Army CRADAs

		Address Warfighting Needs	Reduce Cost	Strengthen the Industrial Base	Promote Basic Research	Assure Quality
A1	Advanced Technology for High Resolution Physics Based Interactive Simulations	●	●		●	●
A2	Blanket CRADA Between Ford, General Motors, Chrysler and the U.S. Army Tank-Automotive Research, Development and Engineering Group				●	
A3	Construction Equipment Performance Optimization			●	●	●
A4	CORE-LOC Concrete Armor Unit			●	●	
A5	Development of Biodegradable Polymers			●	●	
A6	Development of Novel Imaging System for Medical, Non-Destructive Testing & Investigation of Micro-electronic Circuits			●	●	
A7	Evaluation of Electron Cyclotron Resonance Plasma Technology	●		●	●	●
A8	Formulation of a Liposomal Transdermal Vaccine System and Other Novel Pharmaceuticals	●		●	●	●
A9	Full Scale Fabrication & Optimization of Composite Cylinder Processing		●	●	●	
A10	Vaccines for Infectious Desease	●		●		●

A1

Title: Advanced Technology for High Resolution Physics Based Interactive Simulation

Federal Partner: U.S. Army Communications and Electronics Command, Night Vision and Electronic Sensors Directorate, (NVESD)

Federal POC: Max Lorenzo

Non-Federal Partner: Silicon Graphics, Inc., (SGI)

Non-Federal POC: Bob Paddison and Judith Pafford

Status: Open

Summary:

SGI negotiated CRADAs with CECOM, Night Vision and Electronic Sensors Directorate and the U.S. Army Research Laboratory in the area of simulation technology.

NVESD's team has expertise in sensor simulation, building optimized databases, and immersion techniques. NVESD uses off-the-shelf dedicated equipment to implement sensor simulation and three dimensional noise for special effects. NVESD interest was in pursuing the development of technology to simulate additional sensors and optimize databases associated with them.

ARL's interest was in developing a simulation system to provide the appropriate combination of physical models to simulate the effects and interaction of the synthetic environment and the end-user.

The purpose of this agreement with NVESD was to develop an enhanced operational and modeling and simulation capability for individual combatants across three domains of Advanced Concepts and Requirements (ACR), Research, Development and Acquisition (RDA), and Training, Exercises, and Military operations (TEMO). It was NVESD's objective to support military needs and objectives while fostering development of novel software/hardware for optimized terrain and sensors with substantial commercial potential to ensure economic military success of the U.S.

There has been some general collaboration and sharing of information between engineers, such as synthetic environmental terrain data. SGI hosted the NVESD POC at its simulation laboratory where he worked to optimize his application. There were a number of retirements and resignations of people involved with this CRADA on both sides which, in addition to the lack of specific objectives, resulted in less than optimal accomplishments.

Value/Benefits to DoD:

Supports DoD Management Principle: Address Warfighting Needs

One goal of this CRADA is to provide enhanced simulation capabilities for individual combatants. Simulations allow technologies to be evaluated by the user in the context of their particular functionality providing a thorough evaluation of concepts early in the technology development cycle.

Supports DoD Management Principle: Reduce Cost

This CRADA focuses on the use of simulation instead of field data and testing resulting in substantial cost reductions.

Supports DoD Management Principle: Promote Basic Research

The intent of this CRADA was to share information from both sides. General collaboration and information sharing on synthetic environmental terrain data occurred between engineers.

Supports DoD Management Principle: Assure Quality

The Night Vision and Electronic Sensors Directorate partnered with SGI because of SGI's reputation as the leading manufacturer of high performance visual and enterprise computing

systems. SGI's was to provide graphics and computer technology to support the development of high fidelity, interactive synthetic environments for training and operational use.

Benefits to Non-Federal Partner:

The interaction among partners in this CRADA will provide SGI with information to make refinements to existing hardware and software products and enhancements to designs of future products that will make them more useful to their customers and end-users.

A2

Title: Blanket CRADA Between Ford, General Motors, and Chrysler and the U.S. Army Tank-Automotive Research Development and Engineering Center (TARDEC)

Federal Partner: U.S. Army Tank-Automotive Research, Development, and Engineering Center

Federal POC: Doug Miller

Non-Federal Partner: Ford Motor Company, Chrysler and General Motors

Status: Open

Summary:

The Big Three auto makers jointly signed this "Blanket" CRADA (also referred to as "Master" or "Umbrella" CRADA). Unlike most CRADAs this blanket CRADA set a precedent by fast-tracking all future R&D between the auto makers and the Army. It uses established language agreed to by all parties. When any one of the Big Three wishes to enter into a CRADA all that is needed is a 2-3 page statement-of-work. This agreement allows the Big Three to streamline the labor intensive CRADA process from several months to just a few days saving administrative costs on all sides.

One research effort performed under this CRADA was the use of TARDEC's Visualization Laboratory by General Motors. General Motors funded 100 test subjects to use their Visualization Laboratory. The Visualization Laboratory is a facility designed to simulate tank-development technology in a virtual-reality setting created by an on-site super computer network. The Army uses the facility to test tank designs under simulated battlefield conditions prior to developing costly prototypes. General Motors used the laboratory to gain information on visual perception at intersections, in bad weather conditions, blind spots, and on the impact of different vehicle colors and outdoor light on drivers. General Motors used this data for design and redesign of vehicles. General Motors also provided their data to the Army.

The blanket concept has worked well for these partners because both industry and government had similar technical interests and the industries were located in close proximity to each other. Before this CRADA was established there was little interaction between the auto industry and the Army despite similar needs.

Although the intent of this CRADA is to promote basic research, individual projects pursued under this agreement may support other DoD S&T management principles.

Value/Benefits to DoD:

Supports DoD Management Principle: Promote Basic Research

The sharing of data and equipment from experiments, such as from the Visualization Laboratory Research, will advance research for both the Army and the auto industry given the similarities that exist between two.

Benefits to Non-Federal Partner:

General Motors was able to leverage its resources by utilizing TARDEC's Visualization Laboratory. One new application arising from General Motor's research in the Visualization Laboratory was the addition of a third brake light to the Cadillac STS making it more perceptible to other drivers.

Other Benefits:

This Blanket CRADA is unique in that it facilitated a complex strategic partnership between the Army and multiple industrial partners.

A3

Title: Construction Equipment Performance Optimization

Federal Partner: U.S. Army Cold Regions Research and Engineering Laboratory

Federal POC: Sally Shoop

Non-Federal Partner: Caterpillar, Inc. Peoria, IL and Goodyear Tire and Rubber Co., Akron, OH

Non-Federal POC: Paul Corcoran, Caterpillar, Inc and Mike Trinko, Goodyear Tire and Rubber Co.

Status: Open

An example of the types of tire-terrain interactions being modeled

Summary:

Current tire models do not consider the interaction of the tire with deformable media such as soil or snow, focusing only on interactions with pavements. The goal of this CRADA is to develop a numerical model simulating the interaction between tires and deformable surfaces such as thawing and soft soils. This project will integrate the experimental and numerical simulation of tractive loading on deformable terrain with numerical models of tire deformation resulting in a three dimensional finite element simulation of tire-terrain interaction. The expected result of this collaboration is a design tool with the capability to design tires that perform more efficiently on unpaved roads, off-road, and in all-season conditions including snow and thawing soils. In addition, the technology will be used to explore the effects of tire and terrain variables on vehicle performance and terrain damage.

Value/Benefits to DoD:

Supports DoD Management Principle: Strengthen the Industrial Base

The technology being developed in this CRADA is truly a dual-use technology in that this tool can be applied to the development of commercial as well as military products. In the commercial sector, the use of this tool will greatly improve the efficiency of off-road, mud and snow, and heavy vehicle tires, increase construction site productivity by improving vehicle traction, and therefore decrease cycle time, fuel costs, tire wear, and time lost due to immobilization, surface damage and repair or reclamation costs. DoD will use this tool to improve tire design and specification, improve performance prediction for off-road vehicles and provide the capability to predict rutting of and soil damage to unsurfaced roads and Army training grounds.

Supports DoD Management Principle: Promote Basic Research

This CRADA will further DoD and Corps of Engineers efforts in the development of Army mobility models, virtual prototyping of vehicles, and virtual proving ground concepts as well as providing a capability to predict rutting of and soil damage to unsurfaced roads and Army training areas.

Supports DoD Management Principle: Assure Quality

The work being performed under this CRADA is highly proprietary and has generated a great deal of interest within the technical community. The development of this tool will put the two non-federal partners ahead of their competition while at the same time having direct military applications.

Benefits to Non-Federal Partner:

The benefit to Caterpillar will be improved tire performance on earth moving and mining equipment based on the use of the design tool in their design process. The benefits to Goodyear will be the application of a new process within their design and development process which will further product improvements.

Other Benefits:

The development of this CRADA between the three parties has broken down barriers and has allowed for free-flowing conversations and technical exchange.

A4

Title: CORE-LOC Concrete Armor Unit

Federal Partner: U.S. Army Engineers' Waterways Experiment Station, (WES)

Federal POC: Jeff Melby and Phil Stewart

Non-Federal Partner: A. R. Wijnberg, South Africa

Status: Open

Summary:

Engineers at WES developed CORE-LOC, an innovative coastal protection armor unit. CORE-LOC has several advantages over its competitors. A CORE-LOC armor layer has outstanding interlocking features and is extraordinarily efficient, dissipating the maximum amount of wave energy with the least amount of concrete, therefore requiring significantly less material than existing armor units. It also has a reserve stability that other structures don't have.

The objective of this CRADA was to gain the acceptance of new armor units by the coastal engineering community which is normally a very slow process. The cost of failure is typically so large that few are willing to risk trying new technology.

This CRADA allowed WES engineers to work with design engineers at A. R. Wijnberg in the model testing and prototype construction of the world's first breakwater built with CORE-LOC concrete armor units. The assistance provided by WES engineers was critical to the proper model testing of the CORE-LOC structure, as it was to the placement of CORE-LOCs on the prototype structure. A. R. Wijnberg was willing to recommend CORE-LOC for this breakwater and work with WES engineers to successfully conduct model tests and actually construct the breakwater at Port Saint Francis, South Africa.

A product commercialization that is application specific was achieved. Wijnberg's faith in the Corps of Engineers' product for protection for a peninsula and breakwater provided an early opportunity to field test the new armor unit.

Value/Benefits to DoD:

Supports DoD Management Principle: Strengthen the Industrial Base

Although the Army Corps of Engineers is unique to DoD in that it services both civilian and military needs, CORE-LOC is a good example of a dual-use technology resulting from research that serves both the civilian and military sectors. Knowledge gained in wave prediction phenomena was applied in the development of CORE-LOC which is used in civilian breakwater applications.

Supports DoD Management Principle: Promote Basic Research

Each time WES works with an engineering firm to provide a specific design for a particular application of CORE-LOC, knowledge is gained that can be applied to future designs. WES developed the technology and continues to develop it.

Benefits to Non-Federal Partner:

The non-federal partner was able to successfully construct the breakwater at Port Saint Francis, South Africa.

Other Benefits:

The early support for CORE-LOC has developed into an active foreign market. Money in the form of both royalties and reimbursable studies is helping to leverage WES' R&D funding.

This project greatly strengthened WES' negotiating position in licensing the CORE-LOC concrete armor unit. With projected royalties of $2.00 to $5.00 per metric ton, a single half-mile long breakwater built with 12 ton armor units could result in royalties of over $1/2-million. Each

CORE-LOC unit weighs about 2 tons requiring these units to be built on site. Therefore, patent applications have been filed in over 40 countries and trademark applications filed in many others. The CORE-LOC concrete armor unit is now licensed to four companies, each having an assigned geographic territory. These territories include Europe and South America, North America, Japan, and South Africa. In the near future, annual royalties could easily exceed $1 million.

A5

Title: Development of Biodegradable Polymers

Federal Partner: U.S. Army Natick Research, Development and Engineering Center

Federal POC: Dr. Jo Ann Ratto

Non-Federal Partner: Zeneca (Imperial Chemical Industries (ICI) Americas, Inc.)

Status: Closed

Biodegradable cup and bag coated with Biopol polymer

Summary:

The objective of this CRADA was to investigate the feasibility of utilizing Zeneca's bacterial polyester, which is produced in a patented process, as water resistant, biodegradable coatings on paper and starched-based film. It was hoped to develop a biodegradable coating for paper to replace polyethylene, which is not biodegradable.

Zeneca has patented an innovative fermentation process whereby biodegradable polymers are produced from corn and other agricultural feedstock. The microorganism, alcaligenes eutrophus, which occurs widely in soil and water, converts the carbohydrate (glucose) in the feedstock to resin. By the end of the fermentation process, the microorganisms accumulate up to 80% of their dry weight as resin. The process harvests the resin by breaking open the cells and extracting and purifying the polymer. Various other organisms in the environment also consume the resin as a source of carbon.

Sold under the trade name "Biopol," the polymers have many of the properties of traditional plastics, but can be processed by conventional techniques. They are stable, durable, and moisture-resistant. The Biopol cup is a paper cup coated with a biodegradable plastic developed for the Navy. The technology involves plastic extrusion processing to coat the paper from which the cups are formed. The cups were tested to meet the military specifications and were tested for biodegradation in the marine environment.

This effort was funded by the Navy for compliance with the MARPOL Treaty, which is the Marine Pollution Treaty.

Value/Benefits to DoD:

Supports DoD Management Principle: Strengthen the Industrial Base

The work performed under this CRADA in developing a biodegradable coating for paper to replace polyethylene has military and non-military applications for use in biodegradable utensils, cups, trays, bags, meat wrappings, etc.

Supports DoD Management Principle: Promote Basic Research

This CRADA supported knowledge-share in a number of ways. Zeneca supplied samples of biodegradable materials and information on processing and blending of the materials onto starch-based and cellulose materials. Natick and Zeneca cooperated in formulating new compatible blends and laminates of biodegradable plastic. Natick formed the materials into commercially usable items and fully characterized the mechanical and physical compatibility of these items with current operational activities, current storage stability requirements, and with handling and disposal requirements both in the field and on board ship. Natick also conducted biodegradability assays in simulated and actual marine and soil environments, respirometry testing and nutritional availability studies with these materials.

Benefits to Non-Federal Partner:

This CRADA partnership has provided Zeneca with the opportunity to run full-scale production of the Biopol material. Material from these production runs were manufactured, by another vendor, into 500,000 Biopol cups.

A6

Title: Development of Novel Imaging System for Medical, Non-Destructive Testing and Investigation of Microelectronic Circuits

Federal Partner: U.S. Army Communications and Electronics Research, Development and Engineering Center, Night Vision and Electronic Sensors Directorate (NVESD)

Federal POC: Conrad Terrell

Non-Federal Partner: Marvin E. Lasser, Inc.

Non-Federal POC: Marvin Lasser

Status: Closed

Summary:

CECOM has sponsored the development of uncooled thermal imaging since 1979. In January of 1991, this work was declassified. The uncooled technology differs from the traditional thermal imaging systems in that the detector array is operated at or near ambient room temperature, rather than at a cryogenic temperature. A one-stage thermoelectric stabilizer is used to control the detector array temperature, to keep the operating point near a detector material ferroelectric phase transition.

The objective of this CRADA was to investigate the possibility of exploiting uncooled thermal imaging technological developments for ultrasonic imaging applications utilizing the piezoelectric, rather than the ferroelectric, properties of one particular uncooled detector material. These ultrasonic imaging applications include medical diagnosis and non-destructive testing of devices such as microelectronic circuits.

In medical imaging, a 2-dimensional ultrasonic focal plane array would be used for spatial display of anatomical structures allowing a relatively inexpensive diagnosis, in many cases without requiring a surgical procedure. A probe, similar to a computer mouse, is placed on the body and rotated over the area of interest. Ultrasonic waves are transmitted into the area under investigation, reflect back to the probe, and are then transduced by the focal plane array with the resulting images displayed on a computer monitor for analysis. One particular disadvantage associated with ultrasonic imaging is the fuzziness of the images, making interpretation somewhat difficult. Other disadvantages relate to equipment size and cost.

Marvin E. Lasser, Inc., is focusing on improvements to ultrasonic imaging medical diagnostic instrumentation, in particular, higher performance and lower cost ultrasonic imaging instrumentation. Ultrasonics permits doctors to examine patients for small differences in tissue composition. The technique is especially useful in diagnosing cancer in body parts such as breasts, testicles, the thyroid and the appendix.

Initial discussions between CECOM and Lasser centered upon adapting Texas Instrument's (TI) uncooled focal plane array for the ultrasonic imaging application. The TI focal plane array was made from Barium Strontium Titanate (BST) material. Since BST is a piezoelectric as well as a ferroelectric material, it was thought that it could serve as an ultrasonic as well as an infrared transducer. Technical discussions on the proposed idea at TI showed a lack of interest on TI's part, partly because TI believed that BST was not a good piezoelectric material and partly because the TI uncooled infrared thermal imaging readout chip was too complex to be adapted to such a different application.

Lasser has subsequently found interest in the idea at LORAL Infrared Imaging Systems (LIRIS), another company with expertise in developing readout integrated circuits for uncooled thermal imaging systems. Technical discussions between Lasser and LIRIS, arranged by NVESD, resulted in a working relationship between the two companies which led to the development of a functional 128 X 128 element ultrasonic imaging array.

In the five years since the inception of the CRADA between NVESD and Lasser, Lasser has continued the development of a commercially viable ultrasonic imaging system.

Value/Benefits to DoD:

Supports DoD Management Principle: Strengthen the Industrial Base:

The work in this CRADA focused on uncooled focal plane arrays, one of the current long-term investment initiatives for DoD. It is anticipated that alternate commercial applications for infrared imaging technology would benefit DoD by sharing in the development costs.

Supports DoD Management Principle: Promote Basic Research:

Knowledge was advanced in using uncooled focal plane arrays for ultrasonic imaging applications.

Benefits to Non-Federal Partner:

The non-federal partner enriched his knowledge in using ultrasonic imaging in medical diagnostic instrumentation. Additional work resulted in a CRADA with ARL in the same technology area and an SBIR with the Air Force.

A7

Title: Evaluation of Electron Cyclotron Resonance Plasma Technology

Federal Partner: U.S. Army Communications and Electronics Research, Development and Engineering Center, Night Vision and Electronic Sensors Directorate, (NVSED)

Federal POC: Jack Dinan

Non-Federal Partner: Texas Instruments, (TI) (now Raytheon)

Non-Federal POC: Robert Keller

Status: Open

Summary:

The artificial retina in all high performance focal plane arrays which are sensitive in the 8 - 17 micron region of the infrared spectrum is made of mercury cadmium telluride, a member of the semiconductor family of materials. The retina is synthesized by depositing thin films of mercury cadmium telluride onto rigid substrates. These planar layers must be transformed into electrically isolated pixels - the analog of the rods and cones of the human retina. For fifteen years, the industrial baseline process for doing so has been to form mesas and trenches in the layers by dipping them into a liquid etchant. All second generation focal plane arrays are manufactured with this technology. Army requirements for higher standoff distances and target recognition capability have led to concepts for a next generation of arrays whose pixels will be considerably smaller and more closely spaced then those for currently available arrays. A barrier to fabricating these smaller features is rooted in the isotropic nature of wet chemical etching. Material is removed as rapidly along the surface of the wafer as it is in a direction perpendicular to the surface. The widths of trenches are too great for next generation arrays.

During the early part of this decade, Texas Instruments Inc. (TI) was one of the three premier suppliers of first generation infrared systems to the military. To meet second generation requirements, TI had chosen a device architecture which was unique and which required precise control over trench widths and depths. Manufacturing yield at TI for second generation focal plane arrays was low, due in part to the need to wet etch.

In 1993, NVESD anticipated the need for small feature widths and along with several university and industrial laboratories, made a decision to explore the suitability of a new vapor phase etching process as a potential replacement for liquid phase etching.

In 1996, TI hired a scientist who had studied plasma etching as a university student and who had published his results. NVESD contacted this scientist and invited him for a visit. It became evident during a series of visits and discussions that each organization had strengths which perfectly complemented each other. A CRADA was then negotiated to develop a working relationship to take advantage of the strengths each organization had in the technology area of infrared focal plane arrays in order to further the development of the next generation focal plane array.

In the CRADA it was agreed that TI would contribute the very high quality and many-layered mercury cadmium telluride samples which they routinely make. NVESD would then etch these samples in its electron cyclotron resonance plasma etching apparatus. TI would then measure electrical and structural properties of the etched layers to assess suitability for the TI device architecture.

TI has now purchased a plasma reactor identical to the one at NVESD in order to continue the research effort, eventually they hope to integrate this technology into their production line.

Value/Benefits to DoD:

Supports DoD Management Principle: Address Warfighting Needs

The Army is very interested in focal plane arrays for use as sensors in tanks, helicopters and some missiles. These sensors act as an artificial retina and detect thermal radiation. They are used in heat seeking missiles where they can hone in on a target that is warmer than its surroundings. They are also used in night vision navigation applications where again they can sense a target from its thermal radiation.

Supports DoD Management Principle: Strengthen the Industrial Base

Work in the area of focal plane arrays is one of the current DoD long-term investment initiatives in technology maturation. Under this CRADA, a new process is being developed that may be integral to the manufacturing of next generation focal plane arrays for use in both military and commercial products.

Supports DoD Management Principle: Promote Basic Research

After one year, the etching process looks promising. A few milestones towards developing the next generation FPA have been achieved. Certain features of arrays etched with a plasma were exploited to give a robust manufacturing process. The etching process produced a FPA 128 pixels by 128 pixel with each pixel being 24 microns by 24 microns. This CRADA advanced the knowledge necessary for the future production of next generation focal plane arrays in which the pixels are smaller and closer together.

Supports DoD Management Principle: Assure Quality

This CRADA was developed to take advantage of the strengths each organization had in the technology area of infrared focal plane arrays in order to further the development of the next generation focal plane array.

Benefits to Non-Federal Partner:

TI benefited from being able to work with the plasma etching process before purchasing an identical piece of processing equipment to that which they were using at the government site. TI is one of four or five companies that sells infrared focal plane arrays to the government for night vision applications. This new process, once perfected, will be used in manufacturing military products.

Other Benefits:

NVESD scientists and those from E-OIR Measurements (on-site collaborators), have filed a patent disclosure based on these new uses for plasma etching. The concept, which was disclosed, is not identical to the technology developed by NVESD/TI, but the ideas generated during this collaboration led directly to this disclosure.

Although no joint research papers have been published at this time, NVESD has published some results of the progress in developing the plasma etching technique. These publications include “An a-Si:H Vacuum Compatible Photoresist Process for Fabricating Device Structures in HgCdTe,” Journal of Electronic Materials, 27 (1998) 689 and “Spectroscopic Ellipsometry Study of HgCdTe Epilayer Surfaces. During ECR Plasma Etching,” Materials Research Society Symposium Proceedings, 450 (1997) 293.

A8

Title: Formulation of a Liposomal Transdermal Vaccine System and Other Novel Pharmaceuticals

Federal Partner: Walter Reed Army Institute of Research (WRAIR)

Federal POC: Dr. Carl Alving

Non-Federal Partner: Medical Technology and Practice Patterns Institute, Inc. (MTPPI)

Non-Federal POC: Dennis Cotter, MTPPI and Dean Lewis, Iomai

Status: Open

Summary:

The Medical Technology and Practice Patterns Institute, Inc. is dedicated to the development and transfer of medical technology through the Vision for World Health Project. MTPPI has identified the need to introduce an alternative vaccine delivery system to reduce the cost and increase the accessibility of vaccination, especially in Third World settings. A transdermal vaccine delivery system fulfills this objective and is appropriate to the charters and goals of both WRAIR and MTPPI.

A liposomal transdermal vaccine system would allow immunization without the need for sterile needles, syringes, and trained personnel, as well as would avoid the complications associated with puncturing the skin. The goal of this CRADA is to develop vaccine adjunct technology to devise an effective, safe and easily administered delivery mechanism for vaccination.

As a result of this CRADA a new means of transdermal vaccine delivery was discovered. An article on the technology has been published in Nature magazine. Two patent applications have been filed on inventions created under this CRADA and a third is in preparation. A major licensing agreement has been executed between WRAIR and MTPPI and sublicensing arrangements with commercial developers and end-users of the technology have begun. Substantial resources (revenues and professional scientific staff) have come into WRAIR under this CRADA with MTPPI.

Gregory M. Glenn, Mangala Rao, Gary R. Matyas, and Carl R. Alving, “Skin Immunization Made Possible by Cholera Toxin,” Nature, Vol. 391, No. 6670, 851, February, 26, 1998.

Value/Benefits to DoD:

Supports DoD Management Principle: Address Warfighting Needs

The first trial to be conducted under this CRADA was for a vaccine of particular interest to the Army, E. coli endotoxin technology, for soldiers diarrhea. The vaccine will be used in field operations.

Supports DoD Management Principle: Strength the Industrial Base

The research conducted under this CRADA has advanced the process of bringing needle-free vaccine technology to market. The skin patch vaccines developed under this CRADA will have direct commercial applications. This type of vaccine delivery system has applications to many vaccines such as those being developed for HIV, etc. In addition to vaccines for human use, it is currently being considered for use on pets.

Supports DoD Management Principle: Promote Basic Research

The preclinical research conducted under this CRADA has led to the first clinical trial for a vaccine for E. coli endotoxin technology. This first FDA-approved Phase I clinical trial has been completed. Phase II and Phase III must now be competed prior to filing a new drug application (NDA), followed by licensing by the FDA. It is anticipated that the Phase II trial will be completed in FY99. For most products, it typically takes 5 to 10 years and an investment of $50 million to $200 million to complete all testing phases, including NDA filing, for licensing by the

FDA. For the vaccine being investigated under this CRADA, research has been ongoing for less than two years.

Supports DoD Management Principle: Assure Quality

MTPPI's use of the WRAIR laboratory space as well as MTPPI conducting the human trials at the WRAIR allowed core competencies in military relevant technologies to be maintained.

Benefits to Non-Federal Partner:

A major licensing agreement has been executed between WRAIR and MTPPI and sublicensing arrangements with commercial developers and end-users of the technology have begun.

A9

Title: Full Scale Fabrication & Optimization of Composite Cylinder Processing

Federal Partner: U.S. Army Research Laboratory

Federal POC: Dana Granville

Non-Federal Partner: Composite Development Corporation (CDC)

Status: Closed

Summary:

ARL entered into this CRADA to investigate a new way to make constant-cross-section, high performance composite products. CDC, a subsidiary of Fiberspar and Tube Corporation, one of the nation's largest producers of carbon fiber tubing with a major market share of windsurfing masts, booms, and bases. CDC believed that composite materials could help make a superior hockey stick, but it did not have the capital to invest in an assembly line to test the idea. CDC then approached ARL for their expertise in polymer composite design and testing. Under the CRADA, CDC used ARL's state-of-the-art equipment to test a manufacturing technique called pultrusion, where fibers spooled at one end are continuously drawn through a resin bath and then pulled into a heated die, where they are cured. The cured material is then pulled from the die in a continuous form for cutting into any desired length, such as the four feet necessary for a hockey stick.

This CRADA looked at evaluating different resin systems using the pultrusion technique. CDC was particularly interested in epoxy/urethanes and acrylic/epoxy formulations.

Value/Benefits to DoD:

Supports DoD Management Principle: Reduce Cost

The lessons learned from this collaborative effort will help the Army to produce constant-cross-section profile items such as helicopter stringers and stiffening elements at a lower finished cost per pound.

Supports DoD Management Principle: Strengthen the Industrial Base

The research conducted under this CRADA has led to advances in manufacturing techniques for stronger, lighter and more durable materials whether it be for low-cost launch tubes, helicopter rotor blades, bridge decks, tent poles or hockey sticks.

Supports DoD Management Principle: Promote Basic Research

This working partnership allowed ARL to further its research in pultrusion manufacturing techniques which can produce stronger, lighter, and more durable materials more quickly and at lower costs. Each party learned a considerable amount about how tougher, hybridized resins can be processed successfully at low viscosities with pultrusion, as well as improved methods of "feeding" glass and carbon fiber into pultrusion die "on-the-fly."

Benefits to Non-Federal Partner:

CDC was able to use Army experts and equipment in an experimental processing program to manufacture and test a new world-class product without a large investment in equipment.

A10

Title: Vaccines for Infectious Diseases

Federal Partner: Walter Reed Army Institute of Research

Federal POC: Dr. Ken Eckles

Non-Federal Partner: Ora Vax, Inc.

Non-Federal POC: Tom Monas

Status: Open

Summary:

There have been and continue to be a number of efforts being pursued under this CRADA in the area of vaccine development. The work focuses on vaccine production of product that is producible for use in Phase I and Phase II clinical trials. WRAIR has the controlled facilities required for this type of production. Ora Vax's focus is to work on the manufacturing and commercialization aspects of vaccines and is assisting in the QC/QA manufacturing capability at WRAIR.

The initial work under this CRADA was to develop a new vaccine technology for E. coli protection that would be packaged in biodegradable polymers and taken orally. As the polymers dissolve, antigens are released to stimulate immunity. Polymers comprising the microcapsule can be specifically formulated for a "time release" over days or months. The objective of this technology was to eliminate the need for multiple injections of vaccines. Returning to a clinic for multiple shots is a problem in developing countries, remote areas and military operations. The stabilizing effect of microencapsulation also allows vaccines to be shipped and stored without refrigeration which is important in tropical areas of the world where it is difficult to preserve a vaccine. However, after a market assessment, the work on the E. coli vaccine was dropped from Ora Vax's product portfolio.

Under this CRADA, Ora Vax is currently working with WRAIR on the manufacturing of a vaccine for peptic ulcers that can lead to stomach cancer. A market analysis indicated that this vaccine would be a $1B/year opportunity.

This CRADA was also amended to address an additional product, a Japanese encephalitis vaccine.

Value/Benefits to DoD:

Supports DoD Management Principle: Address Warfighting Needs

The vaccines being studied under this CRADA will support the general health of the soldier. The objective of the microencapsulated diarrheal vaccine was to give this vaccine to soldiers just before deployment providing months of E. coli protection.

Supports DoD Management Principle: Strengthen the Industrial Base

The vaccines being developed under this CRADA have dual-use applications. In addition to protecting soldiers, an E. coli vaccine would protect approximately 28 million people (8 million from the U.S.) who travel to developing countries each year.

Supports DoD Management Principle: Assure Quality

In this CRADA, Ora Vax provides resources and revenue to support the WRAIR in mission critical technology areas.

Benefits to Non-Federal Partner:

Ora Vax is able to use the WRAIR controlled laboratory facilities to produce a product usable in Phase I and Phase II clinical trials. Ora Vax can then use the data to get FDA approval to conduct further trials.