1. Systems Vision and Value Added of the Center

Recent advances in engineering and the enabling sciences provide an unprecedented opportunity for revolutionary developments in biological interface materials and technologies. The ERC will develop enabling technologies, built on a strong foundation of the fundamental sciences, which will work in harmony to generate revolutionary breakthroughs and commercialization in multiple areas of patient care and biomedical devices. The ERC lead institution, North Carolina Agricultural & Technical State University (NCAT), and its core partner institutions, the University of Pittsburgh (Pitt) and the University of Cincinnati (UC), global research partner, the Hannover Medical School (MHH), Germany, and other global and national partners that include industrial partners, innovators, and state and local government entrepreneurial networks, will work in unison to achieve the system vision.

1.1 Systems Vision

The vision of the NSF Engineering Research Center is to revolutionize metallic biomaterials and underlying sciences and technologies leading to engineered systems that will interface with the human body to prolong and improve quality of life, coupled with the development of a vibrant, diverse workforce well-prepared for the multidisciplinary and global challenges and opportunities of the new millennium.

The major goal is to revolutionize metallic biomaterials and smart coatings with built-in responsive biosensory capabilities which can adapt to biological changes to create novel bio-functional Engineered Systems: Craniofacial and Orthopedic Applications, Cardiovascular and Thoracic Devices, and Responsive Biosensors and Neural Applications.

1.1.1 Transformational Research in Metallic Biomaterials

Through the intertwining of carefully-planned, cutting edge research on a global level among partner institutions the ERC-RMB will create engineered systems (ESs) related to: 1) Craniofacial and Orthopedic Applications, 2) Cardiovascular and Thoracic Devices and 3) Responsive Biosensors and Neural Applications. The three (3) ESs (ES1, ES2, ES3) will be driven by three (3) overarching research thrust areas comprised of enabling technologies and fundamental knowledge:

- Thrust #1: New materials development
- Thrust #2: Materials processing/characterization and device modeling (chemical, physical, mechanical, modeling)
- Thrust #3: Biocompatibility testing

These thrust areas work harmoniously to generate revolutionary breakthroughs in multiple areas of patient care.

Multi-university/multidisciplinary teams will facilitate the various device and application testbeds within ES1, ES2 and ES3, which serve as proving grounds with the versatility and adaptability to translate thrust areas and fundamental science into engineered systems (ESs) capable of addressing barriers to device and application creation and commercialization.

The purpose of this ERC is, therefore, to transform current medical and surgical treatments by creating "smart" implants for craniofacial, dental, orthopedic, cardiovascular, thoracic and neural interventions. The ERC will develop and investigate biodegradable systems that combine novel bioengineered materials based on magnesium with miniature sensor devices that can control the integrity of implants as well as facilitating the release of biological factors and drugs to promote healing.

Biodegradable systems offer significant therapeutic advantages over implants used today. The mission for the ERC is to deliver on the potential of bioengineering and nanotechnology to dramatically improve treatments for, orthopedic, craniofacial, cardiovascular and thoracic ailments. The promise is that new kinds of implants and biodegradable metals may be used that can grow and adapt to the human body and eventually dissolve when no longer needed. These innovations would particularly benefit pediatric patients suffering from cleft palate, angular deformities of long bones, limb length discrepancies, or trauma including fractures that require pins and screws for repair. Biodegradable metal implants would reduce the expense and spare children the pain of multiple procedures used to implant, then later remove, refit and re-implant the current generation of devices. Another important application is to improve metallic wire mesh stents that are currently used to treat blockages in airways, sinus, and other ducts. Stents can elicit immune responses leading to the growth of scar tissue and the formation of blood clots. If blockages form, these stents are difficult to remove and additional stents must be inserted. Biodegradable stents could reduce or eliminate the need for additional invasive procedures. Sensors and other neural applications developed by the ERC will provide new information on the biological response of the body to implanted devices.

Breakthrough activities include new alloying techniques to produce tunable degradable metallic implants, new improved versions of existing clinical-use plates and screws, innovative coating technologies to yield special surface functionalities and methods to develop new sensors for monitoring/controlling implant corrosion and studying bone growth.

1.1.2 System-level Requirement Metrics and Deliverables of the ERC

The ERC technical team has the scientists, industrial entrepreneurs and technical expertise, and the toxicology, clinical and FDA leaders with exceptional past and day-to-day experience in addressing the system level requirements.

With the newly developed strategy, as a first step, the ERC formed a device team which is working with the industry experts, clinicians and FDA leaders in defining the design parameters for others team members to work towards. Special attention was given to those low-hanging areas that can impact the commercial productivity immediately in the respective ES areas.

The ERC team is also providing special attention to the challenges of interfacial biocompatibility through well managed coordination, facilitating device development throughout the entire center. While the materials team develops and processes various metals and alloys, Biofunctional Surface Modification (ceramic, metal or polymers) is coordinated by a specific leader for the entire center. Similarly, toxicology, biocompatibility, controlled release, and *in vivo* analysis are coordinated by specific leaders for the entire ERC making the system-level requirements and deliverables much easier.

Research efforts of technical thrusts and fundamental science now cut across the needs of each ES test bed to address barriers and facilitate effectively the ES1, ES2 and ES3 device and application requirements. Accordingly, Year 2 projects have been redefined and consolidated from the first year (that ended Sep 2009), relative to the new strategic plan. The following scientific reorganization best leverages the growing strength and competencies housed within ERC-RMB. We used color coding on the reorganized overarching research thrust areas to facilitate effective thought processes.

The organizing principle of the new strategic plan also considers the introduction of new devices and new thrusts and fundamental science needs. For example, the ES2 thoracic device testbed is enabled by the development of new science and technologies that will find application in a variety of soft tissue devices and applications, including aortic stents. Technologies may also spin off from these projects to affect industries beyond the biomedical device industry.

The organizing principle also recognizes that not every testbed device or research project will produce desired outcomes. The flexibility of the strategic plan recognizes the potential for obsolescence and provides opportunities for researchers and students working in cross-cutting areas to shift resources to successful as well as new devices and applications as ERC-RMB matures. The launch of a candidate testbed device begins with the identification of preliminary design objectives. Design objectives serve as targets for new biomaterial development and characterization. Using preliminary design objectives, ERC-RMB researchers can quickly determine whether a device or application is technically feasible and thus eligible for consideration within hard tissue, soft tissue or neural tissue testbeds. Preliminary design objectives also provide the basis for multidisciplinary interactions among enabling technology and fundamental science project leaders. These interactions serve to identify complimentary expertise that resides between the three core partners as well MHH and GKSS.

All these reorganized strategy plans for impacting technologies in fact present a commercial opportunity in and of themselves. As evidence of this, our team has several intellectual property filings in this area. Our university technology management teams, as well as our industrial collaborators, believe that various ERC activities and associated spinoff sciences, ideas and technologies are particularly ripe with commercial potential (for details, please see Section 1.2.6 or click on Industrial Collaborations and Technology Transfer Interactions)

1.2 Value Added and Broader Impacts

The overall goal of the ERC-RMB is to achieve the following outcomes and impacts during the ERC's lifetime.

- achieve excellence in the proposed areas of research through a true interdisciplinary approach within and with leading partner nano/bioengineering research institutions
- establish a new generation of revolutionary biological metallic interface materials by integrating enabling sciences and technologies
- develop creative, adaptive and innovative engineers
- improve graduation rates (undergraduate through doctoral) in nano/bioengineering areas, especially among women, socially and economically disadvantaged, and African-American students
- train the 21st century STEM (Science, Technology, Engineering and Mathematics) workforce (pre-college and college) and provide students with technical education relevant to 21st-century careers in advanced processing, bioengineering and materials – a workforce that can compete with any worker in the world
- train STEM teachers at all levels to enable the workforce hurt by the current state of the economy to create new opportunities for themselves in cutting-edge-technologies
- facilitate economic and healthcare development in the U.S. through innovation to broaden the scope of technologies to treat disease, and to strengthen the global position the US health care system
- generate revolutionary technologies via sharing of resources and ERC-generated knowledge base to create a pathway to both extend and improve the quality of life; and
- foster a culture of innovation in bioengineering research and education and providing for entrepreneurship and economic development that will help the USA succeed in a global economy by directly engaging small innovative firms, industries and practitioners and technology transfer officers

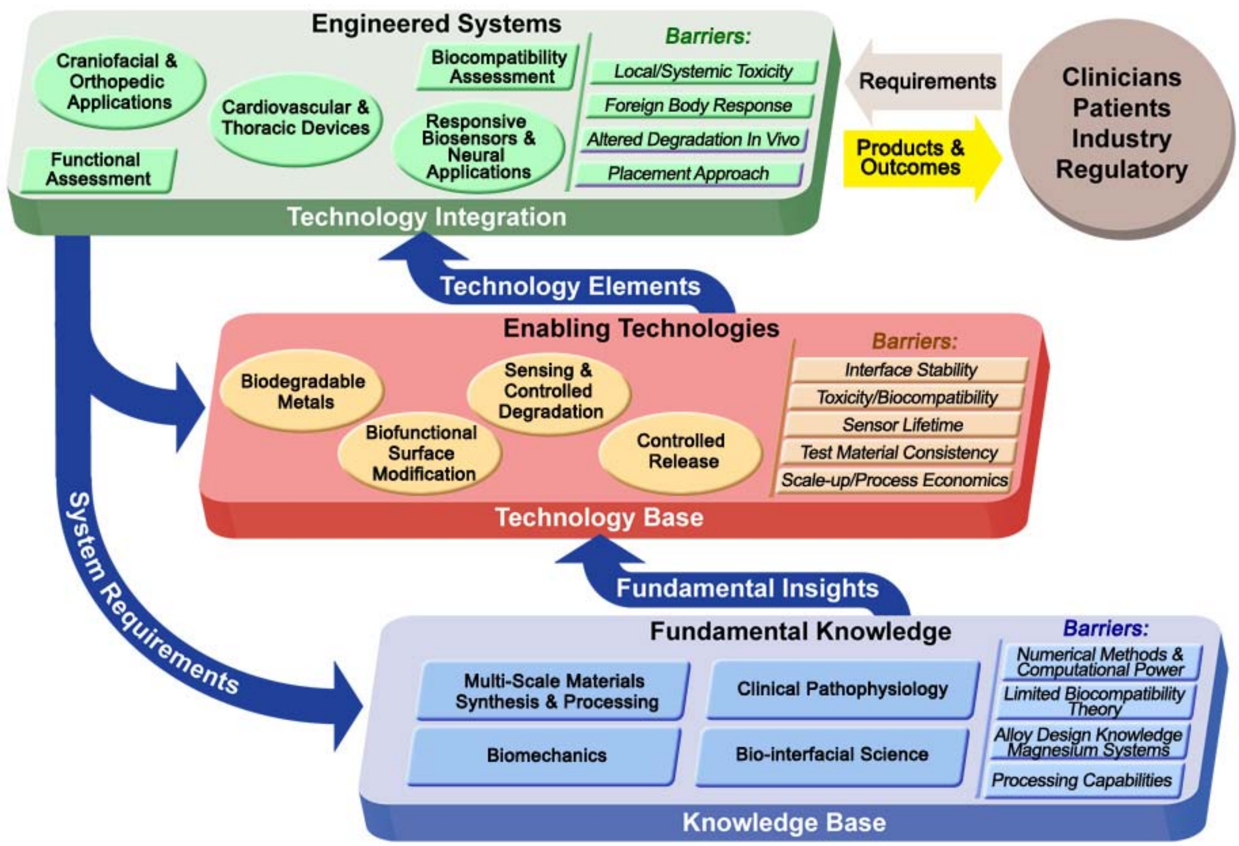
1.2.1 Curricular Education and Outreach

- develop undergraduate and graduate curricular materials themed on the ERC-RMB research thrusts, aimed at fostering research innovation and global entrepreneurial skills
- establish the nation's 1st bioengineering degree granting activities at an HBCU and initiating BS, MS and PhD programs in the field of bioengineering at NCAT

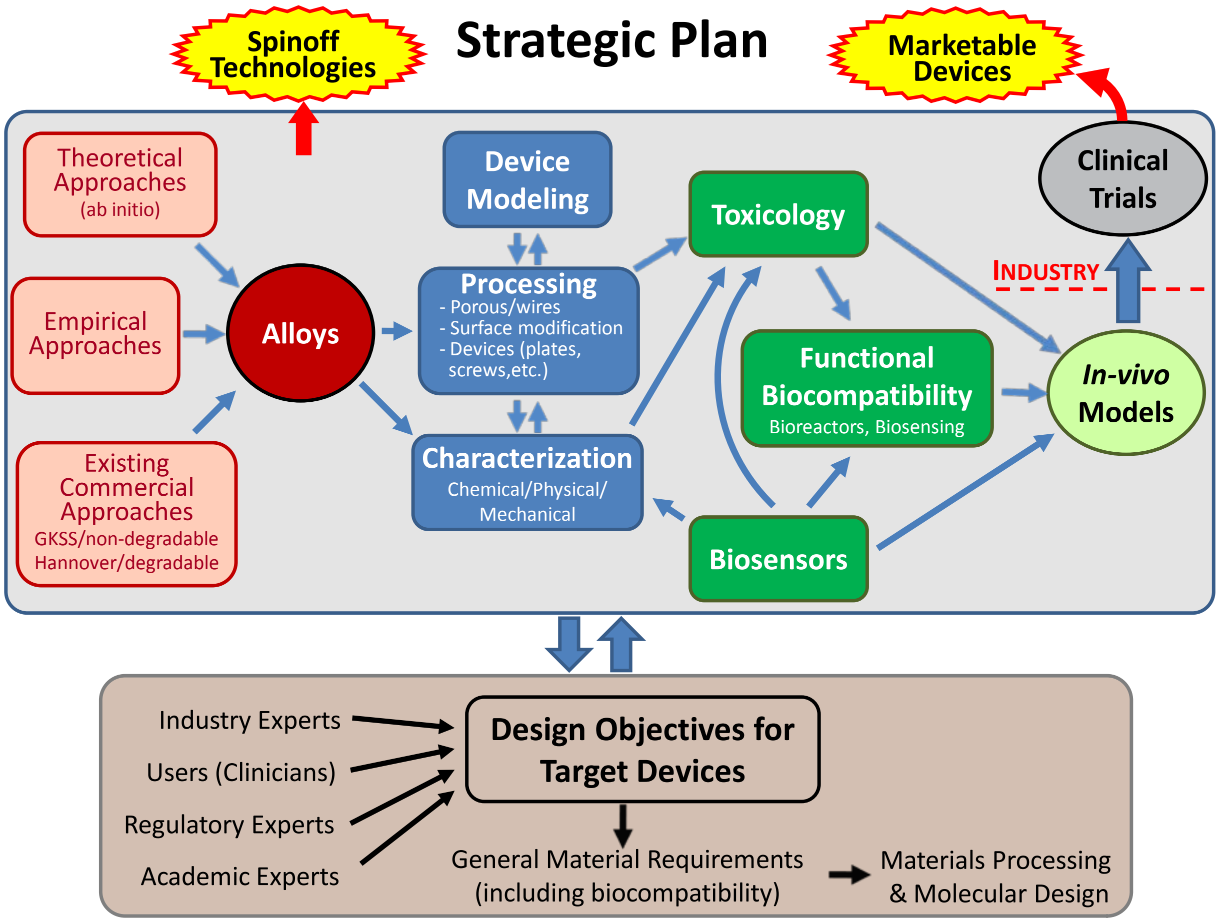
- become an information resource for parents and students considering careers in the engineering and life sciences
- work with experienced secondary STEM educators to develop curriculum units
- offer research/training opportunities in bioengineering to secondary STEM educators
- maintain longitudinal data to evaluate the effectiveness of curricular initiatives and outreach activities
- create a culture of innovation in bioengineering research, entrepreneurship and economic development by directly engaging small innovative firms, industries and practitioners

1.2.2 Integrative Construct of the ERC-RMB to Achieve the Above Outcomes and Impacts

The interdisciplinary team, with investigators from NCAT, Pitt and UC, was reformed this past year based on the improved 3-plane strategic framework that includes barriers (figure below), developed based on SWOT analysis and feedback from the Year 01 Site Visit Report, complemented by a research strategic plan and an education and outreach (E&O) strategic plan (figures follow 3-plane chart). Our scientists and educators worked specifically on the strategic plans for the ERC activities over the past year. This has greatly helped in refining and carefully planning cutting-edge research, education and economic activities on a global level among partner institutions for the future.



ERC-RMB: Updated 3-Plane Strategic Framework with Barriers



ERC-RMB: Research Strategic Plan

During Year 2, the ERC team developed a new strategic plan to operationalize the NSF 3-plane strategic framework. The strategic plan serves as the organizing principle that focuses the multidisciplinary research conducted within enabling technologies and fundamental knowledge to address barriers associate with each engineered system (ES) test bed.

Based on ES test beds and ES-related biomedical devices and applications, the new strategic plan combines enabling technologies and fundamental knowledge into three overarching research thrust areas: 1) new materials development; 2) materials processing/characterization and device modeling; and 3) biocompatibility testing. In the figures, please note that gray regions relate to device or testbed-related activities. Red/salmon corresponds to new materials development. Blue refers to materials processing/characterization and device modeling and green indicates biocompatibility testing. Each of the ESs has multiple projects from these thrust areas, presented in later pages. The thrust areas also comprise growing research and education competencies within ERC-RMB.

These research thrusts were developed by leveraging complementary expertise between the three core partners and MHH as well as GKSS, Hamburg. These research thrusts support academic experts working with specific devices and applications to generate new metals and metal alloys that adhere to ES-specific device design objectives. Because device PIs are formally engaged with patients, clinicians, companies and regulators, new biodegradable metals and metal alloys as well as existing commercial biomaterials can be tested for mechanical integrity and biocompatibility relative to each biomedical device. These data ostensibly form the basis of metallic biomaterials feasibility studies with an emphasis on commercialization. Device-based performance data created by research thrusts for each ES can be validated by practitioners prior to costly clinical trials. A feedback loop is created between companies, regulators and ERC PIs such that all relevant data are shared between participants regardless of the study boundaries. This new strategy focuses ample ERC resources as well as resources available through industry and the regulatory environment on challenges and barriers specific to each ES, thereby accelerating the development and commercialization of revolutionary biomedical devices.

The research strategic plan emphasizes multi-disciplinary, engineered systems approaches to the development of revolutionary metallic biomaterials-based devices and applications. Scientific reorganization of the enabling technologies and fundamental science into research thrusts optimized the device mix within each ES. Thoracic devices were added to ES2 and neural applications were added to the ES3 test bed. The ERC-RMB ESs are:

- ES1: Craniofacial and Orthopedic Applications
- ES2: Cardiovascular and Thoracic Devices
- ES3: Responsive Biosensors and Neural Applications

The following paragraphs list briefly revised goals and objectives for each ES.

ES1: Craniofacial and Orthopedic Applications

This engineered system investigates the use of biocompatible metals and alloys as hard tissue substitutes. The low corrosion resistance of Mg, especially in electrolytic and aqueous environments becomes useful for biomaterial applications, where the *in vivo* corrosion of magnesium involves stimulatory effects on the growth of new bone tissue. ES1 research focuses on the growth of new bone tissue and the functional integrity of hard tissue implanted devices during bone tissue healing. Mg and Mg-based alloys can also be coated with bioresorbable ceramics and novel signaling biomolecules including: growth factors, DNA and proteins. Integration of ES1 research with advancements in biosensor technology will result in the development of “smart” hard tissue biomaterials where controlled corrosion can be “triggered” once the regeneration process of the mineralized tissue has advanced to an acceptable level of maturation.

ES2: Cardiovascular and Thoracic Devices

This engineered system evaluates a variety of biodegradable metals and metal coatings that exhibit suitable corrosion rates in blood as well as the required initial mechanical strength and elasticity as the material degrades. These soft tissue substitutes must address the potential for metallic structures to abrade nearby soft tissue structures resulting in infection or catastrophic bleeding that often accompanies a permanent foreign body implant. The use of biodegradable metals, combined with appropriate surface modification and controlled release strategies will alleviate some of these concerns. State-of-the-art computational techniques are also being utilized to analyze the mechanical performance of the biocompatible Mg alloy in device form, leading to positive treatment outcomes that do not depend on a permanent implant.

ES3: Responsive Biosensors and Neural Applications

This engineered system investigates physical and chemical limitations of metallic and metallic alloy implants. Specifically, it is developing technologies that can control the inherent high corrosion rates of novel biomaterials and to reduce or eliminate harmful corrosion by products that cause tissue necrosis, pain and delayed healing time. Because neurons are electrogenic cells that form complex biological entities capable of effecting recognition, neural applications and the effects of metallic biomaterials on neural processes are also studied.

All the ESs are driven by the enabling technologies and critical, fundamental knowledge shown under the middle plane and bottom plane of the 3-plane chart. The three ESs (ES1, ES2, ES3) will be driven by three (3) overarching research thrusts comprised of enabling technologies and fundamental knowledge, working harmoniously to generate revolutionary breakthroughs in multiple areas of patient care

- Thrust #1: New materials development
- Thrust #2: Material processing/characterization and device modeling (chemical, physical, mechanical)
- Thrust #3: Biocompatibility testing

Research efforts of technical thrusts and fundamental science now cut across the needs of each ES test bed to address barriers and facilitate effectively the ES1, ES2 and ES3 device and application requirements. Accordingly, Year 2 projects have been redefined (please see Table of Research Projects, below) and consolidated from the first year (ended Sep 2009), relative to the new research strategic plan just presented. Colors correspond to research thrust areas as described the narrative immediately following the research strategic plan.

Research Projects Based on New Strategic Plan and Thrust Areas

Legend:

(yellow)	Engineered System
(pink)	New materials development
(blue)	Materials processing/characterization and device modeling
(green)	Biocompatibility testing
(grey)	Device / application

#	Project	Co-Leader(s)	Project Title	Project PI
ES1: Craniofacial and Orthopedic Applications			**ES1 Leader:** Prashant Kumta - University of Pittsburgh **ES1 Co-Leader:** Sergey Yarmolenko - North Carolina A&T **ES1 Co-Leader:** Charles Sfeir - University of Pittsburgh	
1	**ACL Connector**	**S. Y. Woo**	Biodegradable Metallic Scaffolds and Biosensors to Regenerate ACL Insertion to Bone Following ACL Reconstruction	S. Y. Woo

#	Project	Co-Leader(s)	Project Title	Project PI
2	**ACL Repair**	**S. Y. Woo**	Regeneration of the Anterior Cruciate Ligament by Application of Porous Metallic and Extracellular Matrix Bioscaffolds	S. Y. Woo
3	**Toxicity**	**A. Barchowsky**	In Vitro Toxicity Testing and Biocompatibility High Content Studies	A. Barchowsky
4	**Biocompatible Ceramic Coatings**	**D. Kumar/P. Kumta**	**4.1** Development of Ceramic Biomaterials for implant Applications Using Pulsed Laser Deposition and Magnetron Sputtering	D. Kumar
			4.2 Functionalized Organic-Inorganic Coatings for 3D Magnesium-based Scaffolds-Biocompatible Ceramic Coatings	P. Kumta
5	**Proteinaceous Coatings**	**E. Beniash**	**5.1** Use of Phage Display to Design Coating Peptides with High Affinity Magnesium Alloys	E. Beniash
			5.2 Biomimetic Coating of Mg Based Alloys for Enhanced Bone Regeneration and Resorption Control	C. Sfeir
			5.3 Functionalized Organic-Inorganic Coatings on 3D Magnesium-based Scaffolds	P. Kumta
6	**TMJ Device**	**A. Almarza**	Interface of Bone-Ligament-Tendon for Bone and Bone-Ligament and Disc for TMJ	A. Almarza
7	**Metal-on-metal Coatings**	**P. Kumta/S. Yarmolenko**	**7.1** Functionalized Organic-Inorganic Coatings on 3D Magnesium-based Scaffold-Biocompatible Metal-on-Metal Coatings	P. Kumta
			7.2 Development of Biocompatible Metallic Thin Film Coatings	S. Yarmolenko
8	**Theoretical Material Development**	**P. Kumta**	Alloy Design Using First Principles Density Functional Theory and Ab-initio Calculations	P. Kumta
9	**Biocompatible Alloys**	**P. Kumta/ Z. Xu**	**9.1** Processing of Porous and Nonporous 3D Magnesium Alloys	P. Kumta
			9.2 Processing of Novel Porous and Nonporous Biodegradable Magnesium Alloys	Z. Xu
10	***In vitro* Assessment of Alloys**	**C. Sfeir**	*In vitro* Assessment of Alloys and Composite Structures using Traditional Cell Signaling Pathways	C. Sfeir
11	**Amorphous alloys**	**P. Kumta**	Processing of Porous and non-Porous Metastable Magnesium-based Alloys	P. Kumta
ES2: Cardiovascular and Thoracic Devices			**ES2 Leader:** William Wagner - University of Pittsburgh **ES2 Co-Leader:** Salil Desai - North Carolina A&T	
1	**ASD/PFO**	**T. Gilbert**	Development of a Fully Degradable Atrial Septal Defect Device	T. Gilbert
2	**Tracheal Stent**	**T. Gilbert/ J. Waterman**	Evaluation of Magnesium-based Alloys for Airway Stenting	T. Gilbert/ J. Waterman
3	**Synthetic Coatings**	**W. Wagner/ S. Desai**	**3.1** Biodegradable Elastomeric Coatings with Controlled Drug Release for Biodegradable Metallic Materials	W. Wagner

#	Project	Co-Leader(s)	Project Title	Project PI
			3.2 Non-thrombogenic Surface Modifications for Metallic Blood Contacting Devices	W. Wagner
			3.3 Understanding Controlled Release of Multilayer Coatings Using Direct-write Ink Jet Method	S. Desai
			3.4 Smart Controlled Release Coatings for Magnesium Implants and Sensors	T. Cui
4	**Device Modeling**	**R. Mohan/D. Schmidt**	Predictive Models for Metallic Bioabsorbable Stent-Tissue Interactions	R. Mohan/D. Schmidt
ES3: Responsive Biosensors and Neural Applications			**ES3 Leader:** William Schulz - University of Cincinnati **ES3 Co-Leader:** Yeoheung Yun, North Carolina A&T **ES3 Co-Leader:** Vesselin Shanov, University of Cincinnati	
1	**Sensors**	**W. Heineman**	**3.1** Sensor Development and Miniaturization	W. Heineman
			3.2 Carbon Nanotube Nanoelectrode Array Based Biosensors: New Approach to Ultrasensitive, Implantable Sensors for Bone Regeneration and Healing	P. Kumta
2	**Corrosion**	**Y. Yun**	Corrosion Characterization of Biodegradable Metals and Coated Structures	Y. Yun
3	**Biocompatibilit y**	**Z. Dong/C. Sfeir**	**4.1** *In vivo* Biocompatibility and Toxicity Assessment of Magnesium and Magnesium Alloys and Coatings	Z. Dong
			4.2 *In vivo* Assessment of Magnesium Alloys	C. Sfeir
4	**Ultra High Purity Metals and Nanotube Development**	**V. Shanov**	Magnesium and Carbon Nanotubes-based Materials for Implant, Biosensor and Scaffold Applications	V. Shanov
5	**Nerve Repair**	**S. Pixley**	Tissue Engineering and Biodegradable Metal Implants, Controlled Release and Miniature Sensors	S. Pixley

The organizing principle of the new strategic plan also considers the introduction of new devices and new thrusts and fundamental science needs. For example, the ES2 thoracic device testbed is enabling the development of new science and technologies that will find application in a variety of soft tissue devices and applications including aortic stents. Technologies may also spin off from these projects to affect industries beyond the biomedical device industry.

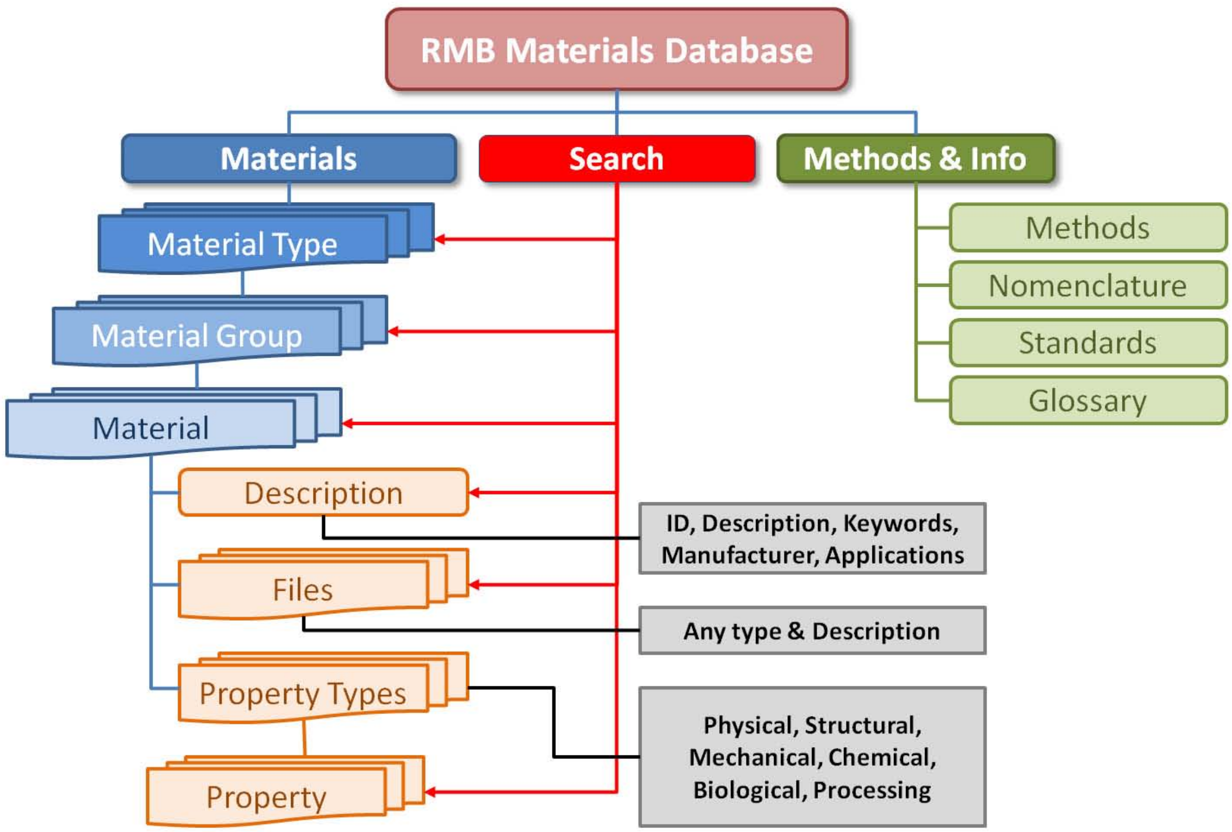
The organizing principle also recognizes that not every testbed device or research project will produce the desired outcomes. The flexibility of the strategic plan recognizes the potential for obsolescence and provides opportunities for researchers and students working in cross cutting areas to shift resources to successful as well as new devices and applications as the ERC matures. The launch of a candidate testbed device begins with the identification of preliminary design objectives. Design objectives serve as targets for new biomaterial development and characterization. A table of design objectives has been developed (please see Section 2.1 or click on <u>Design Objectives Table</u>) and is a constantly-evolving roadmap towards the creation of materials by design, with inputs from industry experts, clinicians, regulatory experts and academic experts.

Using preliminary design objectives ERC researchers can quickly determine whether a device or application is technically feasible and thus eligible for consideration within hard tissue, soft tissue or neural tissue testbeds. Preliminary design objectives also provide the basis for multi-disciplinary interactions among technology thrust and fundamental science project leaders. These interactions serve to identify complementary expertise that resides among the three core partners, MHH and GKSS.

Recently, ERC-RMB also developed a draft concept for a materials database. Creation of materials-by-design requires accurate comparison, verification and monitoring of processes and properties. Standardization and repeatability of testing techniques are also critical for multidisciplinary research located at different institutions, necessitating round-robin testing. Designers should be able to refer to well-established and verified properties and datasheets for standards and materials of interest. This can be done by establishing a universal materials database; in our case, a database available for every ERC-RMB researcher and industrial collaborator. Therefore we have established password-protected and user-dependent online materials database. The draft structure, created by Dr. Yarmolenko, is described below.

RMB Materials Database – Draft Structure

A materials database has been created by Dr. Yarmolenko to collect and exchange materials information among ERC researchers. To provide maximum flexibility, this system provides several features necessary for proper documenting and storage of all kinds of internal information such as original data files, spreadsheets, notes and images with searchable descriptions. Every material can be represented by an unlimited number of records and corresponding files together with information about record creator, date/time, and restrictions on use (passwords or accessibility for specific user groups). Special attention has been paid for the system to work with images and formatted documents. The system stores original image files, and also creates two reduced copies – for preview (medium size) and thumbnail size. Every image can be stored together with a variety of additional information, such as resolution, equipment information, technical detail, comments, notes, keywords, etc. All text fields are stored in HTML format that allows for the preservation of most special formatting features (paragraphs, fonts, colors, tables, images, links, bullets, etc.). Rich-text online editor allows uploading files and images with links to them, that converts every record in a fully-featured document with unlimited sources to use. All these capabilities can create a unique environment for storage and use of any type of information connected with specified material or sample. The schematic of our online materials database structure is presented below.

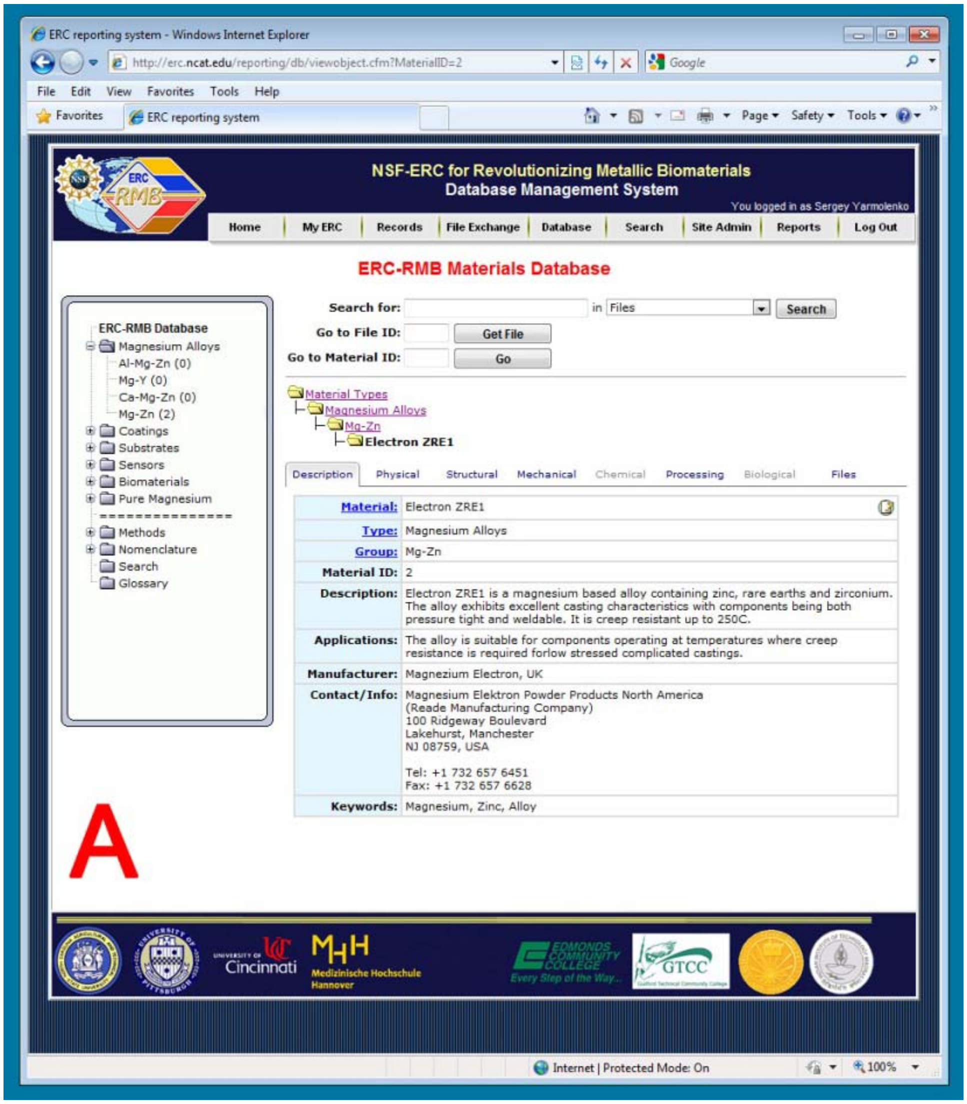


The database has been designed for internal use by ERC-RMB researchers. It has an open architecture – users can create material types (administrators), material groups (power users) and property types (regular users). ERC-RMB system also provides guest access to the database which allows only searching and viewing of unprotected information. Regular users can create records and edit/delete their own records. Power users can edit/delete records of regular users but cannot alter records created by other power users. Administrators can edit/delete all records.

The database consists of three main parts:

- Materials data entry
- Search system
- Information system

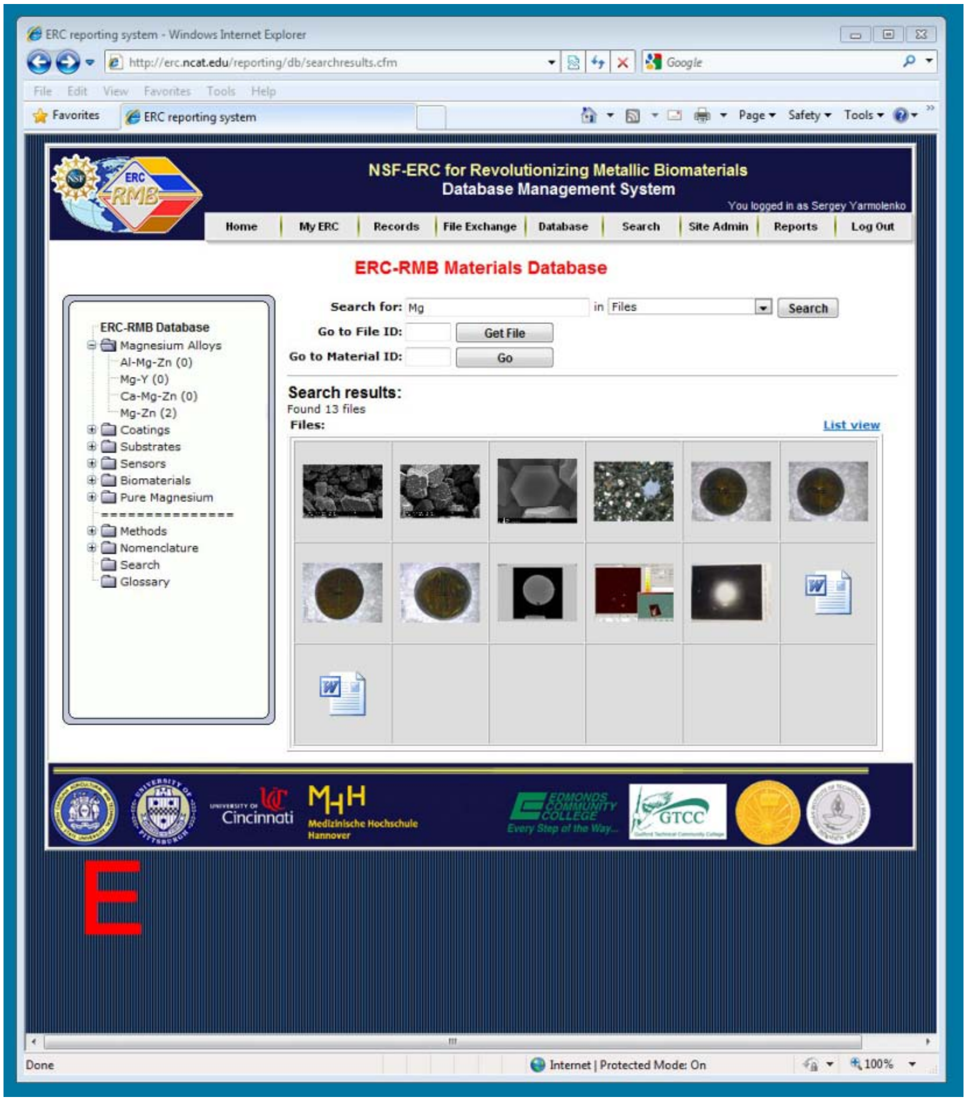
The data entry system is straightforward. To create a new material, a regular user should identify material type and group where he or she is going to create a new material record. The new material creation process consists of one simple form with minimal information required as input. As soon as the record has been created, user(s) can input descriptive information about the material and add/link any property records or files to the material. The record can be added or accessed using one screen through tabs which represent 6 groups of properties: physical, structural, mechanical, chemical, biological and processing. This screen also gives access to the material's descriptive information and collection of files (See Screenshot A on at the end of this narrative). Through a navigation tree on the screen, every material record has access to the list of materials in the current group, list of groups within current material type and list of available materials in the system. This capability helps to quickly navigate among records. All records can be easily edited/deleted using small icons located close to the editable information. The editor appears in a modal window blocking access to the parent screen. That allows the user to perform quick updates of every record without additional navigation. Screenshot A shows the home screen for the system. Screenshot E is an example of file search output.



Screenshots of material record descriptive information

The Search system allows users to perform searches in records shown by red arrows on the diagram. We have to specify what type of information we are looking for: (a) material type, (b) material group or (c) material. Search in material records includes all fields shown in gray boxes. Also separately we can perform searches in descriptors of all files available (example: Screenshot E). The information system will consist of the collection of regulatory documents about methods, standards, theoretical and practical notes supporting data collection. This system is under development as of this writing.

ERC-RMB researchers are working on promising new materials systems as well as commercially-available materials. Based on our initial year 01 activities, we had outlined specific properties and requirements that need to be stored and searchable in the materials database. However, we soon realized that data collection should be flexible enough to accommodate the complexity of collaborative multidisciplinary research. Materials of various types (alloys, coatings, substrates, media, sensing components, chemicals, etc.) should be



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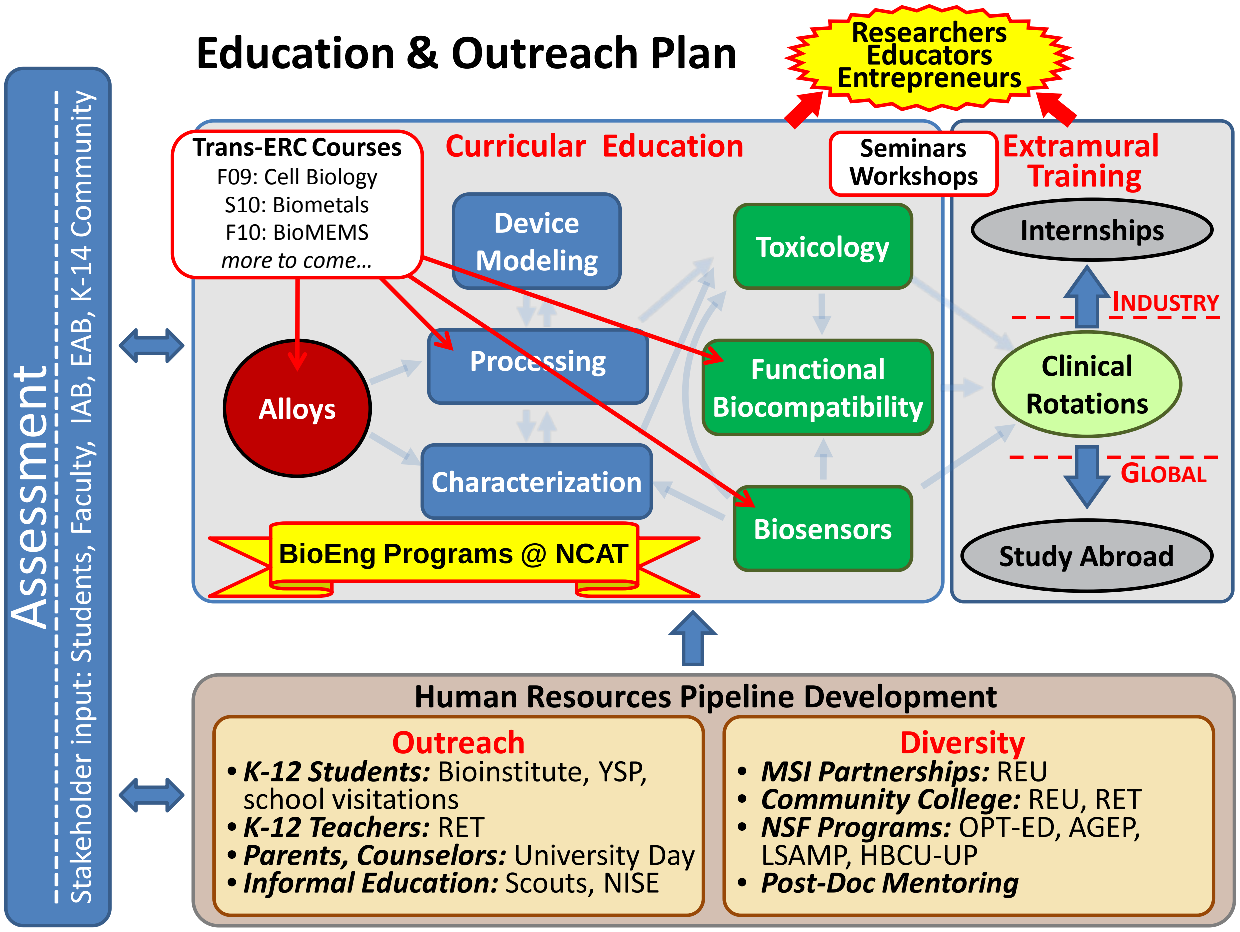
Researchers should have access to various types of properties such as physical, chemical, structural, mechanical, biological and even processing protocols as well as the ability to add new types of properties. Therefore we have designed a database structure which will allow an unlimited amount of records to be attached to every material. Furthermore, the system allows users to add and manage associated images, hyperlinks, attachments, presentations, datasheets, etc. The first release of our materials database is now available for ERC-RMB members.

Education and Outreach Construct

A strategic plan for education and outreach (please see figure below) has been developed in concert with the Center's research strategic plan. All aspects of education and outreach initiatives are designed for effective teaming within and across the ERC partner campuses, leveraging the key competencies of the ERC's staff and students, and are assessed formatively and summatively by qualified personnel. Dissemination is effectively achieved through relevant conferences such as NSF EEC, ASEE, National Educators Workshop, and Rose-Hulman's Best Assessment Practices Workshop.

The human resources pipeline development to recruit qualified students into the University education component is achieved through broad-based outreach programs targeted at elementary and secondary school students, community college students and their teachers, counselors, parents and administrators. These include informal education, parent information sessions, visits by schools to the ERC sites and vice versa, and Young Scholars, Summer Camp, REU and RET programs. Summer programs are designed to allow interaction between student and teacher participants and their faculty/graduate student hosts to fully engage them in the discovery process. Enhanced attention is paid to diversity through strategic partnerships with community colleges, other minority serving institutions and other NSF HRD programs including OPT-ED, AGEP, LSAMP and HBCU-UP. Mentoring plans have been drawn up and are being implemented for mentoring of post-doctoral scholars connected with ERC research.



ERC-RMB – Education & Outreach Strategic Plan

The formal curricular education programs are centered on the technical foci outlined in the research strategic thrust. During the current reporting period, a major effort was undertaken to link the ERC-related educational programs amongst all key institutions (NCAT, Pitt, UC, MHH). To that end, we developed and taught our first two online course offerings in a videoconferencing format from the Pitt site (Fall 2009 please see Appendix XII or click on Cell Biology Syllabus and Spring 2010, please see Appendix XII or click on Biodegradable Alloys Syllabus). Dr. Pai served as the NCAT coordinator for both courses to insure a smooth introduction to NCAT ERC students. Dr. Pixley (UC) served as a co-course instructor for the fall online biology course. Dr. Witte (MHH) served as a guest lecturer during the Spring 2010 Biometals course led by Dr. Kumta (Pitt). The quality of the two online courses was assessed using written instruments developed and administered by Dr. Robin Liles - NCAT.

NCAT, with the support of its partners, is on the verge of starting a baccalaureate and masters degree programs (please see Appendix XVI or click on Excerpts from Degree Program Proposals) in bioengineering in Fall 2010 and Spring 2011, respectively. This is subject to UNC System General Administration approval, anticipated in June 2010. These will be the first at an HBCU. Further, NCAT is also working towards planning and establishing a Ph.D degree program in Bioengineering, which will also be a first at an HBCU. All these will have a major, positive impact on the outcomes of the ERC. NCAT's bioengineering programs will be housed in the Department of Chemical and Bioengineering, chaired by Dr. Leonard Uitenham. As the recruitment of bioengineering faculty members is ongoing at NCAT, plans are already in place for its first bioengineering faculty member (Dr. Yun, who joined March 1, 2010) to develop a graduate course on BioMEMS during the next reporting period. Educational assessment of Year 02 course will inform and shape the development of this 3rd trans-ERC course.

Thus, effective knowledge sharing has been implemented. The strategic education plan for ERC students supplements curricular education with extramural interactions in the form of 'clinical' rotations and industrial internships, with guest lectures/seminars from industry, entrepreneurship institutes and government experts on topics such as regulatory issues, safety, creativity, innovation and entrepreneurships. Increased participation of underrepresented populations in the professoriate and research arena will be promoted through a mentoring plan for post-doctoral scholars that has been developed and is being implemented (please see Appendix VI or click on Post-Doctoral Scholar Mentoring Plan).

1.2.3 Research

Engineered Systems-level Approaches and Advances

Significant activities and impacts related to research advances and productivity (For details, please see Section 2 and also find the research project details in Volume 2)

In order to achieve a focused research impact with commercialization potential in the engineered systems (ESs): ES1) Craniofacial and Orthopedic Applications, ES2) Cardiovascular Devices and Thoracic Devices and ES3) Responsive Biosensors and Neural Applications, the ERC team has developed interdisciplinary multi-institutional projects. During Year 2, the ERC team developed a new strategic plan (please see Section 1.2.2) to operationalize the NSF 3-plane strategic framework. The strategic plan serves as the organizing principle that focuses the multidisciplinary research conducted within enabling technologies and fundamental knowledge to address barriers associated with each engineered system (ES) test bed.

Based on ES test beds and ES-related biomedical devices and applications, the new strategic plan combines enabling technologies and fundamental knowledge into three overarching research thrust areas: 1) new materials development; 2) materials processing/characterization and device modeling; and 3) biocompatibility testing. The thrust areas also comprise growing research and education competencies within ERC-RMB. In the figures of Section 1.2.2, please note that gray regions relate to device or testbed-related activities. Red/salmon corresponds to new materials development. Blue refers to materials processing/characterization and device modeling and green indicates biocompatibility testing. Each of the ESs has multiple projects from these thrust areas, presented later in the same section.

As indicated earlier, a table of design objectives has been developed to meet the needs of the device innovation (please see Section 2.1 or click on Design Objectives Table) and is a constantly evolving roadmap towards the creation of materials by design, with inputs from industry experts, clinicians, regulatory experts and academic experts. Further, we have established a materials database (for details, please see Section 1.2.2 or click on Materials Database).

While the projects are being executed in parallel, the carefully-planned cross-linking supports the goals of effective innovation. During the current (Year 02) reporting period, numerous conference call meetings and in-person meetings occurred between NCAT, Pitt, UC and MHH personnel to aid in establishing the infrastructure necessary as well as various leveraged frontier research for the ERC deliverables.

1.2.4 Research Productivity

For the reporting period, 12 journal papers and 6 peer-reviewed conference proceedings papers were published from ERC-supported projects, with 106 seminars, colloquia and invited talks. There were 10 invention disclosures.

Major Recognition/Awards during the Past Year

- Dr. Borovetz (Pitt) – Conference Chair, Annual Meeting of the Biomedical Engineering Society (BMES), October 7 – 10, 2009
- Dr. Borovetz (Pitt) - Distinguished Professor of Bioengineering – University of Pittsburgh
- Dr. Cui (Pitt) – NSF CAREER Award 2009
- Dr. Desai (NCAT) – NSF CAREER Award 2009
- Dr. Heineman (UC) - Fellow of American Chemical Society (Inaugural Class)
- Dr. Kumta (Pitt) – Fellow of the American Ceramics Society
- Dr. Pai (NCAT) – ASEE Mechanical Engineering Division Chair 2009
- Drs. Pai (NCAT), Sankar (NCAT), Kumta (Pitt) and Schulz (UC) were organizers of a 3-session symposium related to ERC research at the 2009 ASME IMECE Conference in Lake Buena Vista, FL (please see Appendix VIII or click on ASME 2009 Symposium Listing)
- Dr. Sankar (NCAT) – Keynote address at four (4) Major International Materials Conferences
- Dr. Sankar (NCAT) - O. Max Gardner Award Winner 2010 - Highest faculty honor of the 17-campus University of North Carolina Educational System
- Dr. Sankar (NCAT) – Piedmont-Triad Region, NC- Most Influential Persons Award, December, 2009
- Dr. Sankar (NCAT) – Special Invitee for National Academies Meeting at Washington, DC and University Industry Demonstration Project (UIDP) of the National Academies meeting at Atlanta
- Dr. Sankar (NCAT) was invited along with CEOs of Greensboro-area colleges, universities, companies and industries and he presented the ERC perspective on why Google should locate its super-fast fiber-optic network in Greensboro (please see http://www.youtube.com/watch?v=T-_v_-h5yL8)

- Drs. Sankar and Pai were the principal organizers for the 2010 National Educators Workshop (please see Appendix VIII or click on Workshop Brochure) hosted at NCAT in March 2010
- Dr. Shanov (UC), Dr. Witte (MHH) were co-leads along with support from ERC Thrust Team members in organizing the BioMg09 Think Tank Conference in Nov 2009 in Greensboro, NC (please see Appendix VIII or click on BioMg09 Agenda)
- Dr. Wagner (Pitt) - Representative from the Society for Biomaterials to the International Union of Societies for Biomaterials Science and Engineering (IUSBSE)
- Dr. Woo (Pitt) - Honorary Degree of Doctor of Engineering, University Council of The Hong Kong Polytechnic University
- Dr. Woo (Pitt) - Honorary Professorship, Beijing University of Aeronautics and Astronautics

1.2.5 Education Outcomes

Significant activities and impacts related to education & outreach (For details, please see Section 3: University and Pre-College Education)

- The Department of Chemical and Bioengineering at NCAT was officially established July 2009, with Dr. Leonard Uitenham appointed as Chair.
- Website http://www.eng.ncat.edu/bmen/ (please see Appendix XVI or click on Bioengineering Programs Brochure)
- The BS and MS plan received campus-level approval, and was presented March 2010 and April 2010 respectively with the University of North Carolina System General Administration and is awaiting final authorization (positive response tentatively expected by June 2010 (for excerpts, please see Appendix XVI or click on BS Proposal and MS Proposal)
- PhD program proposal is progressing through the internal campus approval process (for excerpts, please see Appendix XVI or click on PhD Planning Proposal)
- In March 2010, Drs. Sankar and Pai organized 2010 National Educators Workshop (please see Appendix VIII or click on 2010 NEW Brochure) at NCAT that stressed the importance of bioengineering and workforce development through community colleges, with participants including ERC partnering university and community college faculty and high school teachers and administrators.
- NSF NC OPT-ED recruitment – North Carolina Opportunity for Education – an NSF-funded program created to seamlessly integrate the various HRD programs such as the Louis Stokes AMP program, HBCU-UP and AGEP. The key members of the ERC are an integral part of the NC OPT-ED activities and 2009 conference and, during the reporting period, leveraged the ERC with the HRD programs. ERC's Dr. Pai and Dr. Lee have been nominated to the NC OPT-ED Steering Committee that organizes the annual Alliance Day in North Carolina.
- During the reporting period, numerous conference call meetings and in-person meetings occurred between NCAT, Pitt and UC education personnel to aid in establishing the

infrastructure necessary for the bioengineering program and as well as trans-ERC courses at all campuses.

- Enhancements have been made to various existing courses to incorporate bioengineering concepts as applicable to ERC goals, and new courses are also being developed
- Special lab tours have been organized and conducted for current students and faculty as part of their existing courses to spark interest in ERC research
- The ERC team continuously hosts and informs a diverse stream of visitors - industry, educators, government officials, teachers and K-14 students at all its campuses
- The ERC's research and education and outreach activities, as well as the bioengineering program of NCAT are being widely publicized for student enrollment and faculty recruitment purposes. This is being done through special presentations, keynote talks and seminars and workshops organized or participated in by the ERC faculty members.
- Many meetings were held with our community college partners Guilford Tech (GTCC) and Edmonds (EDCC) for strategy discussions on joint activities in workforce development.

Progress on Bioengineering Degree Programs and Faculty Hiring at NCAT

The process to implement the Bioengineering program continue to progress. During the 2009-2010 academic the program proposals for BS, MS and PhD were updated and resubmitted to the University administration after the UNC System General Administration declined to entertain requests for new degree program during the 2008-2009 academic year due to severe financial restraints. The BS and MS programs were forwarded to the UNC System General Administration for consideration. Initial Disciplinary Panel Review (technical peer review) of the proposals was conducted by the UNC System via a system wide videoconference on March 3, 2010 for the BS program and on April 7, 2010 for the MS program. The reviews were favorable, and official approval of these programs is anticipated at the UNC Board of Governors Meeting in June 2010. More information on the programs submitted as well as updates on the faculty hiring and student recruitment process are outlined below:

- The Bachelor of Science in Bioengineering (please see Appendix XVI or click on BS Proposal) is a four-year engineering program and will be open to new college entrants and transfer students. We envision that this new program of study will be received very favorably by NCA&T students, and be very well subscribed from the beginning. The growth in the Bioengineering programs is expected to continue in the foreseeable future. The curriculum requirements have been structured to comply with the Accreditation Board for Engineering and Technology (ABET) and accreditation will be sought, with an initial accreditation visit by ABET expected in four years.
- The Master of Science in Bioengineering (please see Appendix XVI or click on MS Proposal) is nominally a two-year engineering program and will be open to highly-qualified students who have completed their BS degree in science or engineering. The MS program emphasizes advanced study in specialization areas (i) biomaterials and biomechanics, (ii) bioimaging, biosignals and biosensors (iii) bioprocessing. These areas

will strengthen the ERC bioengineering activities and will leverage our current graduate research strengths in Mechanical, Industrial, Electrical and Chemical Engineering. The M.S. program provides graduate level education designed to prepare the graduate for Ph.D. level studies or for employment in advanced bioengineering practice in industry, consulting, or government service.

- The Doctor of Philosophy in Bioengineering program (please see Appendix XVI or click on PhD Planning Proposal) will be open to highly-qualified students who have completed their BS degree and MS degree in science or engineering. The Doctor of Philosophy in Bioengineering (PhD) emphasizes advanced study in specialization areas: (i) biomaterials and biomechanics, and (ii) bioimaging, biosignals and biosensors and (iii) bioprocessing. The program provides advanced graduate level education designed to prepare the graduate for research and teaching as well as for employment in the bioengineering industry and government.
- A total of five faculty positions were assigned to the Bioengineering initiative in the reporting period. One has been filled by Dr. Yeoheung Yun (please see Appendix XV or click on Dr. Yun's Resume), who joined the faculty in March 2010. Three new positions for Bioengineering were advertised in January in five different professional publications. A total of 45 applications were received and the interviewing process is in progress. The fifth position has been designated as a joint position between Bioengineering and Biology and application are currently being accepted. All positions are expected to be filled by the Fall 2010 semester.
- Interest remains strong in the both undergraduate and graduate programs among NCA&T student and students from other local colleges and universities. Many of the undergraduate students expressed interest in graduate school, particularly the PhD program.

Educational Collaboration with Pitt and UC

A successful summer internship collaboration was developed during Summer 2009 with Pitt recruiting an NCAT undergraduate (Elden Groover) for their Summer 2009 REU activities. Mr. Groover worked for Dr. Almarza in the CCR and MIRM at Pitt. For Summer 2010, Dr. Almarza has recruited a high-performing NCAT mechanical engineering student (Khaliel Abdelrahiem) as an REU participant.

The mission of the ERC is being incorporated into the bioengineering curriculum at NCAT and into the education programs at the other partner sites. Courses that focus on biomaterials, and specifically metals, which are at the heart of the ERC research mission are being incorporated at all institutions, as exemplified by the courses led by Pitt's Dr Partha Roy (Cell Biology, please see Appendix XII or click on Dr. Roy's syllabus) in Fall 2009 and Pitt's Dr. Prashant Kumta (Biodegradable Metals, please see Appendix XII or click on Dr. Kumta's syllabus) in Spring 2010. This has leveraged the excellent videoconferencing and cyber infrastructure facilities of the member campuses and brought in true trans-ERC collaborations through enabling of knowledge sharing and guest lectures by subject matter experts from partner campuses. The Cell Biology course was led by Dr. Roy was team-taught by Dr. Sarah Pixley (UC), with guest lectures by Dr. Wagner (Pitt) and others. The latest guest lectures in the biometals course running in Spring 2010 are on the subject of "Fundamentals of Biodegradable Magnesium Implants" by Dr. Frank Witte at MHH, and one on "Craniofacial Applications of

Biometals" by Dr. Alejandro Almarza of Pitt's Bioengineering Department and Dr. Bernard Costello of Pitt's School of Dental Medicine. At NCAT, Dr. Pai assumed the overall coordination of these courses and Dr. Liles conducted educational assessment. Two graduate students (Ms. Aliza Alston, Ms. Latisha Taylor) from NCAT's Biology Department led NCAT recitation sections for the Cell Biology course in Fall 2009.

As part of the educational outreach component of the ERC, NCAT's 2009 Summer Nano-to-Bio Institute for high school students involved a collaborative effort between NCAT, Pitt, and the Pittsburgh Tissue Engineering Initiative (PTEI, http://www.ptei.org/section.php?pageID=8). The overall goal of this program is to reach underserved minority middle and high school students, and to actively engage them in the wonders of science at a critical crossroads of their education through a connective, informal science one-week education experience. The program, originally developed in 2004 by Ms. Joan Schanck - PTEI's Director of Education and Workforce Development, has gained momentum and continues to grow. In 2009, Pitt faculty (Dr. Steven Abramowitch) and five Pitt undergraduate students and a Pittsburgh-area schoolteacher worked closely with NCAT's Dr. Waters and undergraduate Jason Bartlett to bring tissue engineering outreach modules to deliver the week-long summer camp – a TV news report on this can be seen at http://www.youtube.com/watch?v=4uNYWrSZ-Qk, a student-produced video can be seen at http://www.youtube.com/watch?v=SvBAl6H6wQU, also please see Appendix X or click on 2009 Summer Camp Announcement) for high school students at NCAT in late July 2009. A new improved version is planned for offering at NCAT July 2010 (please see Appendix X or click on 2010 Summer Camp Announcement).

1.2.6 Industrial Collaboration and Technology Transfer Interactions

The reorganized strategy plans for impacting technologies in fact present a commercial opportunity in and of themselves. As evidence of this, our team has several intellectual property filings in this area. The disclosures are in the fields of materials, sensors, and biomedical applications. Our university technology management teams, as well as our industrial collaborators, believe that various ERC activities and associated spinoff sciences, ideas and technologies are particularly ripe with commercial potential.

The ERC industrial advisory boards and members are intimately involved in guiding focus areas and potential commercialization. NCAT and its core ERC Partners, Pitt and UC, have already collaborated on an MOU that addresses Governance, Financial, Intellectual Property, and Commercial issues. Each Institution has significant experience in administering Technology Transfer and Commercial Licensing Relations and has established successful relationships with Industrial Partners who will contribute to the success of the ERC. We are in contact with the appropriate FDA experts also to advise the ERC team on the regulatory processes and will engage as appropriately related to innovation of materials, implants, and devices developed in the ERC. We are working hand-in-hand with the clinicians, industrial experts and the FDA experts in developing the guidance documents and approval requirements (and satisfying same) for the transformational metallic biomaterials. Once the technical challenges have been solved at the implant/body interfaces (we have presented designs of biodegradable materials, a corrosion control system that are biocompatible and biosafe) there will be an increasing demand for the implant and technology developed through the ERC. The high demand will enhance the commercialization processes with our experienced industrial partners. Our international research partner, the Department of Orthopedic Surgery, Hannover Medical School is already assisting and collaborating to accelerate materials development, clinical testing, and as well as in commercialization of the metallic biomaterials developed through the NSF ERC.

ERC-RMB Invention Disclosures during the past year
Application of Carbon Nanotube Fiber for In-body Biomedical Devices
Composition and Method for Producing Magnesium Based Biodegradable Composite Implants
Composition and Method for Producing Magnesium Biodegradable Material for Medical Implant Applications
Corrosion Measurement for Biodegradable Metal Implants
Device for Controlling Corrosion of Implanted Metallic Biomaterials
Highly Efficient Visible Light Responsive Phototcatalyst
Magnesium and Iron Metallic Screws with Controlled Biodegradability
Mg Nanowires for Biology and Nanomedicine
Permanent and Biodegradable Responsive Implants that Expand and Adapt to the Human Body
Photocatalyst for the Degradation of Organic Contaminants by Sunlight
Self-Expanding Biodegradable Drug-Eluting Metallic Stent for use in Coronary Arteries and Grafts
Therapeutic Mg Alloys to Promote Bone Healing

The ERC has actively and successfully recruited a significant number of new Industrial and Innovation Partner members during the past reporting period. We have been fortunate in having been able to establish relationships with companies with a very wide range of technical interests and directions. This diversified approach allows for the establishment of open dialog and for the expansion of the technical footprint of the ERC. A sampling of the technology transfer interactions follows.

The ERC Industrial Member team includes n-Coat, Hitachi High Technology America, Covidien, Advanced Technical and Regenerative Medicine (ATMR - a subsidiary of Johnson & Johnson) and Biomet. Representatives from each of these companies have been assigned to participate in the IAB in providing guidance to the ERC. Specifically, nCoat Inc. has loaned a Senior Scientist to work fulltime on ERC related research with the goal of developing innovation, commercialization and SBIR proposals. Hitachi America has upgraded the NCAT ERC with full biological characterization features to facilitate ERC research initiatives. In addition, they will provide short courses free of cost and usage of their advanced microscopy facilities at no charge. ATMR (a J&J subsidiary) is facilitating innovation related to ACL repair and fixation devices such as plates and screws. Biomet is actively involved in the TMJ-related areas, while Covidien is collaborating in the stent, staple and sutures area.

Innovation Partners particularly benefit from these efforts as we are now able to include companies that would not normally fall into the category of biomedical device manufacturers. A prime example of this type of expanded synergy is the collaboration of Industrial Member Hitachi High Technology America with Innovation Partner Protochips. Protochips designs and manufactures MEMS based electron microscope stages that have the ability to stabilize images so that chemical and thermal processes can be observed in real time at the molecular or atomic level. This, combined with the advanced electron microscopy technology of Hitachi, offers ERC researchers and other industrial members the opportunity to study material formation and corrosion degradation at a level not previously attainable. Innovation partner Ex-One is helping in the 3-D inkjet printing technique for developing novel porous structures for bioimplant materials. KeraNetics out of Wake Forest University will be collaborating on the neural applications area. ECOSIL and General Nano are participating in material degradability and sensors area.

From the devices perspective and system requirements, it is anticipated that since sensors are Class II biomedical devices, FDA approval can potentially be easier to obtain than for drugs. Moreover, the first applications of sensors will be for research used to aid design of the implant, and commercialization is not immediately needed. Sensors will be initially used *in vitro* with cell assays, then in animal models, and later in human clinical trials to help design implants to have appropriate strength and corrosion characteristics, and to ensure biocompatibility for different applications. Sensors will not need to be implanted in humans in many of the final applications, and in these cases commercialization is not a concern.

1.2.6 Team and Its Diversity

The ERC-RMB team has excellent interdisciplinary participation. As the center grows, we will welcome other personnel as needed from related areas. Participation of underrepresented groups as members of the leadership faculty, research faculty, and student teams since the Center's inception is shown in Tables 1 and 1a. We continue to work on aggressively recruiting minority PhD students through visitations to programs where underrepresented students have a strong interest in graduate bioengineering education. New appointments to the leadership teams during the current reporting period include: Ms. Lois Deve - Administrative Director of the ERC, Dr. Leonard Uitenham - Chair of the Bioengineering Program, Dr. Jenora Waterman (Assistant Professor of Animal Science) - research team, Dr. Robin Liles - Associate Director for Educational Assessment, Christopher Smith (PhD student) – SLC Co-Chair for NCAT.

Table 1. Quantifiable Outputs

Outputs	Early Cumulative Total [1]	September 1, 2008 - February 28, 2009	Sep 01, 2009 - Feb 28, 2010	All Years
Publications That Result from Center Support				
In Peer-Reviewed Technical Journals	0	3	12	**15**
In Peer-Reviewed Conference Proceedings	0	4	6	**10**
In Trade Journals	0	0	0	**0**
With Multiple Authors:	0	7	18	**25**
Co-authored with ERC Students	0	6	12	**18**
Co-authored with Industry	0	0	1	**1**

Outputs	Early Cumulative Total [1]	September 1, 2008 - February 28, 2009	Sep 01, 2009 - Feb 28, 2010	All Years	
With Authors from Multiple Engineering Disciplines	0	3	14	**17**	
With Authors from Both Engineering and non-Engineering Fields	0	3	7	**10**	
with authors from multiple institutions	0	3	11	**14**	
Publications That Result from Associated Projects in the Strategic Plan					
In Peer-Reviewed Technical Journals	0	11	12	**23**	
In Peer-Reviewed Conference Proceedings	0	2	8	**10**	
Publications Resulting From Sponsored Projects					
In Peer Reviewed Technical Journals	N/A	0	0	**0**	
In Peer Reviewed Conference Proceedings	N/A	0	0	**0**	
Participating Industrial and Practitioner Organizations					
Members	0	9	9	**18**	[2]
Affiliates	0	1	1	**2**	[2]
Contributing Organizations	0	0	0	**0**	[2]
ERC Technology Transfer					
Inventions Disclosed (submitted to agencies by researchers or technology transfer office)	0	0	10	**10**	
Patent Applications Filed	0	0	0	**0**	
Patents Awarded	0	0	0	**0**	
Licenses Issued	0	0	0	**0**	
Spin-off Companies Started	0	0	0	**0**	
Estimated Number of Spin-off Company Employees	0	0	0	**0**	
Building Codes Impacts	0	0	0	**0**	
Technology Standards Impacts	0	0	0	**0**	
New Surgical and other Medical Procedures Adopted	0	0	0	**0**	
Degrees to ERC Students					
Bachelor's Degrees Granted	0	0	0	**0**	
Master's Degrees Granted	0	0	4	**4**	
Doctoral Degrees Granted	0	0	0	**0**	
ERC Graduates Hired by					
Industry:	0	0	0	**0**	
ERC Member Firms	0	0	0	**0**	
Other U.S. Firms	0	0	0	**0**	
Other Foreign Firms	0	0	0	**0**	
Government	0	0	0	**0**	
Academic Institutions	0	0	4	**4**	
Other	0	0	0	**0**	
Undecided/Still Looking/Unknown	0	0	0	**0**	
ERC Influence on Curriculum					
New courses based on ERC research that have been approved by the curriculum committee and are currently offered [4]	0	1	3	**4**	
Currently offered, on-going courses with ERC content	0	4	4	**8**	
New Textbook Chapter Based on ERC Research	0	0	0	**0**	
New Textbooks Based on ERC Research	0	0	1	**1**	

Outputs	Early Cumulative Total [1]	September 1, 2008 - February 28, 2009	Sep 01, 2009 - Feb 28, 2010	All Years
Free-Standing Course Modules or Instructional CDs	0	1	2	**3**
New full degree programs based on ERC research	0	0	0	**0**
New degree minors or minor emphases based on ERC research	0	0	0	**0**
New certificate programs based on ERC research	0	0	0	**0**
Active Information Dissemination/Educational Outreach				
Workshops, Short Courses, and Webinars [3]	0	7	8	**15**
Number of participants that attended activity	N/A	265	410	**675**
Seminars, Colloquia, Invited Talks, etc.	0	21	106	**127**
ERC Sponsored Educational Outreach Events for K-12 students	0	5	14	**19**
Number of students that attended activity	0	454	741	**1195**
Number of teachers that attended activity	0	42	186	**228**
ERC Sponsored Educational Outreach Events for Community College or Undergraduate students	0	6	11	**17**
Number of students that attended activity	0	57	1,018	**1075**
Number of faculty that attended activity	0	16	244	**260**
Personnel Exchanges				
Student Internships in Industry	0	0	3	**3**
Faculty Working at Member Firm	0	0	0	**0**
Member Firm Personnel Working at ERC	0	1	2	**3**

[1] For Centers in operation for more than five years.
[2] Cumulative count of Individual Firms/Organizations may not equal the sum across all years.
[3] For years prior to 2009, the values include 'Workshops and short courses to industry' and 'Workshops and short courses to non-industry groups'
[4] New courses currently offered and approved by the curriculum committee are only counted in the first year that they are offered so there is no multiple counting of these courses.

Table 1a: FY2009 Average Metrics Benchmarked Against All Active ERC's and the Center's Tech Sector

Metric	Average All Active ERC's FY2009 (20 ERC's)	Average Biotechnology Sector FY2009 (7 ERC's)	Average for Class of 2008 - FY 2009 (5 ERC's)	ERC for Revolutionizing Metallic Biomaterials at North Carolina A&T State University Total FY2009	ERC for Revolutionizing Metallic Biomaterials at North Carolina A&T State University Total FY2010
Industrial Member Firms	18	11	9	9	9
Small	38%	45%	55%	100%	22%
Medium	14%	8%	4%	0%	0%
Large	48%	47%	40%	0%	78%
Non-Industry Sector Firms	1	0	0	0	0
Total Member Organizations	19	11	9	9	9
Affiliate Organizations	1	2	1	1	1
Contributing Organizations	1	2	1	0	0
Total Membership Fees Received	$	$	$	$	$

Metric	Average All Active ERC's FY2009	Average Biotechno-logy Sector FY2009	Average for Class of 2008 - FY 2009	ERC for Revolutioni-zing Metallic Biomaterials at North Carolina A&T State University Total	ERC for Revolutioni-zing Metallic Biomaterials at North Carolina A&T State University Total
Direct Sources of Support [1]	$				
NSF	67%	67%	71%	61%	51%
Industry	9%	13%	3%	0%	2%
Other Federal	0%	0%	0%	0%	0%
Academic	20%	18%	16%	39%	37%
State	2%	1%	5%	0%	10%
Other	2%	1%	6%	0%	0%
Associated Project Support	$				$
ERC Personnel & Educational Participants[2] [3]	1,770	658	304	674	2,362
Leadership Team [7]	14	13	16	23	21
Faculty [2] [4]	43	38	39	46	57
Graduate Students [2]	73	62	64	29	52
Undergraduate Students [2]	26	17	16	9	35
REU Students	11	14	5	4	7
K-12 Teachers [3]	108	15	18	42	186
K-12 Students [3]	1,437	457	130	454	741
Faculty that attended ERC Sponsored Educational Outreach Events [3]	2	2	3	16	244
Community College or Undergraduate students that attended ERC Sponsored Educational Outreach Events [3]	26	8	11	57	1,018
% Women [5] [6]	60%	52%	22%	27%	25%
% Underrepresented Racial Minorities [5] [6]	22%	17%	13%	24%	25%
% Hispanic [5] [6]	20%	13%	5%	4%	5%
Publications	**Average**	**Average**	**Average**	**Total**	**Total**
In Peer Reviewed Technical Journals	23	16	12	3	12
In Peer Reviewed Conference Proceedings	29	17	8	4	6
Multiple Authors: Co-Authored With ERC Students	32	18	6	6	12
Multiple Authors: Co-Authored With Industry	4	3	1	0	1
Intellectual Property	**Average**	**Average**	**Average**	**Total**	**Total**
Invention Disclosures	4	6	1	0	10
Patent Applications	4	6	0	0	0
Patents Awarded	2	4	0	0	0
Licenses (patents, software)	3	1	1	0	0
Education and Outreach Outputs	**Average**	**Average**	**Average**	**Total**	**Total**
New Courses Developed	1	2	1	1	3
Currently offered, on-going courses with ERC content	10	4	13	4	4
New Full Degree Programs	0	0	0	0	0
New degree minors or minor emphases	0	0	0	0	0
New certificate programs based on ERC research	0	0	0	0	0

[1] Includes new support (unrestricted cash, restricted cash, and in-kind donations) from table 9 only. Residual funds carried over from previous years are not included in benchmarking figures.
[2] Includes total ERC Personnel from table 7.
[3] Includes participant values from Table 1 Quantifiable Outputs.
[4] Includes Directors, Education Program Leaders, Thrust Leaders, Senior Faculty, Junior Faculty, and Visiting Faculty from table 7.
[5] These data do not include K-12 Student or Teacher Participants in the percentage calculations. Demographic data are not collected for K-12 Student or Teacher Participants.
We only collect the total number of K-12 Student and Teacher Participants.

[6] The percentage calculations are based on the following categories of Personnel only: Faculty, Graduate Students, Undergraduate Students, REU Students, Directors, Thrust Leaders, Research Thrust Management & Strategic Planning, Administrative Director, and Industrial Liaison Officer.

[7] Includes Directors, Thrust Leaders, Education Program Leaders, Research Thrust Management & Strategic Planning, Administrative Director, and Industrial Liaison Officer.

1.3 Highlights of Significant Achievements and Impacts

All the highlights, significant achievements and the impacts are listed in the 'Systems Vision section of this volume under the 'Response to SWOT Analysis of Site Visit Report' (please see Section 1.1 or click on SWOT Analysis and Achievements and Impacts). Detailed write-ups were generated on three selected highlights (following pages) of the ERC-RMB and forwarded to Dr. Court Lewis of NSF in January 2010 to satisfy the requirements of the Government Performance and Results Act (GPRA).

Engaging Underrepresented Populations in the Excitement of STEM
"A Critical Next Generation Workforce"
NSF ERC for Revolutionizing Metallic Biomaterials

During the reporting perios, the ERC-RMB's Education and Outreach programs cast a wide net to reach and excite a diverse audience from all academic levels in the school, community college and university systems, as well as to parents and the lay community. A full scale assessment of E&O activities were also carried out by faculty-graduate student team from the NCAT School of Education.

The undergraduate students recruited during the year were joined in summer (6 weeks) by students (12) recruited from partner and other regional institutions (community colleges and a Hispanic-serving university) for an REU program as well as by teachers (5) from the community colleges and school system for an RET program. REU and RET teachers also attended the enrichment seminars in summer, visits to local industries, and the teachers additionally received instruction on development of effective learning modules delivered by a subject matter expert from the local school system. During 2009, ERC students and staff were active in visiting local schools for STEM related activity (over 400 students were served at their home schools or at local workshop/competition venues) as well as hosting student, teachers and family members (over 450 served – mostly underrepresented minorities) connected with local schools as well as statewide. Targeted underrepresented populations were reached through our strategic partnerships with organizations including schools in predominantly minority-serving locations, NC-LSAMP, and AGEP. At NCAT, a daylong STEM related camp for Girl Scouts (~ 20 Girl Scouts) and a week-long summer camp called the Nano-to-Bio Institute (~20 high school students) were conducted. All the outreach activities received effective and positive media coverage

Graduate students and undergraduates recruited formed the nuclei of faculty - student research teams that began work in Sp09, and continued to function effectively in Summer 2009. During Summer09, a seminar series was started that included presentations by faculty, post doc and graduate students on specific research topics, as well as by guest speakers on enrichment topics such as research methodology, effective use of data collection and visualization software, presentation skills, graduate study and funding opportunities. A Student Summit organized at NCAT enabled mingling and discussion between ERC students/faculty/scientists from all the partner institutions. This has been supplemented by periodic tele-meetings of the Student Leadership Council, as well as frequent travel between campuses of faculty-graduate student teams for research exchanges. Further, NCAT, Pitt and UC ERC students and faculty participated effectively in the 2009 Bio Medical Engineering Society Conference in Pittsburgh. An inter-campus collaboration has led to the students taking leadership in generating the ERC's first newsletter, in Sp 2010. During F09, Sp10 NCAT (many minority students), Pitt and UC graduate students made good use of the cyberinfrastructure by taking Pitt-led courses introducing the Principles of Cell Biology and Principles of Biodegradable Metals along with modules on creativity and innovation.

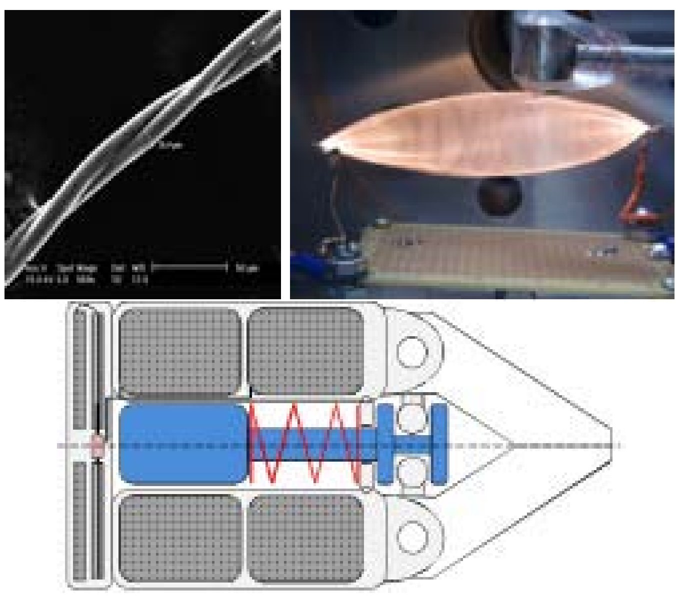
(a) 2009 Summer Awards Ceremony at NCAT (b) 2009 Student Leadership Council Retreat at NCAT

Breakthrough in Synthesis of Centimeter-long Carbon Nanotubes

The Engineering Research Center (ERC) for Revolutionizing Metallic Biomaterials (RMB), launched in September 2008, has already obtained breakthrough results in catalytic synthesis of centimeter-long carbon nanotube (CNT) arrays through chemical vapor deposition (CVD). Based at North Carolina Agricultural and Technical State University (NCAT), the RMB is the first NSF-funded ERC to be headquartered at an Historically Black College and University (HBCU). NCAT's partner institutions in the Center are the University of Cincinnati and the University of Pittsburgh. The RMB Center's goal is to "transform current medical and surgical treatments by creating 'smart' implants for craniofacial, dental, orthopedic, and cardiovascular interventions."

The Center's current research efforts are aimed at scaling up the process and developing the manufacturing tools and methods that industry needs to "mass produce" aligned carbon nanotubes. The ERC's multi-campus, multidisciplinary team is exploring the use of CNT arrays for manufacturing biosensors, electrodes, and as scaffolds for supporting neurite growth and nerve regeneration. The scientific challenge is to make the CNT materials stronger and more electrically conductive, and to make the manufacturing technology scalable to provide industrial quantities of material. The RBM Center is working on a number of end-use applications for carbon nanotubes, including a simple carbon electric motor and a surgical micro-robot

This project will continue to deliver high-quality CNT materials, including towers for biosensors and yarn for scaffolds supporting neurite growth. The collective long-term experience of U.S.-based researchers in this field, along with its state-of-the-art facilities for manufacturing carbon nanotubes, make the U.S. a global leader in the synthesis, processing, and application of CNT materials for advanced biomedical and electronics applications.



The Engineering Research Center for Revolutionizing Metallic Biomaterials (RMB) is developing applications for carbon nanotubes, including (top left) 2 ply CNT yarn, (top right) carbon electric motor, and (bottom) a concept for a surgical micro-robot.

NC A&T SU NSF- Gen 3 Engineering Research Center on the Move - Globally!

The NSF Gen 3 Engineering Research Center (ERC) for Revolutionizing Metallic Biomaterials (RMB) based at NC A&T SU (first time that an ERC is headquartered at an HBCU) worked proactively to set a strong global leadership presence. The whole premise is to transform current medical and surgical treatments by creating "smart" implants to improve treatments for cardiovascular, orthopedic and craniofacial ailments. The promise is that new kinds of implants designed using biodegradable metals can grow and adapt to the human body they are implanted in and eventually dissolve when no longer needed. That would spare patients from pain and expense of the multiple procedures used to implant, then later remove, refit and re-implant the current generation of devices.

During 2009, Hannover Medical School (MHH) a world leader in biomedical and engineering research worked closely with the ERC team as the global research partner. Dr. Frank Witte, the Director of Biomaterials Research, Orthopedic Surgery at the MHH, and an authority on metal implants, visited NC A&T and the ERC university partners several times to move the research ahead. Through MHH, a research relationship with GKSS (Germany's federally funded research facility) has also been established. GKSS is one of the world leaders in biodegradable magnesium application development.

Further, a team of scientists from the ERC visited Germany and initiated strategic activities with the Presidents, Directors and scientists of MHH, GKSS and the Gabriel Lippmann Institute in Luxembourg. The idea is aimed at conducting globalized research coupled with multiple site distance learning, while integrating global entrepreneurial ideas for creating the next generation workforce to undertake and solve a variety of complex problems facing the medical field. The visit also facilitated the establishment of the first ERC-RMB satellite for the European Union (EU) to actively connect members of the ERC -RMB with potential researchers and industries in Europe for collaborative research and funding with the parent ERC in the USA. The partnership includes, in addition to the joint research activities, provisions for visiting scholars and student exchange programs, and jointly organizing biomaterials-related conferences etc. Already the ERC has organized many videoconference based meetings of researchers and students for research and education purposes regularly and as well as student exchange programs

Further, this global initiative resulted in organizing the First BioMg09 Think-Tank Workshop in Greensboro, NC on November 6-7, 2009. The meeting brought together faculty and students of the ERC with our industrial partners in the health sciences and materials processing fields from the U.S., Germany, and Canada (figure). The world leaders through various technical presentations brain stormed the status of biodegradable metals research and a strategic plan of the ERC along with various seamless integrated projects and priorities to address the transformational areas under innovation in metals design, processing and interfacial assessment both *in vitro* and *in vivo*.

2. Strategic Research Plan and Overall Research Program

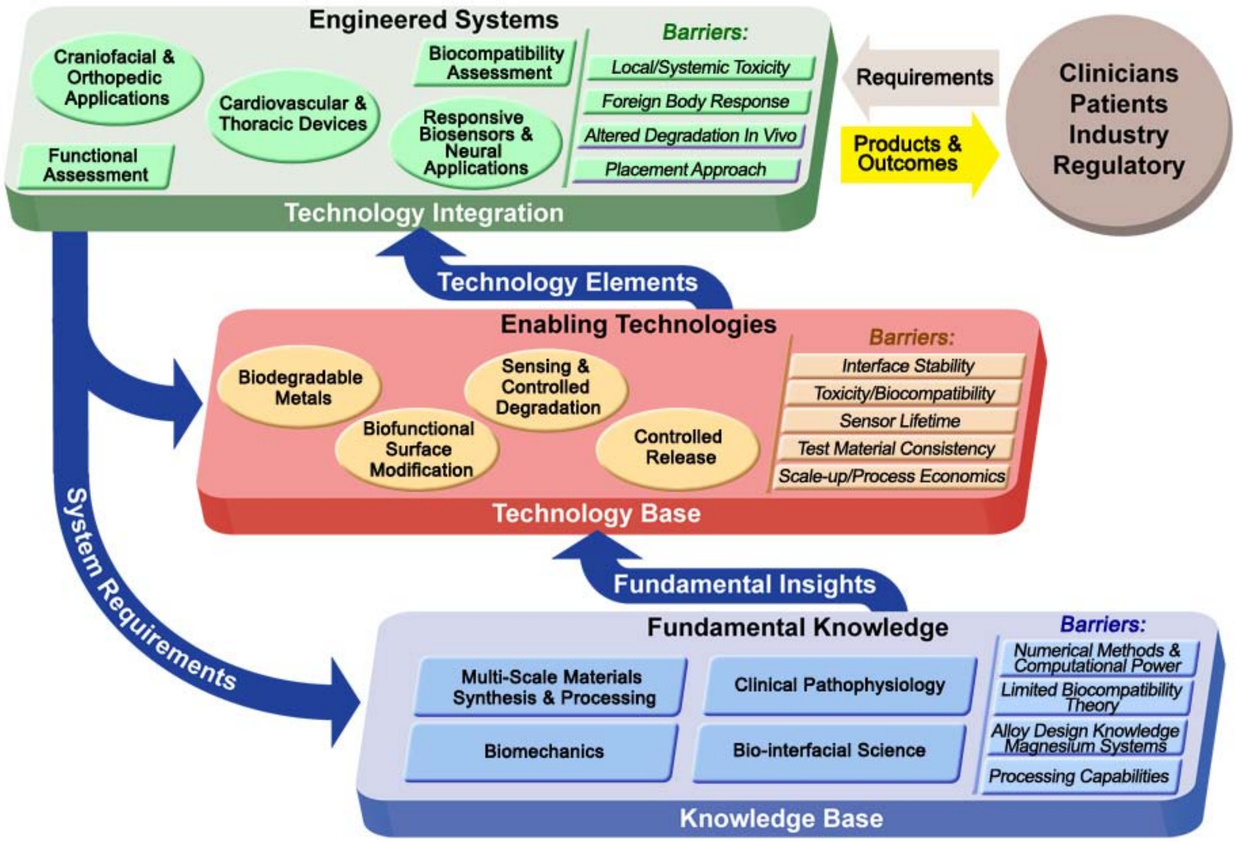
During the reporting period, ERC-RMB redefined the strategic research plan and overall research program to address the Year 01 Site Visit Report SWOT Analysis. While the following paragraphs briefly describe the steps taken, more details were presented earlier in this volume in the SWOT Analysis discussion (please see Section 1.1 or click on SWOT Analysis) and the pages following it.

During Year 02, the ERC team developed a new strategic plan to operationalize the NSF 3-plane strategic framework. Both figures are seen in Section 2.1 ahead. The strategic plan serves as the organizing principle that focuses the multidisciplinary research conducted within enabling technologies and fundamental knowledge to address barriers associated with each engineered system (ES) test bed.

Based on ES test beds and ES-related biomedical devices and applications, the new strategic plan combines enabling technologies and fundamental knowledge into three overarching research thrust areas: 1) new materials development; 2) materials processing/characterization and device modeling; and 3) biocompatibility testing. In the figures, please note that gray regions relate to device or testbed-related activities. Red/salmon corresponds to new materials development. Blue refers to materials processing/characterization and device modeling and green indicates biocompatibility testing. Each of the ESs has multiple projects from these thrust areas, presented in a table in Section 2.1 after the research strategic plan. The thrust areas also comprise growing research and education competencies within ERC-RMB.

Full details of the strategic thought processes used in developing research plans that address the SWOT Analysis, along with thrust groupings and focused projects were given in an earlier section: "Integrative Construct of the ERC-RMB to Achieve the Above Outcomes and Impacts" (please see Section 1.2.2 or click on Integrative Construct). Information was also presented on the RMB materials database (please see Section 1.2.2 or click on Materials Database). Further, in Section 2.1, following the table of thrusts and projects, is a table detailing the preliminary design objectives for the devices and applications. As indicated earlier, this table is a constantly evolving roadmap towards the creation of materials by design, with inputs from industry experts, clinicians, regulatory experts and academic experts.

2.1 ERC Strategic Research Plan with Barriers



ERC-RMB: Updated 3-plane Strategic Planning Chart with Barriers