Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group

The Surgical Sciences, Biomedical Imaging, and Bioengineering (SBIB) IRG will review applications for research grants that address topics in a variety of areas at the interface between a physical science or engineering and biomedical or clinical research. Major areas include: (1) Development of molecular probes and contrast agents; development of molecular imaging techniques; and basic, applied, and pre-clinical aspects of the design and development of medical imaging systems (including hardware, software and mathematical methods of image analysis) for studying organs or whole animals (including humans). (2) Application of computational sciences to knowledge and information in biomedicine, healthcare and their integration. (3) Development of: biomedical sensing and measurement instrumentation; diagnostic instrumentation creating knowledge to enhance organ system function and recovery; innovative biologics, materials, processes, implants, devices; and informatics approaches to prevent, diagnose, and treat disease. (4) Surgery and anesthesiology; host response to sepsis and injury; surgical and microsurgical therapies; surgical critical care and emergency medicine; treatment of trauma; multi-organ responses to surgery; and surgical aspects of transplantation, immunobiology, and organ preservation.

The following study sections are included within this IRG:

- Biomedical Imaging Technology (BMIT)
- Medical Imaging (MI)
- Biomedical Computing and Health Informatics (BCHI)
- Bioengineering, Technology, and Surgical Sciences (BTSS)
- Surgery, Anesthesiology, and Trauma (SAT)
- SBIR Biomedical Imaging (SBMI)
- SBIR Bioengineering, Surgical Sciences and Technology (SBTS)
- SBIR Biomedical Sensing, Measurement and Instrumentation (SSMI)

The study sections of the Surgical Sciences, Biomedical Imaging, and Bioengineering (SBIB) IRG are among the first of the new or reorganized study sections to be proposed for implementation. As a result, some of the recommendations for other IRGs that may share interests in areas of research with the SBIB IRG are not yet complete. Therefore, the proposed “shared interest” guidelines for each of the study sections listed below are tentative, pending further input from the remaining study section design teams, the scientific community, the CSR Advisory Committee, and the Director of CSR.

Biomedical Imaging Technology (BMIT)

The Biomedical Imaging Technology (BMIT) study section reviews grant applications involving basic, applied, and pre-clinical aspects of the design and development of medical imaging systems, their components, software, and mathematical methods; as well as related technologies, for studies at the organ, small or large animal, and human scale.

Specific Areas Covered by BMIT Include:

- Component technologies used in the design, development, implementation, testing and application of imaging systems, such as: image detectors and related energy conversion devices, ionizing and non-ionizing radiation detectors, magnets and coils, and other technologies used in devices to acquire medical image data.

- Physics and mathematics of medical imaging devices and systems for hardware and software development: application of methods of applied mathematics for solving inverse problems using iterative, non-iterative, deterministic and probabilistic approaches; and analysis of complex dynamical systems.

- Methods of processing medical images: display, and computational resources for reconstruction, registration, segmentation, visualization, and analysis of 2-, 3-, and 4- (or higher) dimensional data sets.

- Medical image analysis used in conjunction with other sources of image and non-image data, including: multi-media data, data transmitted and archived in databases for data mining, artificial intelligence, computer vision, and computer-aided diagnosis.

- Presentation for human observers, images derived from voluminous multi-dimensional data sets by visualization, including: man-machine interfaces; real-time interactive systems; multi-modality fusion; multi-temporal data sets; and workstation software and hardware design, implementation, and psychophysical testing.

- Development of image-based methods and strategies to characterize tissue by deriving estimates of their local and global biophysical, biochemical, biological, and imaging properties.

- Image-guided surgical or physical interventions that require high performance computing and display of images for interactive man-machine environments that simultaneously, or sequentially, diagnose, plan, treat, update, and follow-up.

- Integration of imaging system component technologies with one or multiple modalities, (including high performance computing environments and software) to accomplish specific medical tasks.

Shared Interests Within the IRG:

- With MI: Where emphasis is on the development of molecular probes, contrast agents, or molecular imaging techniques, the application would be referred to MI; where emphasis is on the design or development of medical imaging systems, their components, or software the application would be referred to BMIT.

- With MI regarding imaging proposals: Where equipment, software and technique development are underway simultaneous with the development, evaluation, and validation of the imaging application. In general, proposals that emphasize the application or validation of *in vivo* imaging approaches would be referred to MI; those that emphasize the design or development of medical imaging systems, their components, or software would be referred to BMIT.

Shared Interests Outside the IRG:

- With the Bioengineering Sciences and Technologies (BST) IRG: The development of instrumentation, techniques, or procedures for imaging molecules or organelles is an area of shared interest. If the purpose of imaging is to address questions of pathology, diagnosis, or treatment assignment would be to BMIT. If the objective of the imaging is to investigate mechanisms or fundamental biological questions, assignment would be to BMT.

- With organ-system and disease IRGs: Review venue should be based on the nature of the scientific questions being addressed. In general, applications for which the emphasis is on the design or development of medical imaging systems, their components, or software would be referred to BMIT; where the emphasis is on obtaining structural, functional, or behavioral information the application would be referred to an organ-system or disease IRG.

Medical Imaging (MI)

The Medical Imaging (MI) study section reviews proposals involving the application and validation of *in vivo* imaging of humans and animals, including early phase clinical studies of medical imaging systems, molecular probes and contrast agents, software, molecular imaging techniques, and related technologies. The underlying technologies may be refined and optimized during testing in response to research questions or clinical needs.

Specific Areas Covered by MI Include:

- Evaluation of improvements in technologies underlying medical imaging systems.

- Studies of widely available medical imaging systems to evaluate novel medical applications.

- Pre-clinical, Phase-I, and -II clinical trials of medical imaging systems and accessories.

- Prediction, selection, and monitoring of therapeutic response based on imaging studies, with or without exogenous agents, using one or more modalities, especially for multi-temporal investigations to measure changes relative to a pretreatment baseline.

- Applications of imaging systems and modification of diagnostic methods for use in: screening; characterizing physiological effects, such as normal tissue tolerance or low-level radiation effects; and assessing risk.

- Image-guided interventions in integrated diagnostic and therapeutic systems.

- Methodology for validating medical imaging systems including: reference objects, databases, quality control criteria, software metrics, and related components.

- Medical-image-observer performance: modeling, metrics, calibration, standards, and simulation of an ideal observe using principles of psychophysical experimentation.

- *In vivo* strategies and methods for characterizing tissue, and distinguishing between normal and pathologic states, based on estimates of biophysical, (biomechanical, bioelectrical, etc.) biochemical, metabolic, perfusion/diffusion, or other properties determined locally or globally by imaging.

- Development of surrogate endpoints based on quantitative imaging for use in clinical trials of medical devices, pharmaceuticals, biologics and other therapeutic interventions.

- Incorporation of the results of imaging in medical decision making: modeling imaging systems and applications; application of medical imaging to various populations and throughout the phases of growth and development; use of imaging in outcome evaluation; and cost modeling of medical imaging systems and their applications.

- Development and application of standards for control of image quality and imaging software using reusable, portable, extensible and open source approaches.

- Integrative, correlative and comparative studies of normal and pathologic states that employ multi-modal, multi-temporal, and multi-dimensional medical imaging systems and techniques.

- Prediction, selection and monitoring therapeutic response by administering agents and imaging, to detect the location, amount, and fate of the agent in normal and diseased tissues. This implies multi-temporal, image-based evaluation of tracers and metabolites in a detailed anatomic framework that could require multiple modalities and post-processing of complex data sets.

- Diagnosis of functional disorders and classification of tissue as normal or pathologic based on exogenous agents that may be tailored to specific cellular processes or genetic expressions.

- Synthesis of new diagnostic agents or therapeutic pharmaceuticals used in medical imaging studies with attention to quality control, toxicology, biodistribution, and breakdown products; these studies often involve radiochemistry, pharmacokinetics, and pharmacodynamics.

Shared Interests Within the IRG:

- With BMIT regarding imaging proposals where equipment, software and technique development are underway simultaneous with the development, evaluation, and validation of the imaging application: In general, proposals that emphasize the design or development of medical imaging systems, their components, or software would be referred to BMIT; those that emphasize the application or validation of *in vivo* imaging approaches would be referred to MI.

Shared Interests Outside the IRG:

- With the Biological Chemistry and Macromolecular Biophysics (BCMB) IRG: In general, the synthesis of radiolabeled compounds involving metal complexes would be referred to BCMB, however, if imaging studies are involved MI would be appropriate

- With the Bioengineering Sciences and Technologies (BST) IRG: The development of techniques or procedures for imaging molecules or organelles is an area of shared interest. If the purpose of imaging is to address questions of pathology, diagnosis, or treatment assignment would be to MI. If the objective of the imaging is to investigate mechanisms or fundamental biological questions, assignment would be to BST.

- With the Digestive Sciences (DIG) IRG: In general, studies of the toxicity, biodistribution, breakdown products, pharmacokinetics and pharmacodynamics of pharmaceutical compounds would be reviewed in DIG; if the compound is used in conjunction with imaging studies review could be in MI.

- With organ-system and disease IRGs: Review venue should be based on the nature of the scientific questions being addressed. In general, proposals involving the initial application or validation of an *in vivo* imaging approach would be referred to MI; where imaging is being used as a tool to study a condition, process, therapy, etc., the application would be referred to an organ-system or disease IRG.

Biomedical Computing and Health Informatics (BCHI)

The Biomedical Computing and Health Informatics study section reviews proposals involving both basic research and applications of computational science to knowledge and information in biomedicine, healthcare and their integration. The focus is on the development and application of computational modeling and computational sciences to biomedical and clinical problems. This includes methods and techniques from such disciplines as software engineering, telecommunications, human-computer interaction, advanced computing architectures, and knowledge/information management. This study section reviews all grant mechanisms, including SBIR and STTR.

Specific Areas Covered by BCHI Include:

- Application of modeling methods to various levels of normal and pathophysiological processes.

- Application and development of human-centered computing (human-machine interfaces) to biomedical and clinical systems, including the application of social sciences, cognitive sciences, ergonomics and the study of collaboration to engineer-usable effective software systems.

- Application of intelligent systems to biomedical and clinical problems.

- Mathematical modeling of physiological functions/systems, where the outcome is of medical/clinical import.

- Application of data analysis, management, and mining to areas such as: electronic medical records, picture archiving, tele-imaging, consumer informatics, population-based databases, and probabilistic atlases.

- Development of medical and biomedical knowledge and information-management systems, including ontologies and controlled vocabularies.

- Application of clinical and biomedical software engineering, including validation of software in clinical settings.

- Development of telemedicine systems.

- Development of computer-assisted diagnosis and treatment systems with data other than imaging data.

- Integration of genomics and proteomics information with clinical information.

- Application of advanced computing architectures to questions in biomedical and clinical information and knowledge management.

- Application of virtual environments to the solution of biomedical and clinical problems.

- Development and dissemination of standards in biomedical computing and health informatics.

- Development and application of evaluation and validation techniques for biomedical and health informatics systems and applications.

Shared Interests Within the IRG:

- With BMIT, and SBMI: In general, grant applications that focus on specific methods, techniques or validation of medical and biomedical imaging questions would be referred to BMIT or SBMI; if the focus is on informatics, it would be referred to BCHI.

- With BTSS and SSMI: In general, grant applications that develop or use informatics in the context of developing medical devices and instrumentation would be referred to BTSS or SSMI; if the focus is on informatics, it would be referred to BCHI.

Shared Interests Outside the IRG:

- Applications in which informatics is used as a tool in the biomedical discovery process, or to support clinical studies, would be assigned to the study section dealing with the particular biomedical or clinical topic. If the focus of the application is on informatics, but uses a biomedical discovery, process, or clinical question to demonstrate and/or validate the informatics approach, it would be referred to BCHI.

- With the Bioengineering Sciences and Technologies (BST) IRG: In general, the development of mathematical models would be referred to BST; if the purpose of the model is to inform medical decision making the application would be referred to BCHI.

- With the Bioengineering Sciences and Technologies (BST) IRG, the Biobehavioral and Behavioral Processes (BBBP) IRG, the Molecular, Cellular, and Developmental Neuroscience (MDCN) IRG, and the Integrative, Functional, and Cognitive Neuroscience (IFCN) IRG: Grant applications that focus on computational neuroscience should be referred to BST, BBBP, MDCN, or IFCN rather than to BCHI.

Bioengineering, Technology, and Surgical Sciences (BTSS)

Applications reviewed by BTSS integrate physical, chemical, or mathematical sciences and engineering principles to study physiology, medicine, behavior, or health. These applications exhibit a systematic, quantitative, and integrative way of thinking about and approaching the solution of problems important to physiology and clinical medicine. They advance fundamental and applied concepts, creating knowledge for enhancing the function and recovery of organ systems; or they develop innovative medical instruments, materials, processes, implants, devices, and informatics approaches for the prevention, diagnosis, or treatment of disease. Surgical science applies biomedical devices and instruments to the diagnosis, and treatment of disease and injury. Pre-clinical studies involving the application of devices and instrumentation are also included.

Specific Areas Covered by BTSS Include:

- Development of advanced tools and techniques that permit tissue engineering.
- Development of cellular and tissue-engineered constructs, including: design, construction, and pre-clinical and clinical evaluation of function.
- Development of therapeutic devices and systems (such as artificial organs and cardiovascular devices), implantable medical devices (such as stents, grafts, and valves), and devices for the delivery of bio-molecules and drugs.
- Application of biomedical technology to diagnosis, measurement and instrument-development.
- Design, development and evaluation of medical devices, using animal models and pre-clinical human studies.
- Design and development of endosurgical procedures, catheter-based surgery, minimally invasive surgery, microsurgical procedures, monitoring devices, and robotics.
- Vertically integrated development of medical devices from bench to bedside, including: pre-clinical human studies, translational development, and clinical validation.
- Fluid mechanics studies of circulation, microcirculation, and transport systems.
- Development and evaluation of surgical systems and technologies using animal models and pre-clinical human studies.
- Biomechanics, including: tissue and organ mechanics and the mechanics of injury.

Shared Interest Within the IRG:

- With BMIT: Studies of the development of new technology, system design, detector methods or image acquisition systems would be referred to BMIT; applications that emphasize the integration of physical, chemical, mathematical or engineering principles in the study of physiology or medicine would be referred to BTSS.

- With BCHI: Grant applications that focus on informatics would be referred to BCHI; while those that develop or use informatics in the context of developing medical devices or instrumentation would be referred to BTSS.

- With SAT: Grant applications focused on anesthesiology, critical care, surgery, sepsis, and wound repair would be referred to SAT; applications in which the emphasis is on the integration of physical, chemical, mathematical or engineering principles in the study of physiology, medicine, or surgery would be referred to BTSS.

Shared Interests Outside the IRG:

- With the Bioengineering Sciences and Technologies (BST) IRG: In general, applications concerned with the fundamental aspects of biomaterials and biocompatibility, cell and tissue engineering, or molecular and cellular mechanics would be referred to BST; grant applications involving the integration of physical, chemical, mathematical or engineering principles in the study of physiology or medicine would be referred to BTSS. In general, applications proposing the development of molecular or nano-scale vehicles to deliver drugs, genes, or gene products would be referred to BST; applications proposing the development of macroscopic vehicles to deliver therapeutic agents would be referred to BTSS.

- With the Cardiovascular Sciences (CVS) IRG: There is a shared interest between CVS and BTSS in the bioengineering design and development of implantable cardiovascular devices. Applications should be assigned to BTSS or to CVS depending on the focus of the study.

- With the Musculoskeletal, Oral, and Skin Sciences (MOSS) IRG: In general, studies of orthopedic and dental devices would be referred to MOSS; studies involving tissue engineering could be referred to MOSS or to BTSS depending on the focus of the study.

- With the Digestive Sciences (DIG) IRG: In general, applications concerned the kinetics or metabolism of pharmaceuticals would be referred to DIG; those focused on the development of the drug delivery system would be referred to BTSS.

- With all organ-specific IRGs: In general studies focused on a particular organ system would be referred to the appropriate organ-specific IRG; applications where the emphasis is on the integration of physical, chemical, mathematical or engineering principles in the study of the physiology or pathology of the organ system would be referred to BTSS.

Surgery, Anesthesiology, and Trauma (SAT)

Surgery, Anesthesiology, and Trauma reviews grant applications in the complementary disciplines of surgery and anesthesiology, as well as in surgical critical care. Sepsis studies that are reviewed by SAT are in general limited to multi-organ or systemic host injury responses to complex insults such as trauma, disseminated infection, or surgical stress; many such responses occur as postoperative complications. Anesthesiology and surgical critical care are more comprehensively reviewed.

Specific Areas Covered by SAT Include:

- Metabolic, hormonal, or inflammatory/immune injury responses to trauma, burn, sepsis, hemorrhage, ischemia-reperfusion, cardiopulmonary resuscitation, or surgical stress.
- Genetic determinants of response to injury, and genetic or pharmacologic approaches to promote modulation of injury.
- Pathogenesis and amelioration of shock and multiple organ dysfunction/failure.
- Pathogenesis/amelioration of hypoxic or oxidative cell/ tissue insults.
- Multi-modal treatment of critical injury, including nutritional support.
- Wound healing, including tissue repair/regeneration.
- Pharmacology of general and local anesthetics, including mechanisms of general and local anesthesia and of anesthetic side effects.
- Pain mechanisms and pain management in surgery and anesthesiology.
- Surgical aspects of organ, tissue, and cellular transplantation.
- Surgical aspects of organ preservation.
- Surgical approaches to organ/tissue-specific disease, injury, or repair.

Shared Interest Within the IRG:

- With BTSS: Applications dealing with anesthesiology, surgical critical care or multi-organ or systemic injury responses to complex insults in the perioperative setting would in general be referred to SAT; those in which the emphasis is on integrating physical, chemical, mathematical or engineering principles with the above areas would be referred to BTSS.

Shared Interest Outside the IRG:

- With the Genes, Genomes, and Genetics (GGG) IRG: In general, applications that focus on genetics would be referred to GGG; applications that focus on injury or the

treatment of injury, including those with a genetic component, would be referred to SAT.

- With the Immunology (IMM) IRG: In general, applications dealing with inflammatory injury responses mediated by immune activation in trauma, burn, wound, hemorrhage, ischemia-reperfusion, or post-operative sepsis would be referred to SAT; those dealing with response to inflammatory injury in a non-surgical context would be referred to IMM. In general, organ/ tissue/ cellular transplantation applications that are immunology focused (e.g., that deal with recipient rejection of, or tolerance to, donor xeno- or allografts) would be referred to IMM; transplantation applications that focus on surgery, for example, studies of organ/ tissue/ cell injury responses to hypo- or normo-thermic ischemia-reperfusion insult would be referred to SAT.

- With the Infectious Diseases and Microbiology (IDM) IRG: In general applications focusing on immune responses to local and/or disseminated infection (i.e., post operative wound infection, abscess or sepsis) would be referred to SAT; applications focusing on immune response to infection in a non-surgical context, or which focus on the infectious agent, would be referred to IDM.

- With the Hematology (HEME) IRG: In general applications dealing with hypo- or hyper-coagulability or complement activation in the context of surgery (trauma, hemorrhage, post-operative sepsis) would be referred to SAT; those dealing with coagulability or complement activation in non-surgical contexts would be referred to HEME.

- With the Cardiovascular Sciences (CVS) IRG: In general, studies of cardiovascular problems would be referred to CVS; those dealing with ischemia-reperfusion injury to organs/ tissues in a surgical context would be referred to SAT. However, studies of cardiac function in response to myocardial ischemia/reperfusion injury associated with cardiac surgery or cardiopulmonary bypass would be referred to CVS.

- With the Endocrinology, Metabolism, Nutrition, and Reproductive Sciences (EMNR) IRG: In general, studies of metabolic or hormonal responses to hypoxic, oxidative, or surgical insults would be referred to SAT. In general, studies of nutritional support in the treatment of metabolic (excluding those of the digestive system) or hormonal disorders and diseases would be referred to EMNR; studies of nutritional support in the context of surgical care (including the treatment of burns, trauma and sepsis) would be referred to SAT.

- With the Digestive Sciences (DIG) IRG: In general, applications dealing with gastrointestinal aspects of trauma, burns, and surgical critical care would be referred to SAT; applications focused on ischemia would be referred to DIG or SAT depending on the focus of the study. Applications focused on nutritional support in the treatment of digestive diseases would be referred to DIG; studies of nutritional support in the context of surgical care (including the treatment of burns, trauma and sepsis) would be referred to SAT. Applications focused on other aspects of the gastrointestinal system would be referred to DIG.

- With the Respiratory Sciences (RES) IRG: In general, applications dealing with pulmonary aspects of trauma, burns, ischemia, and surgical critical care would be

referred to SAT; applications dealing with other aspects of lung, including responses of the pulmonary system to surgical procedures, would be referred to RES.

- With the Integrative, Functional, and Cognitive Neuroscience (IFCN) IRG: In general, studies of neural mechanisms and perception of pain would be referred to IFCN, studies of pain the context of surgery or anesthesia would be referred to SAT.

- With organ-specific IRGs: In general, studies of organ-specific disorders treated surgically would be referred to the appropriate organ-specific IRG; studies (1) dealing with multi-organ or systemic injury responses to organ-specific disorders (e.g., hemorrhagic shock from a ruptured aortic aneurysm or sepsis developing from a liver abscess) or (2) focused on the design, development, or validation of novel surgical procedures would be referred to SAT.

SBIR Biomedical Imaging (SBMI) (SBIR/STTR)

The SBIR Biomedical Imaging (SBMI) study section reviews SBIR and STTR grant applications involving basic, applied and pre-clinical aspects of the design and development of medical imaging systems, their components, software and mathematical methods, and related technologies. Also reviewed are proposals involving the application and validation of *in vivo* human and animal imaging, including early phase clinical aspects of medical imaging systems, agents, software and mathematical methods, or related technologies. During testing, the underlying technologies may be refined or optimized in response to research questions and clinical needs.

Specific Areas Covered by SBMI Include:

- Prediction, selection, and monitoring of therapeutic response by administration of agents accompanied by imaging to detect the location, amount, and fate of normal and pathologic structures. This implies multi-temporal image-based evaluation of tracers and metabolites in a detailed anatomic framework that could require multiple modalities and post-processing of data sets.

- Diagnosis of functional disorders and classification of tissue as normal or pathologic based on exogenous agents that may be tailored to specific cellular processes or genetic expressions.

- Studies of component technologies used in the design, development, implementation, testing, and application of imaging systems (such as: image detectors and related energy conversion devices, ionizing and non-ionizing detectors, magnets and coils).

- Physics and mathematics approaches to the development of medical imaging devices and systems (hardware and software): for example, the analysis of complex dynamical systems and the application of methods of applied mathematics to solving inverse problems using iterative, non-iterative, deterministic, and probabilistic approaches.

- Medical image processing methods: display, and computational resources for reconstruction, registration, segmentation, visualization, and analysis of 2-, 3- and 4- or higher dimensional data sets.

- Analysis of medical images in conjunction with other sources of non-image data including: multi-media data, data transmitted and archived in databases for data mining, artificial intelligence, computer vision, and computer-aided diagnosis.

- Presentation for human observers, images derived from voluminous multi-dimensional data sets by visualization, including: man-machine interfaces; real-time interactive systems; multi-modality fusion; multi-temporal data sets; and workstation software and hardware design, implementation, and psychophysical testing.

- Development of image-based methods for characterizing tissues using estimates of their local and global biophysical, (biomechanical, bioelectrical, etc.) biochemical, metabolic, and biological properties.

- Correlative and comparative studies of normal and pathologic states using multi-modal, multi-temporal, and multi-dimensional imaging systems and techniques.

- Image-guided interventions in integrated diagnostic and therapeutic systems. These often require high performance computing and display for interactive man-machine environments.

- Integration of unique imaging systems to accomplish specific tasks.

- Evaluation of prototype and widely available medical imaging systems and accessories, when there are improvements in underlying technologies.

- Methodology for validating medical imaging systems, including: reference objects, databases, quality control criteria, software metrics, and related components.

- Use of imaging to predict, select, and monitor therapeutic responses.

- Applications of imaging systems and modification of diagnostic methods for use in: screening, characterizing physiological effects (such as normal tissue tolerance or low-level radiation effects), and assessing risk.

- Use of principles of psychophysical experimentation and modeling to develop medical-image-observer performance metrics, calibration standards, and simulations of an ideal observer.

- Development of surrogate endpoints based on quantitative imaging for use in clinical trials of medical devices, pharmaceuticals, and other therapeutic interventions.

- Development and application of standards for control of image quality and imaging software using reusable, portable, and extensible open source approaches.

- Synthesis of new diagnostic agents or therapeutic pharmaceuticals used in medical imaging studies.

Shared Interest Within the IRG:

- With BCHI: In general, grant applications that develop or use informatics in the context of developing medical imaging devices and instrumentation would be referred to SBMI; while those that the focus is on informatics would be referred to BCHI.

Shared Interests Outside the IRG:

- With the Bioengineering Sciences and Technologies (BST) IRG: The development of instrumentation, techniques, or procedures for imaging molecules or organelles is an area of shared interest. If the purpose of imaging is to address questions of pathology, diagnosis, or treatment assignment would be to SBMI. If the objective of the imaging is to investigate mechanisms or fundamental biological questions, assignment would be to BST.

- With organ-system and disease IRGs: Review venue should be based on the nature of the scientific questions being addressed. In general, applications for which the emphasis is on the design or development of medical imaging systems, their components, or software would be referred to SBMI; where the emphasis is on obtaining structural, functional, or behavioral information the application would be referred to an organ-system or disease IRG.

Bioengineering, Surgical Sciences, and Technology (SBTS) (SBIR/STTR)*

This study section reviews grant applications for the small businesses initiative programs (SBIR and STTR) involved in innovative research and technology development of biomedical devices and systems for treating human diseases. They involve integration of biomedical devices into living systems; or propose systematic, quantitative, and integrative approaches to thinking about and addressing problems important to physiology or clinical medicine.

These bioengineering and surgical science projects integrate physical, chemical, or mathematical sciences and engineering principles into the study of biology, medicine, behavior, and health. They develop innovative biologics, materials, processes, implants, and devices, for the prevention, diagnosis, or treatment of disease. Surgical sciences integrate the device and instrumentation applications into living systems. Studies involving minimally invasive surgery, microsurgery, computer-assisted surgery, and robotics are reviewed in this study section. Pre-clinical studies and studies focused on applications of device/instrumentation are included.

Specific Areas Covered by SBTS:

- Therapeutic devices and systems: including artificial organs, implantable medical devices, bio-molecule delivery/immobilization devices, and prosthetic devices.

- Advanced techniques and devices that permit tissue engineering, endosurgical approaches, catheter-based surgery, minimally invasive surgery, microsurgical procedures, robotics, and image-guided intervention.

- Development of cellular and tissue-engineered constructs, including: design, construction, and pre-clinical and clinical evaluation of function.

- Development of vertically integrated medical devices, including: pre-clinical human studies, translational medical device development and clinical device validation.

- Optimization of design, development of standards, and monitoring and evaluating medical devices.

Shared Interest Within the IRG:

- With SBMI: Grant applications proposing the design or development of medical imaging systems, their components, software, or methods of image analysis would be referred to SBMI. Applications proposing the design or development of diagnostic or therapeutic devices or their components would be referred to SBTS.

Shared Interests Outside the IRG:

- With the Bioengineering Sciences and Technologies (BST) IRG: In general, bioengineering projects would be referred to BST if the focus of the study is technology development or if the results of the developmental effort could apply to multiple devices; if specific medical or medical research device(s) are being developed, the project would be referred to SBTS, or to an organ-system IRG.

- With the organ-system IRGs: Applications having a bioengineering or device development focus could be referred to SBTS or to the organ-system IRG depending on the focus of the application. In general, if the device relates to multiple organs, the application would be referred to SBTS.

Biomedical Sensing, Measurement and Instrumentation (SSMI) (SBIR/STTR)*

This study section reviews grant applications for the small businesses initiative programs (SBIR and STTR) involving biomedical sensing, measurement, and the development of diagnostic and therapeutic instrumentation. Research that focuses on the development of innovative sensors ranges from fundamental physical, mechanical or chemical transduction through basic measurement principles to the design of novel instruments for clinical use.

Specific Areas Covered by SSMI Include:

- Sensor technology: use of sensor technology (including micro- and nanotechnology and micro-electromechanical systems) in the development of medical and medical research instrumentation.

- Measurement devices and systems: Instruments for the physiological monitoring of patients or experimental animals.

- Instruments for the diagnosis or treatment of disease.

- Techniques and technology for processing and controlling physiological signals.

- Techniques and technology for remote medical diagnosis and computer-assisted diagnosis and therapy.

Shared Interests Within the IRG:

- With SBMI: Grant applications proposing the design or development of medical imaging systems, their components, software, or methods of image analysis would be referred to SBMI. Applications proposing the design or development of instruments for diagnosing disease or physiological monitoring of patients or experimental animals would be referred to SSMI.

- With SBST: Grant applications involving the use of biomedical devices for diagnosing or treating human disease would be referred to SBST; if the focus is on instrument development the application should be referred to SSMI.

- With BCHI: Grant applications that the focus is on informatics would be referred to BCHI; while those that develop or use informatics in the context of developing medical devices and instrumentation would be referred to SSMI.

Shared Interests Outside the IRG:

- With the Bioengineering Sciences and Technologies (BST) IRG: In general, applications would be referred to BST if the focus of the proposal is technology development, if the instrument being developed will be used in basic research, or if the purpose of the instrument is not known the proposal would be referred to BST; if the instrument will have medical or medical research applications the proposal would be referred to SSMI.

- With the organ-system IRGs: Applications having a bioengineering or instrument development focus could be referred to SSMI or to the organ-system IRG depending on the focus of the study. In general, studies relating to multiple organs would be referred to SSMI.

* If the total number of SBIR/STTR grant applications assigned to is SSMI and SBST is small the two will meet as a single study section.