ELISA) for the diagnosis of brain injury for both civilian and military situations
- G. ***IviGene:*** Need to overproduce antigens for vaccines for immuno therapy.
- H. ***Integrated Plant Genetics:*** Immediate need to clone and express several genes that can be used to make commercially valuable enzymes.
- I. ***Restoragen, Inc.:*** a Nebraska-based firm developing treatments for diabetes has indicated strong interest in relocating to Alachua in order to utilize the proposed services.

9. **Impact of the Center's relationship with out of state businesses.**

None for this period

**10. Leveraging of financial resources including the obtaining of public and private matching funds as well as direct Federal grants or contract.**

The CERHB is pursuing a \$2M Public Works Grant from the Economic Development Administration (EDA). This grant will aid the renovation of One Innovation Drive that will house the biopharmaceutical manufacturing facility. The fact that this initiative will provide significant employment to an economically distressed region qualifies CERHB for the Federal Grant. The State funding that established CERHB makes the proposal attractive to the EDA.

On September 16, 2003, a five-member team that included the Director of CERHB gave a presentation to officials at the EDA Regional Office in Atlanta. The presentation underlined the reasons why the project will be successful and how it will help improve the local and regional economy.

**11. Interest of direct collaboration with Venture Capital entities.**

The UF office of Technology Licensing (OTL), a partner of the CERHB, is in active contact with Venture Capital firms (Ballast Point and Lovett Miller) interested in local biotechnology start-ups housed at the UF Sid Martin Biotechnology Development Incubator.

**University of Florida Specific Standards:**

**1. Status of the purchase of the buildings to house the Center of Excellence.**

The real estate negotiation with Regeneration Technologies, Inc. for the purchase of two buildings (22,500 ft<sup>2</sup> each) that will house the CERHB's Biopharmaceutical Manufacturing, Research, and Educational Facilities is in progress. The buildings are located at One and Two Innovation Drive in Alachua, FL in Progress Corporate Park, which is proximal to UF's Sid Martin Biotechnology Development Incubator.

**2. Status of the construction of the Vector Production facility, the microbial fermentation facility, and the cell culture facility.**

Design and construction will commence once the purchase of the buildings is complete.

**3. Status of the joint program with Santa Fe Community College related to the Biotech training program, the High-Tech training program, and the Regulatory Affairs training program.**

The Director of CERHB serves on the executive committee of the Florida Consortium for Biotechnology Workforce Development (FCBWD). In September 2003, the Consortium received a \$1.25M Grant from Workforce Florida, Inc. to establish an on-line course for biotechnology training. The three principle participants are: Santa Fe Community College, Florida Community College at Jacksonville, and Hillsborough Community College. The on-line curriculum will be a portal for students interested in biotechnology education to access the hands-on training offered by CERHB.

**4. Status of the joint program with the Florida Community College in Jacksonville in a course study in Bioinformatics.**

A search is underway for new faculty at UF in Bioinformatics.

**5. Status of the development of an IDP track in Biotechnology in the UF College of Medicine.**

This has not yet been initiated.

**6. Status of new companies plans to move into the new Center of Excellence.**

The rapid testing and development of new therapeutic biologic drugs is hindered by the lack of capacity for cGMP compliant manufacturing of biopharmaceuticals of a quality suitable for human use. CERHB will provide biopharmaceutical manufacturing infrastructure needed for drug development to local and regional biotechnology companies and institutions. One Innovation Drive will be renovated to house up to 15,000 square feet of class 10,000 and class 100,000 cleanrooms and supporting space for biopharmaceutical manufacturing.

CERHB is currently seeking an internationally renowned private biopharmaceutical manufacturer to establish or expand its current business at the One Innovation Drive facility in Alachua. In August 2003, an Ad Hoc committee was formed to identify potential private biopharmaceutical manufacturers. This committee included members of the private biotechnology community as well as civic leaders: Brent Christensen (Gainesville Area Chamber of Commerce), Susan Washer (Applied Genetic Therapy Corporation), Weaver Gaines (Ixion), Lou Kessler (Ixion), James White (Entomos), Michael Young (Affiliated Engineers, Inc.), Keith Allaun (Eno River Capital), and John Rogers (EcoArray). The committee formulated a list of candidate companies.

# **Center of Excellence for Regenerative Health Biotechnology**

## **Summary of Activities** July 1, 2003-September 30, 2003

1. Hired Director: Richard O. Snyder, Ph.D.
2. Formed Ad Hoc committee to identify Contract Manufacturing Partner
3. Formed a search committee and began recruitment of Epigenetics faculty
4. CERHB Director joined the executive committee of Florida Consortium for Biotechnology Workforce Development
5. Began application process for a \$2M renovation grant from the Economic Development Administration.
6. Designed and began improvements for the UF Human Applications Laboratory

