

OHIO BOARD OF REGENTS

Consideration of a Joint Use Agreement between University of Toledo and the Cleveland Clinic Foundation.

RESOLUTION

WHEREAS, the 126th Ohio General Assembly enacted H.B. 699 which includes a specific capital appropriation of \$50,000,000 to Ohio Board of Regents for the Third Frontier Wright Capital projects; and

WHEREAS, the 126th Ohio General Assembly enacted H.B. 530 which includes a specific capital appropriation of \$50,000,000 to Ohio Board of Regents for the Third Frontier Wright Capital projects; and

WHEREAS, Section 291.10, Third Frontier Project, in H.B. 530 and Section 235.10.50, Third Frontier Wright Capital, in H.B. 699 specifies the funds shall be used to make grants awarded on a competitive basis, and shall be administered by the Third Frontier Commission; and

WHEREAS, a Wright Mega-Centers of Innovation award to the University of Toledo was ratified by the Third Frontier Commission at its meeting on December 15, 2006 in the amount of \$12,037,078; and

WHEREAS, the Ohio Board of Regents' Rule 3333-1-03 requires that a joint use agreement between the institution for which funds are appropriated and the organization which will own or lease and operate facilities to be constructed or improved with such funds must be approved by the Chancellor; and

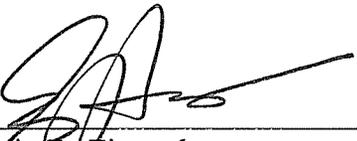
WHEREAS, University of Toledo and the Cleveland Clinic Foundation have presented a joint use agreement for approval by the Ohio Board of Regents; and

WHEREAS, the agreement has been reviewed and its format is found to be appropriate, its description of extent and nature of use has been specified, and the commitment extends no less than fifteen years, and it is in conformity with Rule 3333-1-03; and

WHEREAS, the parties have determined that the value of the use is reasonably related to the amount of the appropriation; and

NOW, THEREFORE,

BE IT RESOLVED: that the Joint Use Agreement between University of Toledo and the Cleveland Clinic Foundation, and attached and made a part hereof, be approved.



Eric D. Fingerhut
Chancellor

10/7/07

Date

Joint Use Agreement between the University of Toledo and the Cleveland Clinic
Foundation

BACKGROUND

H.B. 699 and H.B. 530 include specific capital appropriations totaling \$100,000,000 to the Board of Regents for Third Frontier Wright Capital projects. Section 291.10, Third Frontier Project, in H.B. 530 and Section 235.10.50, Third Frontier Wright Capital, in H.B. 699 specifies the funds shall be used to make grants awarded on a competitive basis. The grant awards shall be administered by the Third Frontier Commission.

A Wright Mega-Centers of Innovation award to the University of Toledo was ratified by the Third Frontier Commission at its meeting on December 15, 2006 in the amount of \$12,037,078. The higher education capital funds will support the construction of two facilities on Cleveland Clinic Foundation (CCF) property. CCF will lease one of the facilities for at least 15 years and will own the second facility. As required in Ohio Administrative Code section 3333-1-03, the University of Toledo submitted a Joint Use Agreement for consideration and approval by the Chancellor.

REVIEW

Throughout the entire term of the agreement, CCF agrees to provide the following to the University of Toledo and other public higher education institutions -

- a. Shared administrative space, laboratory facilities, and conference rooms will be available to the University of Toledo and other public higher education institutions on a non-paying or cost-only basis.

In addition, CCF and the Global Cardiovascular Innovation Center (GCIC) – working with public higher education institution partners – will prepare and submit joint National Institutes of Health proposals and Small Business Innovation Research grant requests. Also, GCIC will offer institution partners access to a venture capital consortium. This consortium will review potential investments in private companies formed to commercialize technologies developed at partner institutions.

The agreement conforms to Ohio Administrative Code as follows –

- The format of the agreement is appropriate
- The commitment extends no less than fifteen years
- The value of use to Ohio higher education institutions is reasonably related to the amount of the appropriation

RECOMMENDATION

Staff recommends Chancellor approval of the Joint Use Agreement between the University of Toledo and the Cleveland Clinic Foundation.

JOINT USE AGREEMENT ANALYSIS

Institutions Involved University of Toledo/Cleveland Clinic Foundation

Project Title Global Cardiovascular Innovation Center

Capital Bill HB 699 Item CAP-068, Third Frontier Wright Capital

Capital Bill HB 530 Item CAP-068, Third Frontier Project

- Yes 1. Is the facility to be built/improved identified specifically by address or location?
- Yes 2. Does the non-profit organization now own the property or have a long term lease? If not, when will it control the property?
- Yes 3. Does the agreement provide for use of the facility for at least 15 years from the time that it is ready for occupancy?
- Yes 4. If the agreement is terminated, is there a pro rata reimbursement clause? Is the reimbursement formula correct?
- Yes 5. Will funds be used only for capital improvements and not operating costs?
- Yes 6. Will the non-profit hold the institution harmless for all operation/maintenance costs?
- Yes 7. Will the non-profit comply with federal, state and local laws and rules?
- Yes 8. Is the non-profit required to competitively bid as outlined generally in ORC Chapter 153 (published ads, sealed bids, public opening, award to lowest responsive and responsible bidder, etc.)?
- Yes 9. Does the contract provide for a 1.5% administrative fee for the institution?
- Yes 10. Does the agreement require that amendments be approved by the Board of Regents?
- Yes 11. Is a drawdown schedule or payment procedure included?
- Yes 12. Are the extent and nature of spaces and uses adequately described?
- Yes 13. Are the terms and conditions of use of the facility described?
- Yes 14. **Has the institution demonstrated that the value of the use of the facility is reasonably related to the amount of the appropriation? (See attached worksheet)**
- Yes 15. Is the facility insured?

Joint Use Agreement Worksheet

The Ohio Board of Regents

July 27, 2007

Direction: The purpose of this worksheet is to enable a campus to demonstrate how the value of the uses that will be derived from a Joint Use Agreement is reasonably related to the value of the state capital appropriation made to the partner entity. Section I is to be filled out by the staff of the Board of Regents. Sections II and III are to be filled out by the partner campus.

Example: A campus wishes to enter into a Joint Use Agreement with a 501(C)(3) entity for a state appropriation of \$12,037,078. The annual debt service paid by the state on this appropriation is about \$925,364 per year, for 20 years. To demonstrate that the value of the uses of the facility is reasonably related to the state appropriation, the sum of the campus' educational uses of the facility should roughly equal \$925,364 per year for 20 years.

Section I: State appropriation information.

- | | |
|--|----------------------|
| 1. Amount of state appropriation provided: | \$ <u>12,037,078</u> |
| 2. Estimated annual debt service on the appropriation: | \$ <u>925,364</u> |
| 3. Term of the state bond, in years: | <u>20 years</u> |

Section II: Estimated value of use of the facility.

Use(s) of the facility*	Annual value of use	# of years
a. <u>See attached explanation</u>	\$ _____	_____
b. _____	\$ _____	_____
c. _____	\$ _____	_____
d. _____	\$ _____	_____
e. _____	\$ _____	_____
f. _____	\$ _____	_____

(* List additional uses on separate page as needed.)

Section III:

On a separate page, explain how each use listed in Section II was valued for this analysis.

- NIH Funding – the Cleveland Clinic and the GCIC is committed to working with all of the GCIC partners in preparing and submitting joint NIH proposals for funding for cardiovascular research.
 - Estimated value: Year 1 = 2 grants x \$150,000 value per grant = \$300,000. Market value of 20 years with no change in market value is \$6,000,000.
- The Cleveland Clinic and the GCIC will encourage partnering companies to collaborate with Ohio public colleges for their Small Business Innovation Research grant requests.
 - Estimated value: Year 1 = 2 SBIRs x \$75,000 value per grant = \$150,000. Market value of 20 years with no change in market value is \$3,000,000.
- Provide access to Investment Consortium – the GCIC has a powerful network of at least 9 venture capital firms that have expressed interest in the consortium and reviewing all potential partner spin-offs for possible investing. All partnering institutions will have benefit of the VC firms taking first look at the technology.
 - Estimated value: Year 1 = 1 Investment x \$500,000 value per grant = \$250,000. Market value of 20 years with no change in market value is \$5,000,000.
- Conference Room with audio/video and video conferencing capabilities: 1,000 sq ft of dedicated conference room and video conferencing capabilities to be provided to all member institutions at no fee.
 - Estimated Value: Year 1 = \$350/hour x 10 hours/month x 12 months = \$42,000. Market value of 20 years with no change in market value is \$840,000.
- Student internships – the GCIC will accept up to two graduate student interns per year during the 5 year grant period. Additionally, partnering GCIC partnering companies will be encouraged to accept other graduate students for internships. Student interns will be accepted from any partnering Ohio institution.
 - Estimated Value: Year 1 - \$15/hour x 1,000 hours/year x 2 students = \$30,000. Market value of 20 years with no change in market value is \$600,000.
- Research Assistance – the Cleveland Clinic and the GCIC will provide research assistance and accessibility to all collaborating institutions at a reduced fee. Up to a 20% discount on all services will be provided to all Ohio public colleges.
- Medical Device Idea Factory – The Department of Biomedical Engineering at CCF will partner with the GCIC in creating the Medical Device Idea Factory which will be available to all GCIC partners at a discounted rate for prototype development and other research needs.
- Intellectual Property Commercialization assistance – the GCIC commercialization team has committed to working with all institutions on out-licensing of cardiovascular related technologies. We will provide our expertise to all GCIC

partners at a discounted rate for all commercialization activities including company financing.

- Vendor Services – The GCIC has brought together several companies to provide an array of services to all partners at a discounted rate. Current services include, patent prosecution, website and marketing development, prototyping and research work, graphic design.
- Educational Programs – the Cleveland Clinic has committed to partnering with a local state institution of higher education in developing a specialized educational program for specialized biomedical engineering certifications. This program will be designed to recruit new students who are interested in this highly specialized program. Students who successfully complete the program would have first consideration for employment within the GCIC, Medical Device Idea Factory or other GCIC partners.
- Faculty Recruitment – With the additional of the educational programs, institutions will have the ability to recruit additional faculty members for support.

JOINT USE AGREEMENT
between
THE CLEVELAND CLINIC FOUNDATION
and
THE UNIVERSITY OF TOLEDO

THIS JOINT USE AGREEMENT (“Agreement”) is made this 19th day of July, 2007 (“Effective Date”), between **THE CLEVELAND CLINIC FOUNDATION**, an Ohio non-profit corporation (“CCF”) and **THE UNIVERSITY OF TOLEDO**, a university of the State of Ohio organized and existing under Chapter 3344 of the Ohio Revised Code (“UT”)(CCF and UT, collectively, the “Parties”).

RECITALS

WHEREAS, the Ohio General Assembly appropriated certain fiscal year 2006 funds to the Third Frontier Commission (“Commission”) for allocation among programs associated with Ohio’s Third Frontier Project; and

WHEREAS, CCF, as the lead organization among a group including CCF, Fairfax Renaissance Development Corporation (“FRDC”), a community development corporation, UT, and other multi-organizational collaborators including universities, clinical centers, and biomedical companies (collectively, the “Participants”), applied to the Commission for a Wright Mega-Centers of Innovation (“WMCI”) capital grant to develop the Global Cardiovascular Innovation Center (“GCIC”), where doctors will develop cardiovascular technology platforms for the treatment, prevention and cure of atherothrombotic vascular disease and valvular heart disease, the two major causes of heart failure; and

WHEREAS, the Commission has awarded CCF a WMCI grant with capital funds totaling \$12,037,078 (“Funds”); and

WHEREAS, pursuant to the authority conferred upon the Ohio Board of Regents (“Board”) in the reappropriation act for capital improvements, and prior to the Board’s recommending release of the Funds, the parties must submit and the Board must approve a joint use agreement satisfying the requirements of Ohio Administrative Code Rule 3333-1-03(E); and

WHEREAS, in addition, Paul Erhardt, Ph.D, a faculty member of UT, will be a co-investigator under the GCIC operating grant (Grant no. 07-024) and will receive \$100,000 per year for the five year period of the grant for work focusing on small molecule screening core, as described in the grant submission.

NOW, THEREFORE, in consideration of the mutual benefits hereunder, it is hereby agreed between the parties as follows:

1. **Purpose of Agreement.** CCF and UT desire to enter into this Agreement in order to facilitate establishment of the GCIC, thereby accelerating development and commercialization of state-of-the art Ohio-based diagnostic testing, drugs and devices for cardiovascular technology platforms. These platforms include the creation of novel devices, cellular and molecular therapies and new biomarkers relating to the causes of heart failure. The Funds received pursuant to this Agreement and to be expended hereunder will be for capital purposes only.
2. **Location of Facilities and Use of Funds.** CCF will receive a total of \$4,080,662 of the Funds over five (5) years. FRDC will receive \$7,956,416 of the Funds and with collaboration by the Participants, will build and initially own the GCIC building, which will be the home for GCIC member companies and the base of operations for the GCIC. CCF will enter into a lease with FRDC covering the GCIC building of not less than fifteen (15) years. CCF will use the

Funds to collaborate on building and equipping approximately sixty-thousand (60,000) square feet of existing space adjacent to the CCF main campus located on the south side of Cedar Avenue, between 100th and 101st Streets, Cleveland, Ohio. The GCIC is also proposing a separate 5,000 sq. ft. pre-clinical facility on the main CCF campus. The amenities in this pre-clinical facility will include three surgical rooms, pre-op and recovery rooms, and offices. The preclinical facilities will be made available for all GCIC partners to perform required small and large animal CV studies for submission of FDA-IND applications and ultimately commercialization.

3. **Budget.** A budget detailing the anticipated capital expenditures is attached as Exhibit A.

4. **Use of Facilities, Equipment and Instrumentation by CCF, UT and Participants.**

Upon completion, the GCIC building and pre-clinical lab facility will be open to full public use by CCF, Participants and industry partners who are then engaged in cardiovascular-related research. This arrangement will be expanded to include additional collaborators as additional programs are developed. All Participants and those that have public access to the GCIC will be required by CCF to obey all applicable CCF policies while on CCF premises, including the GCIC. It is anticipated that shared administrative space, lab facilities and conference rooms will be available to higher educational institutions on a non-paying or cost-only basis. Such should result in a value required under the capital grant. UT has determined that the value of UT's use of the GCIC over the term of this Agreement is reasonably related to the value of the Funds.

5. **Distribution of Funds.**

A. Each Participant in the GCIC project, shall submit to quarterly requests for reimbursement of costs associated with building, equipping and managing the GCIC to CCF for approval. Costs approved by CCF will then be submitted to UT for payment.

Each request will include documentation sufficient to support the amount requested. As soon as reasonably practicable after receipt of each invoice, UT shall submit to the Board a corresponding request for release of grant funds. Upon receipt of such grant funds from the Board, UT shall promptly pay such funds directly to the requesting Participant.

- B. UT shall be entitled to an administrative fee in the amount of \$2,000.00 per transaction, not to exceed six (6) transactions per year. UT shall invoice CCF directly for this administrative fee.

6. **Term and Termination.** The term of this Agreement shall commence on the Effective Date and expire fifteen (15) years after the date upon which the GCIC is ready for occupancy. Either party may terminate this Agreement upon ninety (90) days prior written notice to the other. Upon any such termination of this Agreement or of UT's right to use the GCIC, CCF shall reimburse the State of Ohio an amount determined by dividing the total Funds contributed by the State of Ohio by fifteen (15) and multiplying that sum by fifteen (15) less the number of full years that this Agreement was in effect.

7. **Compliance with Laws.** Each party shall comply with all applicable federal, state and local laws and state administrative regulations. As a recipient of public funds, CCF shall follow the competitive bidding procedures with respect to expenditure of the Funds for the construction of the pre-clinical facility under Ohio Revised Code section 153. UT represents that it has not been debarred, suspended, excluded or otherwise determined to be ineligible to participate in federal healthcare programs (collectively, "Debarred") and acknowledges that CCF shall have the right to terminate this Agreement immediately in the event that UT is Debarred. Accordingly, UT shall provide CCF with immediate notice if during the term of this Agreement UT (i)

receives notice of action or threat of action with respect to its Debarment; or (ii) becomes Debarred.

8. **Indemnification.** CCF shall hold UT, its officers, trustees and employees harmless from all liability for the construction, operation and maintenance costs for the GCIC and any violation by CCF of applicable laws, rules and regulations.

9. **Use of Name.** Neither party shall use the name, logo, likeness, trademarks, image or other intellectual property of the other party for any advertising, promotion or other purpose without the specific prior written consent of the other party as to each such use.

10. **Insurance.** Appropriate levels of insurance for buildings and facilities of the types covered by this Agreement will be maintained by the owner of each of the facilities.

11. **Notices.** All notices to the parties shall be sent by registered or certified mail, postage prepaid, or by national overnight courier, and addressed to the parties at the addresses set forth below, or to such other address as either party shall have designated by prior written notice to the other:

CCF: The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, Ohio 44195
Attn: Chief Operating Officer

with a copy to:

The Cleveland Clinic Foundation
9500 Euclid Avenue H18
Cleveland, Ohio 44195
Attn: General Counsel

UT: The University of Toledo
Mail Stop 944
2801 W. Bancroft
Toledo, Ohio 43606
Attn: Director, Research & Sponsored Programs

11. **Entire Agreement.** This Agreement, including Exhibit A, attached hereto and incorporated herein by this reference, sets forth the entire agreement of CCF and UT relating to the subject matter of this Agreement. Any amendments to this Agreement shall be (i) in writing, (ii) approved by the Board, and (iii) signed by authorized representatives of CCF and UT.

IN WITNESS WHEREOF, the parties hereto have executed this Joint Use Agreement as of the month, day and year signed.

THE CLEVELAND CLINIC FOUNDATION

THE UNIVERSITY OF TOLEDO

By: Jacqueline Whitley

By: Frank J. Calzonetti

Name: Jacqueline Whitley
Senior Director
Office of Sponsored Research

Name: Frank J. Calzonetti

Title: Senior Director

Title: Vice President for Research
Development

Date: July 19, 2007

Date: 6/25/07

APPROVED AS TO FORM
CCF-OFFICE OF
GENERAL COUNSEL
BY [Signature]
DATE 7/12/07
CMSI# _____

APPROVED:

OHIO BOARD OF REGENTS

By: _____
Name: _____
Title: _____
Date: _____

EXHIBIT A

GCIC BUDGET

Capital Fund request for Years 1, 2, 3, 4, and 5 – The Cleveland Clinic Foundation

Buildings/Structures:

Funds in the amount of \$2,500,000 are being requested to construct a 5,000 sq. ft. preclinical facility adjacent to the CCF campus.

Equipment: Commercialization - Funds are for computers, printers, servers, and data capture software. Equipment funds requested for the preclinical surgical suite to include tables, instruments, lights, anesthesia, echo machine, fluoroscopy, and centrifuge.

CV Device – Funds are requested for *Cross Platform Research* for the AutoRetroperfusion Cannula project that will require specialized design and evaluation equipment.

Cellular and Molecular Therapies - Funds are being requested for ImageXpress Ultra Confocal-premium configuration.

Total Equipment – Cost & Cost Share: Total funds requested is \$1,580,662. Cost share will be provided in the amount of \$552,944.

Total Direct Cost and Cost Share for Capital Funds: A total of \$4,080,662 is being requested to support capital funds. Cost share will be provided in the amount of \$552,944 from awarded federal grants and commercially funded research projects and other internal resources.

Capital Fund request for Years 1 & 2: - Fairfax Renaissance Development Corporation

Buildings/Structures:

Funds are requested for Real Property – Incubator to include building and structure, architectural and engineering.

Total Buildings/Structures – Cost and Cost Share: Total funds requested are \$6,536,600 for the construction of the 60,000 sq ft facility. Cost share will be provided by Fairfax in the amount of \$13,073,200.

Architectural, Engineering & Professional Services: Design and planning of the facility.

Total Buildings/Structures – Cost and Cost Share: Total funds requested are \$872,900 for the design and planning of the facility. Cost share will be provided by Fairfax in the amount of \$1,745,800.

Equipment: Funds are being requested to include the following: Dry Labs, Wet Labs, fume hoods, air/vac systems, video conferencing, conference room furniture, cubicles, resource center, ITD equipment, share lab facility equipment. Lab equipment includes: centrifuge, autoclave, freezers, mass spectrometry, fume hood, and miscellaneous equipment.

Total Equipment – Cost and Cost Share: Total funds requested for equipment is \$546,916. Cost share will be provided by Fairfax in the amount of \$1,093,831.

Total Direct Cost and Cost Share for Capital Funds: Fairfax is requesting a total of \$7,956,416 to support capital costs of the proposed research projects. Fairfax will provide \$15,912,831 in cost share.