

COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENT
FOR A PROJECT BETWEEN
THE PITTSBURGH ENERGY TECHNOLOGY CENTER
AND
THE UNIVERSITY OF PITTSBURGH
SCHOOLS OF MEDICINE AND ENGINEERING

This Cooperative Research and Development Agreement is entered into by and between the University of Pittsburgh Schools of Medicine and Engineering (Participant), and the United States Department of Energy's Pittsburgh Energy Technology Center (PETC). The parties agree as follows:

AUTHORITY AND APPLICABLE LAW:

This agreement is authorized by Public Law 96-480 (Stevenson-Wydler Technology Innovation Act of 1980) as amended by Public Law 99-502 (Federal Technology Transfer Act of 1986) and Public Law 101-189 (the National Technology Transfer Competitiveness Act of 1989). In case of default or dispute the federal law will apply in matters currently addressed by federal common law. This is a Research and Development effort, the Uniform Commercial Code of any State does not apply.

Article 1. Definitions

"Cooperative research program" means the research activities described in Article 2 that are jointly undertaken by PETC and one or more non-federal parties that have entered into a Cooperative Research and Development Agreement with PETC for that purpose.

"Invention" means any invention or discovery which is or may be patentable under Title 35 of the United States Code or any novel variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 7321 et seq.).

"Made" in relation to any invention means the conception or first actual reduction to practice of such invention.

"Subject invention" means any invention or discovery of the Participant conceived or first actually reduced to practice in the course of performance of or under this CRADA.

"Technical data" means recorded information, regardless of form or characteristic, of a scientific or technical nature. It may, for example, document research, experimental, developmental, or demonstration, or engineering work, or be usable or used to define a design or process, or to procure, produce, support, maintain, or operate material. The data may be graphic or pictorial delineations in media such as drawings or photographs, text in specifications or related performance or design type documents or computer software (including computer programs, computer software data bases, and computer software documentation).

Examples of technical data include research and engineering data, engineering drawings and associated lists, specifications, standards, process sheets, manuals, technical reports, catalog item identification, and related information. Technical data as used herein do not include financial reports, cost analyses, and other information incidental to CRADA administration.

"Unlimited rights" means rights to use, duplicate, or disclose technical data, in whole or in part, in any manner and for any purpose whatsoever, and to permit others to do so.

"Government" means the Government of the United States of America as represented by DOE/PETC, a party who is contributing to and entering into this CRADA.

"Participant" means CONSOL, a party who is contributing to and entering into this CRADA.

"Proprietary Information" means proprietary data, commercial or financial information which is privileged or confidential, and other information and materials (including equipment and components, compositions, specimens, listings, designs, etc.) which are

protected as trade secrets, which are supplied by a party to this CRADA.

"Generated Information" means data first produced in the performance of the work under this CRADA.

"Protected CRADA Information" means Generated Information that results from the research and development activities conducted under this CRADA that would be protectable as a trade secret or commercial or financial information that is privileged or confidential if the information had been obtained from a non-Federal party participating in a cooperative research and development agreement and not first produced under a Government contract.

"Trade Secret" means a trade secret as that term is defined in the Uniform Trade Secrets Act.

Article 2. Obligations of Parties

Cooperative research performed under this Agreement shall be performed in accordance with the Statement of Work attached hereto as Appendix 1. Any modification to this initial scope shall be by mutual agreement between Participant and PETC.

Article 3. Summary of Funds

Not applicable to this Agreement.

Article 4. Patent Rights

4.1 AUTHORIZATION AND CONSENT (10 CFR § 600.33(b)(5))

The Government hereby gives its authorization and consent for all use and manufacture of any invention described in and covered by a patent of the United States in the performance of this CRADA or any part hereto or any amendment hereto or any subcontract hereunder (including all lower tier subcontracts).

4.2 NOTICE AND ASSISTANCE REGARDING PATENT AND COPYRIGHT INFRINGEMENT (10 CFR § 600.33(b)(6))

The provisions of this clause shall be applicable only if the amount of this CRADA exceeds \$10,000.

(a) The Participant shall report to the Technology Transfer Officer, promptly and in reasonable written detail, each notice or claim of patent or copyright infringement based on the performance of this CRADA of which the Participant has knowledge.

(b) In the event of any claim or suit against the Government on account of any alleged patent or copyright infringement arising out of the performance of this CRADA or out of the use of any supplies furnished or work or services performed hereunder, the Participant shall furnish to the Government when requested by PETC all evidence and information in possession of the Participant pertaining to such suit or claim. Such evidence and information shall be furnished at the expense of the Government except where the Participant has agreed to indemnify the Government.

(c) This clause shall be included in all subcontracts.

4.3 Principal Rights

(a) Allocation of Principal Rights

(1) Retention of Title

The government shall retain title to any subject invention unless the participant is granted the right to elect and retain title. With respect to any subject invention in which the participant is granted the right to retain title, the Federal Government shall have a non-exclusive, non-transferrable, irrevocable, paid-up license to practice or have practiced for or on

behalf of the United States the subject invention throughout the world.

(2) License Rights

The Participant shall retain a non-exclusive, royalty-free license throughout the world in each subject invention to which the Government obtains title. The Participant's license extends to its domestic subsidiaries and affiliates, if any, within the corporate structure of which the participant is a part and includes the right to grant sublicenses of the same scope to the extent that the participant was legally obligated to do so at the time this CRADA was awarded. The license is transferable only with the approval of the DOE, except when transferred to the successor of that part of the participant's business to which the invention pertains.

(b) Invention Disclosure, Election of Title and Filing of Patent Applications by the Parties

(1) Each party shall disclose each subject invention of its employee to the other party within two months after the inventor has disclosed it in writing to the party's personnel responsible for patent matters or within six months after the party becomes aware that a subject invention has been made, whichever is earlier. The disclosure shall be in the form of a written report and shall identify this CRADA and the inventors. It shall be sufficiently complete in technical detail to convey a clear understanding, to the extent known at the time of the disclosure, of the nature, purpose, operation, and characteristics of the invention. The participant shall comply with any restrictive markings on disclosures received from DOE and DOE will protect participant's inventions in accordance with 35 USC 205.

(2) If the participant is granted the right to elect and retain title pursuant to subparagraph (a) (1) above, then participant shall elect in writing whether or not it intends to retain title to any such invention by notifying the DOE at the time of the disclosure or within two years of submitting such disclosure. If the participant elects not to retain title to its employees'

subject invention or fails to elect in the 2-year period, the DOE shall have the right to request that title be assigned to the Government. However, in any case where publication, or sale, or public use has initiated the one year statutory period wherein valid patent protection can still be obtained in the United States, the participant shall make its election not later than 60 days prior to the end of the statutory period.

(3) The participant electing to retain title shall file a United States patent application on the elected invention within one year after election. The participant shall advise the DOE of those foreign countries in which the participant intends to seek patent protection. The participant shall file patent applications in those countries within ten months of the corresponding initial patent application and shall afford the DOE the option to seek patent protection in additional foreign countries in which the participant has not filed patent applications.

(4) The participant electing title or filing a patent application in the United States or in any foreign country shall advise the DOE if it no longer desires to continue prosecution or retain title in the United States or any foreign country. The DOE will be afforded the opportunity to take a title and retain the patent rights in any such foreign country.

(5) The parties agree that each shall bear its own costs of any and all patent filings that may be made by that party.

(6) Each party shall provide the other party with copies of the patent applications it files on any Subject Invention along with the power to inspect and make copies of all documents retained in the official patent application files by the applicable patent office.

(c) Protection of Government's Interests

(1) The participant agrees to require by written agreement its employees, other than clerical and nontechnical employees, to

disclose promptly in writing to personnel identified as responsible for patent matters each subject invention made under this CRADA. Further, the participant agrees that it will require its employees, and they will agree, to execute or have executed and promptly deliver all instruments necessary for the filing and obtaining of patent protection on any subject invention.

(2) The participant agrees to include within the specification of any United States patent application and any patent issuing thereon covering a subject invention the following statement: "This invention was made with Government support under a Cooperative Research and Development Agreement (Identify the cooperative agreement number) awarded by the DOE. The Government has certain rights in this invention."

(d) Reporting Utilization of Subject Inventions

The participant agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the participant or its licensees or assignees.

(e) Preference for United States Industry

The parties shall exercise a preference for U.S. industry in conformance with 35 USC 204.

(f) March-In-Rights

The parties agree that with respect to any subject invention in which they have acquired title, the DOE has the right in accordance with the procedures in 48 CFR 27.304-1(G) to exercise march-in-rights consistent with 35 USC 203.

(g) Other Inventions

Nothing contained in this clause shall be deemed to grant to the Government or to any other party any rights with respect to any invention other than a subject invention, unless expressly provided elsewhere in this clause.

(h) Examinations of Records Relating to Inventions

(1) The Department of Energy, until three years after completion of this CRADA, shall have the right to examine any books (including any laboratory notebooks), records and documents of the participant relating to conception or first actual reduction to practice of inventions in the same field of technology as the work under this CRADA to determine whether any inventions are subject inventions and the participant has complied with the provisions of this clause.

(2) Any examination of records under this paragraph shall be subject to appropriate conditions to protect the confidentiality of the information involved.

(i) Publication

The parties agree that each will refrain from submitting materials for publication without first obtaining prior patent clearance from their respective patent counsel. In the event any proposed publication contains matter disclosing a subject invention on which a patent application has not yet been filed and on which all parties have not indicated a lack of interest in pursuing patent protection, the parties will use reasonable efforts to delay publication a reasonable amount of time to permit the filing of a patent application thereon by an interested party or until such time as all parties have indicated a lack of interest in seeking patent protection.

Article 5. RIGHTS IN DATA ARTICLE

5.1 ALLOCATION OF PRINCIPAL RIGHTS

The Government shall have unlimited rights in all Generated Information and all other information provided by one party to another party for use in the performance of this CRADA, except as such may be identified and marked as Protected CRADA Information or Proprietary Information as indicated below in this clause.

5.2 PROTECTED CRADA INFORMATION

(a) Notwithstanding any other provisions of this rights in data clause, PETC or the participant may (i) claim and mark as Protected CRADA Information any Generated Information produced by their respective employees and (ii) so claim and mark, following mutual agreement of the other party, any Generated Information produced by the other party's employee, provided such Generated Information has near term commercial value. Such claimed Protected CRADA Information will be clearly marked as "Protected CRADA Information," and will be treated as such, and will not be published or disseminated for a period of 5 years from the date such Generated Information is produced and marked without the prior written authorization of the marking party. The marking shall identify the CRADA under which the Generated Information was produced, the date the Generated Information was produced, and shall indicate that such Generated Information shall not be published or disseminated until 5 years from the date the data Generated Information was produced and marked.

(b) Any such marked Protected CRADA Information may be disclosed under obligations of confidentiality for the following purposes:

(1) The Protected CRADA Information may be disclosed to others for emergency repair or overhaul work;

(2) The Protected CRADA Information may be disclosed to others working in the program for purposes of evaluation;

(3) The Protected CRADA Information may be disclosed to other parties assisting in performing work under this CRADA for use in performing the work under this CRADA;

(4) The Protected CRADA Information may be disclosed to other DOE contractors participating in the DOE program to which this CRADA is related, for purposes of conducting research and development programs within the DOE program;

(5) The Protected CRADA Information may be disclosed to other parties under such circumstances as may be mutually agreed by the parties and the DOE.

5.3 LIMITED RIGHTS IN PROPRIETARY INFORMATION

(a) The participant may deliver to the Government, for use in carrying out the work under the CRADA, property which the participant claims to be Proprietary Information. Such Proprietary Information shall be clearly identified as such and marked with a limited rights legend indicating that the property is Proprietary Information of the participant, has been delivered under the subject CRADA, and is to be utilized by others only in the performance of work or evaluation of the work performed under this CRADA. No further use or dissemination of the Proprietary Information will be permitted without the prior written authorization of the participant.

(b) If Proprietary Information is orally disclosed, it shall be identified as such at the time of disclosure and confirmed as being Proprietary Information of the provider in a written summary thereof within ten (10) days.

(c) All Proprietary Information shall be protected, unless and until such Proprietary Information shall become publicly known without the fault of the recipient, shall come into recipient's possession without breach of any of the obligations set forth herein by the recipient, or shall be independently developed by recipient's employees who did not have access to Proprietary Information of provider.

5.4 GOVERNMENT COPYRIGHT LICENSE

Subject to any obligations or restrictions with respect to Protected CRADA Information or any party's Proprietary Information, the Government is hereby granted for itself and for others acting on its behalf a paid-up, nonexclusive, irrevocable world-wide license in copyrighted Generated Information to reproduce, prepare derivative works, distribute copies to the public and perform publicly and display publicly by or on behalf of the Government. The parties also agree not to knowingly include in any material delivered to the Government any material copyrighted by others without first granting or obtaining, at no cost to the Government, a license therein for the benefit of the Government of the same scope as set forth above. If a party cannot obtain such license for the Government, the party shall obtain the written authorization of the Department of Energy Contracting Officer to include such material in the material delivered prior to its delivery.

5.5 PUBLICLY AVAILABLE REPORTS TO DOE

To the extent that reports of the work be conducted under this CRADA are to be submitted to the DOE, the parties, in addition to any reports submitted to the DOE with any restricted legends with respect to dissemination of Protected CRADA Information or Proprietary Information shall also submit a nonproprietary version of the report which the DOE can make freely available to the public as a report of the work being conducted at its facility.

5.6 EXPORT CONTROLS

THE PARTIES UNDERSTAND THAT MATERIALS RESULTING FROM THE PERFORMANCE OF THIS CRADA MAY BE SUBJECT TO EXPORT CONTROL LAWS, AND EACH PARTY IS RESPONSIBLE FOR ITS OWN COMPLIANCE WITH SUCH LAWS.

5.7 NECESSARY DATA

Participant agrees to furnish to DOE those data, if any, which are (1) essential to the performance of work by DOE or its support service contractor personnel or (2) necessary for the health and safety of such personnel in the performance of the work. Any data

furnished to DOE shall be deemed to have been delivered with unlimited rights unless marked as "proprietary information" of Participant.

5.8 PROPRIETARY MARKINGS

Participant agrees that it shall have the sole responsibility for identifying to DOE all documents containing proprietary data which are furnished by or produced under this agreement.

5.9 DESCRIPTION OF WORK

Participant agrees that DOE may prepare a nonproprietary description of the work performed under the agreement, which description shall be subject to unlimited rights of the Government.

5.10 USE OF NAMES IN PUBLICATIONS

PETC may submit for publication the results of the research work associated with this project. Depending on the extent of contributions made, employees of Participant may be cited as co-authors. In no event, however, shall the name of Participant or any of its trademarks and tradenames be used in any publications without its prior written consent.

5.11 CONSULTATION

PETC and Participant agree to confer and consult prior to the publication of Subject Data to assure that no Proprietary Information is released and that patent rights or Protected CRADA data are not jeopardized.

Article 6. Termination

6.1 Participant and PETC each have the right to terminate this agreement upon six (6) months notice in writing to the other party.

Article 7. Disputes

7.1 Settlement. Any dispute arising under this Agreement which is not disposed of by agreement of the parties shall be submitted jointly to the signatories of this Agreement. A joint decision of the signatories or their designees shall be the disposition of such dispute.

Article 8. Liability

8.1 Property. The U.S. Government shall not be responsible for damages to any property of Participant provided to PETC or acquired by PETC pursuant to this Agreement.

8.2 Participant's Employees. Participant agrees to indemnify and hold harmless the U.S. Government for any loss, claim, damage, or liability of any kind involving an employee of Participant arising in connection with this Agreement, except to the extent that such loss, claim, damage or liability arises from the negligence of PETC or its employees. PETC shall be solely responsible for the payment of all claims for the loss of property, personal injury or death, or otherwise arising out of any negligent act or omission of its employees in connection with the performance of work under this Agreement.

8.3 No Warranty. PETC makes no express or implied warranty as to any matter whatsoever, including the conditions of the research or any invention or product, whether tangible or intangible, made, or developed under this Agreement, or the ownership, merchantability, or fitness for a particular purpose of the research or any invention or product.

8.4 Indemnification. Participant holds the U.S. Government harmless and indemnifies the Government for all liabilities, demands, damages, expenses and losses arising out of the use by Participant, or any party acting on its behalf or under its

authorization, of PETC's research and technical developments or out of any use, sale or other disposition by Participant, or others acting on its behalf or with its authorization, of products made by the use of PETC, technical developments. This provision shall survive termination of this Agreement.

8.5 Force Majeure. Neither party shall be liable for any unforeseeable event beyond its reasonable control not caused by the fault or negligence of such party, which causes such party to be unable to perform its obligations under this Agreement (and which it has been unable to overcome by the exercise of due diligence). In the event of the occurrence of such a force majeure event, the party unable to perform shall promptly notify the other party. It shall further use its best efforts to resume performance as quickly as possible and shall suspend performance only for such period of time as is necessary as a result of the force majeure event.

Article 9. Miscellaneous

9.1 No Benefits. No member of, or delegate to the United States Congress, or resident commissioner, shall be admitted to any share or part of this Agreement, nor to any benefit that may arise therefrom; but this provision shall not be construed to extend to this Agreement if made with a corporation for its general benefit.

9.2 Governing Law. The construction validity, performance and effect of this Agreement for all purposes shall be governed by the laws applicable to the Government of the United States.

9.3 Entire Agreement. This Agreement constitutes the entire agreement between the parties concerning the subject matter hereof and supersedes any prior understanding or written or oral agreement relative to said matter.

9.4 Headings. Titles and headings of the Sections and Subsections of this Agreement are for the convenience of references only and do not form a part of this Agreement and shall in no way affect the interpretation thereof.

9.5 Amendments. If either party desires a modification in this Agreement, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of such modification. Such modification shall not be effective until a written amendment is signed by all the parties hereto by their representatives duly authorized to execute such amendment.

9.6 Assignment. Neither this Agreement nor any rights or obligations of any party hereunder shall be assigned or otherwise transferred by either party without the prior written consent of the other party except that Participant may assign this Agreement to the successors or assignees of a substantial Portion of Participant's business interests to which this Agreement directly pertains.

9.7 Notices. All notices pertaining to or required by this Agreement shall be in writing and shall be directed to the signatory(s).

9.8 Independent Contractors. The relationship of the parties to this Agreement is that of independent contractors and not as agents of each other or as joint venturers or partners. PETC shall maintain sole and exclusive control over its personnel and operations.

9.9 Use of Name or Endorsements. (a) Participant shall not use the name of PETC or the Department of Energy on any product or service which is directly or indirectly related to either this Agreement or any patent license or assignment agreement which implements this Agreement without the prior approval of PETC. (b) By entering into this Agreement PETC does not directly or indirectly endorse any product or service provided, or to be provided, by Participant its successors, assignees, or licensees. Participant shall not in any way imply that this Agreement is an endorsement of any such product or service.

Article 10. Duration of Agreement and Effective Date

10.1 Duration of Agreement. It is mutually recognized that the development program cannot be rigidly defined in advance, and that the contemplated time periods for completion of each phase are good faith guidelines subject to adjustment by mutual agreement, to fit circumstances as the development program proceeds. In no case will this Agreement extend beyond 5 years, unless it is revised in accordance with Article 9 of this Agreement. The provisions of Article 4 shall survive the termination of this Agreement.

10.2 Effective Date. This Agreement shall enter into force as of the date of the last signature of the parties.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as follows:

For Participant:

Date_____

PETC Review:

CHIEF COUNSEL

Date_____

For PETC:

DIRECTOR

Date _____

APPENDIX 1

SCOPE OF WORK

OBJECTIVE

The proposed research work involves study of fluid-dynamically induced coagulation of complex fluids (i.e., fluids with strong coagulative, visco-plastic rheological properties) in fluid transport devices. The proposed research work will involve use of PETC's advanced multiphase flow diagnostic equipment and expertise to analyze hemodynamics in artificial hearts currently in use by the University of Pittsburgh School of Medicine and Presbyterian Hospital.

INTRODUCTION

Prevention of coagulation in fluid transport devices is a major concern for both parties of this CRADA. For example, highly cleaned coal products, such as liquified coal and ultrafine coal-liquid mixtures, usually exhibit strong coagulative, visco-plastic properties. This leads to maintenance problems, reduced lifetimes or even catastrophic failure of transport devices (pumps, valves, tubes, etc.).

Since blood is also a strongly coagulative, visco-plastic fluid the same problems plague blood transport devices. Thrombosis, which often leads to a thromboembolism, is the leading cause of complications with artificial hearts. The thromboembolism usually results in death of the patient.

It is believed that hemodynamic parameters play an important role in the thrombosis formation that leads to thromboembolism. A better understanding of hemodynamics in artificial hearts may lead to designs that mitigate thrombosis formation.

Attempts by the University of Pittsburgh School of Medicine (Department of Surgery) to measure hemodynamics in artificial hearts have had limited success. Hemodynamic measurements require advanced diagnostic equipment and expertise that is not presently available at the University of Pittsburgh School of Medicine. The University of Pittsburgh has asked PETC to assist them in measurement of hemodynamics in artificial hearts. It is believed that PETC's expertise and advanced flow diagnostic equipment will be able to produce new and better measurements of hemodynamics in artificial

hearts. Collaboration with researchers in the medical community who have studied this problem extensively will be of a direct benefit to PETC.

APPROACH

The artificial heart devices and associated equipment will be delivered and setup in PETC's Flow Analysis Laboratory (Building 94, Room 01) by the Participant (University of Pittsburgh). This equipment includes

- a Jarvik-7 artificial heart
- a Novacor Ventricular Assist Device (NVAD)
- a Nimbus Axial Flow Pump
- a mock blood flow simulator
- blood simulation fluids

PETC will assist in application of their flow diagnostic equipment to measure hemodynamic parameters at specified locations in the artificial heart devices. The flow diagnostic equipment available includes

- a TSI fiber-optic two-component Laser Doppler Anemometer (LDA)
- a Pulsed Laser Imaging (PLI) system developed by PETC
- a Kodak Spin Physics high speed video camera

PETC personnel, with the assistance of University PETC personnel, will perform a limited number of hemodynamics measurements in these artificial heart devices. A preliminary test matrix is listed below.

<i>Pump Type</i>	Novacor	Nimbus
<i>Hemodynamics Simulated</i>	1. Full fill and empty 2. Incomplete filling and emptying 3. Double beating	1.6 L/min, 100 mmHg 2.3 L/min, 100 mmHg
<i>Region Investigated</i>	1. Inflow valve area 2. Outflow valve area 3. Outflow cross section	1. Rotor surface 2. Journal bearing

This initial phase of this work will be to determine which of the diagnostic techniques are the most productive for different regions of the artificial hearts. The actual test matrix may change based on the results of the initial test phase.

TECHNOLOGY TRANSFER

PETC and the Participant intend to publish, with mutual concurrence, the results of these hemodynamic measurements. Publication and use of information shall be in accordance with Articles 4 and 5 of this agreement. In addition, the University of Pittsburgh agrees that DOE shall have the sole right to determine the character and disposition of data collected at PETC in this study.

TERM OF AGREEMENT - OPEN-ENDEDNESS

Both PETC and the University of Pittsburgh are intending to develop with this document an open-ended CRADA to allow for additional cooperative work wherein the general terms and conditions are already established from the definition of the first task and under which we merely need to negotiate a new SOW. This agreement is renewable every year unless one party terminates before the expiration date. Notice of termination by either party will be made in writing to the other party at least three (3) months before the suggested termination date.

COSTS

Each party will pay their own.