

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

THIS JOINT USE AGREEMENT (“Agreement”) is made this ____ day of December, 2009 (“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 2009 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, UT, Case Western Reserve University (Case), the NASA Glenn Research Center (NASA Glenn), and Norman Noble Inc. (collectively, the “Participants”), applied to the Commission for a Wright Projects Program (“WPP”) capital grant requesting \$2,501,000 (“Funds”) to develop the Nitinol Commercialization Accelerator (“NCA”), through which the Participants will develop and commercialize nitinol based devices; and

WHEREAS, pursuant to the authority conferred upon the Chancellor of the Ohio Board of Regents (“Chancellor”) in the reappropriation act for capital improvements, and prior to the Chancellor’s recommending release of the Funds, the parties must submit and the Chancellor

must approve a joint use agreement satisfying the requirements of Ohio Administrative Code Rule 3333-1-03(E); and

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 NCA, thereby accelerating development and commercialization of state-of-the art Ohio-based nitinol based devices. 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 would receive a total of \$722,000 of the Funds, Case would receive \$1,179,000 and UT would receive \$600,000 over three (3) years. Using these funds, the Participants would establish the NCA by purchasing the equipment listed in the NCA Budget, attached as Exhibit A. CCF, Case, and UT would each provide space at their institution to house the equipment listed in Exhibit A.

3. **Budget and Additional Financial Details of NCA.** A budget detailing the anticipated capital expenditures is attached as Exhibit A. Additionally, the Private Business Use Report is attached as Exhibit B and the Joint Use Agreement Worksheet is attached as Exhibit C.

4. **Use of Facilities, Equipment and Instrumentation by CCF, UT and Participants.** Upon completion, the NCA facilities will be open to full public use by CCF, Participants and industry partners who are then engaged in nitinol based device development and commercialization. This arrangement will be expanded to include additional collaborators as additional programs are developed. All Participants and those that have public access to the NCA will be required by CCF to obey all applicable CCF policies while on CCF premises. 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.

5. **Distribution of Funds.**

A. Each Participant in the NCA project shall submit quarterly requests for reimbursement of costs associated with establishing, equipping and managing the NCA. These requests should be submitted 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 Chancellor a corresponding request for release of grant funds. Upon receipt of such grant funds from the Chancellor, UT shall promptly pay such funds directly to the requesting Participant.

B. UT shall be entitled to an administrative fee in the amount of \$1,000 per transaction, not to exceed six (6) transactions per year, not to exceed \$18,000 over the term of this Agreement. 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 when Funds are released to CCF. 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 NCA, 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, including Ohio House Bill 562 and Ohio Revised

Code Chapter 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. **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.

9. **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.

10. **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: Chief Legal Officer

UT: The University of Toledo
2801 W. Bancroft Street, MS 944
Toledo, Ohio 43606-3390
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 Chancellor, and (iii) signed by authorized representatives of CCF and UT.
12. **Indemnification.** CCF shall hold UT, its officers, trustees and employees harmless from all liability for the construction, operation and maintenance costs for the NCA.

[Remainder of page intentionally left blank]

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 Whatley
Name: **Jacqueline Whatley**
Senior Director
Office of Sponsored Research and Projects
Title: _____
Date: 12/21/2009

By: James Trempe / des
Name: James P. Trempe, Ph.D. _____
Title: Sr. Director, Research Administration
Date: 12-16-2009

APPROVED AS TO FORM
CCF - LAW DEPT.

DATE: 12-21-09 CMSI #: _____
BY: [Signature]

APPROVED:

OHIO BOARD OF REGENTS

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

EXHIBIT A

NCA BUDGET

[SEE ATTACHED]

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EXHIBIT A
NCA BUDGET

Owner	Equipment Description	Cost
CCF	3D strain mapping equipment	\$75,000
CCF	MTS thermomechanical cycling tester	\$250,000
CCF	Laser cutting system	\$250,000
CCF	Shape setting/heat treatment furnace	\$65,000
CCF	Bend & free recovery tester	\$2,000
CCF	Finished stent fatigue tester	\$60,000
CCF	Finished medical device corrosion tester	\$20,000
	Total	\$722,000
UT	Laser cutter with CNC for machining nitinol devices	\$250,000
UT	SPEX mill	\$15,000
UT	Zoz mill	\$50,000
UT	Glove box	\$15,000
UT	High temperature dilatometer	\$70,000
UT	High temperature attachment to X-Ray diffractometer	\$50,000
UT	Cold isostatic press	\$50,000
UT	Infrared camera	\$100,000
	Total	\$600,000
Case	Vacuum arc melter	\$100,000
Case	Vacuum heat treat system	\$150,000
Case	Spectrometer	\$60,000
Case	Vacuum melt spinner	\$235,000
Case	High temperature DSC	\$55,000
Case	Laboratory extrusion press	\$550,000
Case	Flex fatigue tester	\$9,000
Case	High cycle wire fatigue tester	\$20,000
	Total	\$1,179,000

1. CLEVELAND CLINIC

Equipment:

3D strain mapping equipment (\$75,000). All collaborators will use this equipment to assess the strain distribution for the design of robust nitinol prototypes. This is of particular use to the Medical Device Solutions group at the Cleveland Clinic and to engineers at NASA Glenn Research Center.

MTS Thermomechanical Cycling Tester (\$250,000). Both the Cleveland Clinic and NASA will use this custom test equipment to screen alloys for acceptable mechanical cycling properties. In addition, it is essential for the further optimization and understanding of shape memory behavior.

Laser Cutting System (\$250,000). The difficulties inherent in machining nitinol make laser cutting equipment essential for making commercially viable nitinol prototypes. This equipment will be used for the final machining of nitinol prototypes as this activity is ramped up in Year 3.

Shape Setting/Heat Treatment Furnace (\$65,000). This equipment will be used by all the collaborators to shape set nitinol prototypes into their final configuration. It is needed for any nitinol component.

Bend & Free recovery tester (\$2000). This equipment will be used by the collaborators to determine the active austenite to martensite phase transformation temperatures on finished nitinol prototypes. It is essential to verifying that a design and process is adequate for the desired application.

Finished Stent Fatigue Tester (\$60,000). While Medical Device Solutions at the Cleveland Clinic has standard materials testing machines, there is currently no facility for performing fatigue testing on stents.

Finished Medical Device Corrosion Tester (\$20,000). In order to verify that a medical prototype design is suitable for us in vivo, it needs to be tested according to ASTM standards that require a corrosion tester.

Total Equipment amount requested: \$722,000.

Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195

2. CASE WESTERN RESERVE UNIVERSITY

Equipment:

Vacuum Arc Melter (\$100,000). This equipment will be essential for making small quantities of high purity alloys.

Vacuum Heat Treat System (\$150,000). This equipment will be used to perform controlled heat treatments in order to optimize properties and processing.

Spectrometer (\$235,000). To examine chemistry of arc cast and other processed materials.

Vacuum Melt Spinner (\$235,000). This equipment will enable quick alloy design studies of candidate material systems and will require only small amounts (e.g. < 60 grams) of material for each study.

High Temperature DSC (\$55,000). To determine and monitor the effects of changes in chemistry/processing on phase transformations as reactions take place in the Ti-Ni system.

Laboratory Extrusion press (\$550,000). For extrusion of cast ingots prepared by arc melting.

Flex Fatigue Tester (\$9,000). For strain controlled fatigue testing of wires and foils.

High Cycle Wire Fatigue Tester (\$20,000) For stress controlled fatigue testing of wires.

Total Equipment amount requested: \$1,179,000. No overhead is requested on the above equipment.

Case Western Reserve
10900 Euclid Avenue
Cleveland, OH 43606

3. THE UNIVERSITY OF TOLEDO

Equipment:

SPEX mill (\$15,000). This equipment will be useful for making small quantities of experimental compositions of Ti and Ni.

Zoz mill (\$50,000). This equipment will be able to scale up smaller batches to larger quantities of NiTi.

Glove box (\$15,000). To handle ultrafine powders in a protective environment.

High temperature dilatometer (\$70,000). This equipment will monitor changes in the sample dimension in real-time during high temperature sintering.

High temperature attachment to X-Ray diffractometer (\$50,000). To monitor changes in phases as reactions take place in the Ti-Ni system.

Cold Isostatic press (\$50,000). For green compaction of powders.

Infrared camera for characterizing devices (\$100,000)

Laser cutter with CNC capabilities for making devices (\$250,000)

Total Equipment amount requested: \$600,000

University of Toledo
2801 W. Bancroft Street
Toledo, OH 43608

NOTE: Exact locations will be provided once Capital equipment is purchased and tagged.

EXHIBIT B

PRIVATE BUSINESS USE REPORT

[SEE ATTACHED]

**REPORT OF ANY PRIVATE BUSINESS USE OF CAPITAL FACILITIES
FINANCED WITH STATE HIGHER EDUCATION BOND PROCEEDS**

This report must be submitted to the Board of Regents concurrently with the first Controlling board release request for each appropriation line item enacted in each capital act (or created via a transfer of appropriation authority).

1/

INSTITUTION: Cleveland Clinic Foundation

PROJECT TITLE: Nitinol Commercialization Accelerator

APPROPRIATION ACT:

APPROPRIATION LINE ITEM:

APPROPRIATION AMOUNT: \$2,501,000

TOTAL PROJECT AMOUNT: \$2,501,000

2/

Briefly describe the financed project/facility:

The Nitinol Commercialization Accelerator (NCA) will purchase the capital equipment needed to overcome the particular challenges that face nitinol product designers in all phases of commercialization, thereby giving Ohio a competitive advantage in this growing market. The collaborators in the NCA represent some of the nation's best expertise in the areas relative to nitinol product innovation - nitinol alloy development, nitinol device fabrication, medical device design, aerospace, and materials science. Utilizing the equipment purchased, NCA scientists and engineers will pool their talent and resources in a comprehensive, proactive, and focused approach to nitinol design that will bring new alloys and new products to market within the next three years.

3/

Based upon review of the guidelines for determining private business use of facilities financed with State higher education bond funds, there

 X WILL BE WILL NOT BE

private business use in or of the project.

NOTE: If there **WILL BE** any private business use in or of the project, complete the reverse side of this form. If there **WILL NOT BE** any private business use, disregard the reverse side.

4/

Complete this report by signing off on the following certifications:

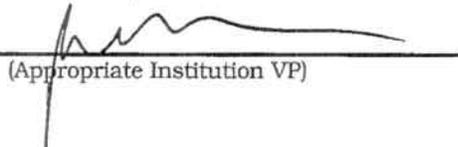
The institution does not intend to sell or otherwise dispose of the financed project or facility, or any part thereof.

None of the State appropriations for the project will be used to make principal or interest payments on, or refund, renew, roll over, retire or replace, any other obligations previously issued by the Institution.

Any expenditures by the Institution that are to be reimbursed from State capital appropriations were made in anticipation of the reimbursement from those appropriations.

To the best of my knowledge, information and belief, all statements and representations in this report (including its reverse side, if applicable) are facts or the expectations of this Institution. Those expectations are reasonable, and there are currently no other facts or circumstances that would or could materially change those statements and representations. The Institution recognizes that those statements and representations will be relied upon by the State for the purposes of its certifications relating to tax exemption of its Bonds as described in certain Treasury Regulations. ***The Institution acknowledges that any change in those facts or expectations may result in different requirements, and that the Board of Regents and OBM should be promptly advised if such changes occur or are anticipated to occur.***

Confirmed By:



(Appropriate Institution VP)

Title _____

Date of Signing: _____

PRIVATE BUSINESS USE REPORT
(Complete Only If Private Business Uses Are Involved)

Indicate below the use of space in the financed facility (in whole or in part) from State bond proceeds. Include space that benefits from or is served by financed improvements to the facility such as utilities, parking or equipment.

POTENTIAL PRIVATE BUSINESS USES (1)	CHECK PRIVATE USES THAT ARE PLANNED (2)	COST OF PROJECT ALLOCATED TO PRIVATE USES (3)	SQUARE FEET IN PRIVATE USE AREA (4)	NATURE OF USE ARRANGEMENT, INCLUDING PAYMENTS, IF ANY (Use separate page if necessary - be sure to describe lease or other payments) (5)
Ad Display Area				
Airport				
Banking/ATM				
Bookstore				
Classrooms				
Concession/News Stand				
Copying/Printing				
Delivery/Shipping				
Dining Room				
Dormitory				
Exercise/Recreation				
Food Court/Cafeteria				
Game Room				
Gymnasium				
Health/Exercise Club				
Hospital				
Hotel/Residences				
Job Training				
Laboratory				
Laundry/Dry-Cleaning				
Library				
Mass Transportation				
Medical Clinic or Office				
Museum				
Office Space				
Post Office				
Publications				
Retail Stores/Shops				
Storage				
Telecommunications				
Theater				
Travel Agency				
Vending				
Other (List)				
CC Equipment	X	\$722,000	N/A	This equipment includes: (1) 3D Strain Mapping Equipment, (2) MTS Thermomechanical Cycling Tester, (3)

				Laser Cutting System, (4) Shape Setting Fluidized Bed, (5) Bend & Free Recovery Tester, (6) Finished Stent Fatigue Tester and (7) Finished Medical Device Corrosion Tester. This equipment, other than items (1) and (2), will be housed on Cleveland Clinic property and will help the Medical Device Solutions group. Items (1) and (2) will be shared between NASA and the Cleveland Clinic for testing nitinol prototypes.
CWRU Equipment	X	\$1,179,000	N/A	This equipment includes: (1) Vacuum Arc Melter, (2) Vacuum Heat Treatment System, (3) Spectrometer, (4) Vacuum Melt Spinner, (5) High Temperature DSC, (6) Laboratory Extrusion Press, (7) Flex Fatigue Tester and (8) High Cycle Wire Fatigue Tester. This equipment will be used to test alloys related to the Nitinol Commercialization Accelerator and will be housed at Case Western Reserve University.

(6) TOTAL PRIVATE USE COSTS: \$1,901,000

(7) TOTAL SQUARE FEET IN PRIVATE USE: N/A

(8) TOTAL SQUARE FEET IN IMPROVED AREA OR FACILITY: N/A

EXHIBIT C

JOINT USE AGREEMENT WORKSHEET

[SEE ATTACHED]

Joint Use Agreement Worksheet

The Ohio Board of Regents

December 4, 2009

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 \$2,501,000. The annual debt service paid by the state on this appropriation is about \$192,267 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 \$192,267 per year for 20 years.

Section I: State appropriation information.

1. Amount of state appropriation provided:	\$ <u>2,501,000</u>
2. Estimated annual debt service on the appropriation:	\$ <u>192,267</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>Graduate Student Stipends</u>	\$ <u>34,000</u>	<u>20</u>
b. <u>Federal & Private Funding</u>	\$ <u>150,000</u>	<u>20</u>
c. <u>Training & Salary Support</u>	\$ <u>9,000</u>	<u>20</u>
d. <u>Summer Coop Students</u>	\$ <u>12,000</u>	<u>20</u>
e. <u>Hands-On Summer Course</u>	\$ <u>5,200</u>	<u>20</u>
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.

- Graduate Student Stipends - the Cleveland Clinic will provide stipends for two Ohio public university graduate students per year. These students will work in Medical Device Solutions. The equipment and facilities will support their research and medical device projects.
 - Estimated value: 2 students at \$17,000/yr = \$34,000/yr.
Over 20 years = \$680,000.
- NIH, Federal, and Private Funding – the Cleveland Clinic and the NCA partners are committed to commercializing nitinol devices and improving their understanding and abilities with this material. The Cleveland Clinic and the NCA partners will apply for and obtain additional funding for projects which benefit from this equipment.

It is anticipated that most of this funding will be awarded to University of Toledo due to their improved equipment, expertise, and understanding of nitinol. The Cleveland Clinic will work directly to help them prepare and submit applications for additional funding of biomedical projects. There will also be future projects that NASA anticipates being funded and the results of this will benefit University of Toledo's nitinol actuator based devices.

- Estimated value: Additional funding of \$150,000/yr.
Over 20 years = \$3,000,000
- Training and Salary Support - the equipment purchased for the NCA will be available to Ohio public universities free of charge, at reduced rates or at cost. The laser, melting, forming and testing equipment needs to be operated by trained and experienced technicians/engineers. CCF, NASA, and Case will cover the training and salary costs so that public universities benefit from their expertise. Over 20 years approximately 12 technicians/engineers would need a total of 36 months of training on the various pieces of equipment. at an average training + salary cost of \$5,000/month
 - Estimated value: 36 x \$5,000/month over 20 years = \$9,000/year
Over 20 years = \$180,000
- Summer Coop Students - as part of the NCA, Norman Noble Inc. will employ two Ohio public university undergraduate coop students per year for the summer to train in the high tech medical device manufacturing industry.
 - Estimated value: 2 students at \$15/hr for 800hrs/yr = \$12,000/yr
Over 20 years = \$240,000
- Hands-On Summer Course - Case and the NCA collaborators will have a hands-on nitinol summer undergraduate course. Students from Ohio public universities will use the testing, melting, forming, and machining equipment in their course projects.

- Estimated value: 100 hrs equipment use at \$65/hr = \$5,200/yr
Over 20 years = \$104,000
- The nitinol prototyping equipment at Case and CCF will be available to Ohio public universities for prototyping and/or teaching purposes for a minimum of 15 years free of charge, at reduced rates or at cost.