

BIOENGINEERING SCIENCES & TECHNOLOGIES (BST) GUIDELINES [Roster]

The Bioengineering Sciences and Technologies (BST) IRG will review research grant applications that focus on fundamental aspects of bioengineering and technology development in the following areas: gene and drug delivery systems, imaging principles for molecules and cells, modeling of biological systems, bioinformatics, statistics and data management, instrumentation, chips and microarrays, biosensors, and biomaterials. A central premise in organizing this IRG is the need for effective review of bioengineering and technology development in early stages before specific practical uses are proven.

The recommendations are that some shared interests among study sections and IRGs are healthy and that bioengineering and technology need review homes where grant applications are assessed on scientific merit, independently of explicit use. Specifically, the areas of gene and drug delivery, micro-scale imaging, biological modeling and bioinformatics, bioinstrumentation, and biomaterials require review in the context of fundamental engineering principles and practice. Thus, to strengthen the advancement of health research, the NIH should ensure commitment to bioengineering and technology development by establishing this cluster of study sections, where research grant applications driven by bioengineering principle or design and validation are expected to be more abundant than those driven by hypothesis or immediate practical use.

The following study sections, each of which would review research project grant (R01) and Small Business and Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grant applications, are recommended for inclusion in the BST IRG:

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The expectation is that each of these study sections will receive 50 or more applications. However, in the event of fewer applications, the Study Section Boundaries Team recommended that MABS and BDMA could be combined, and that MDI and ISD could be combined.

Gene and Drug Delivery Systems Study Section (GDD)

The Gene and Drug Delivery Systems (GDD) study section will consider research applications (R01 and SBIR/STTR) focused on the development and delivery of drugs, genes, and gene products that alter gene function or expression. Areas include the use of engineering principles

and practice for the design and introduction of new strategies and tools to alter gene function or expression:

- Agents delivered: Includes DNA, RNA, RNA interference (RNAi), antisense oligonucleotides, large and small insert vectors, aptamers, peptide nucleic acids (PNAs), small molecule activators and inhibitors, antibiotics, vaccines, peptides, proteins, and other drugs.
- Vehicles: Includes viral and other vectors, liposomes, polyethylene glycol (PEG), and lipid-based transfection agents.
- Delivery strategies: Includes electroporation, ultrasound, receptor mediated translocation, ballistic methods, vesicles, and viral agents.
- Gene regulation of active agents: Includes tissue specificity, external control, nuclear vs. cytoplasmic localization, and targeted integration.
- Expression patterns: Includes tissue and cellular localization, markers for expression, copy number, transcriptional and translational products, and activity-dependent probes.

GDD: Shared Interests Within IRG

- The GDD study section shares interests with the Multi-Dimensional Imaging (MDI) study section in the areas of cellular imaging as a readout, e.g., activity dependent probes, expression patterns, interaction probes, single molecule reporters. Normally, applications focusing on imaging technology and development will be assigned to MDI.
- GDD shares interests with the Instrumentation and Systems Development (ISD) study section in the area of instruments for gene and drug delivery. Applications on nano or microfabricated delivery vehicles and ballistic methods could be assigned to GDD.
- GDD shares interests with the Biomaterials and Biointerfaces (BMBI) study section. Fabrication and synthesis of biomaterials, monitoring of release kinetics and pharmacodynamics, and biomaterials for gene transfer could be assigned to BMBI.

GDD: Shared Interests Outside IRG

- IRG 21 (Surgery, Applied Imaging and Applied Bioengineering/Surgical Sciences, Biomedical Imaging and Bioengineering) shares interests with GDD in the delivery of drugs, genes, and gene products. Proposals requiring implanted delivery devices would normally be reviewed in IRG 21.
- IRG 1 (Biological Chemistry and Macromolecular Biophysics), IRG 2 (Molecular Approaches to Gene Function), IRG 3 (Molecular Approaches to Cell Function and Interactions), IRG 4 (Fundamental Genetics and Population Biology), IRG 5 (Biology of Development and Aging), IRG 7 (Health of the Population), IRG 8 (Risk, Prevention and Health Behavior), IRG 9 (Behavioral and Biobehavioral Processes), IRG 10 (Immunology), IRG 22 (Molecular, Cellular, and Developmental Neuroscience), and IRG 23 (Integrative, Functional, and Cognitive Neuroscience) share basic interests with GDD. Grant applications focused on basic biological mechanisms are relevant to the indicated IRGs. Grant applications focused on the design, development, and introduction of technology in support of gene and drug delivery are relevant to IRG 6 and the GDD study section.

- IRG 11 (Infectious Diseases and Microbiology), IRG 12 (AIDS and Related Research), IRG 13 (Oncological Sciences), IRG 14 (Hematology), IRG 15 (Cardiovascular Sciences), IRG 16 (Endocrinology, Metabolism, and Reproductive Sciences), IRG 17 (Bone, Muscle, Connective Tissue, and Skin), IRG 18 (Digestive Sciences), IRG 19 (Pulmonary Sciences), IRG 20 (Renal and Urological Sciences), and IRG 24 (Brain Disorders and Clinical Neuroscience) share interests. Grant applications focused on organ/disease specific biological mechanisms and therapies are relevant to the indicated IRG. Grant applications focused on developing technologies to introduce genes and drugs in a general cellular context are relevant to IRG 6 and the GDD study section.

Multi-Dimensional Imaging Study Section (MDI)

The Multi-Dimensional Imaging (MDI) study section reviews applications (R01 and SBIR/STTR) that develop, improve and implement quantitative techniques for the static and dynamic visualization of molecules, macromolecular machines and complexes, organelles, cells, and model systems in physiologically active states. Large animal and human studies will not be considered. Examples of methodologies include crystallography, TEM, electron cryomicroscopy, SEM, ESEM, AFM, SFM, confocal and scanning light microscopy, multi-photon microscopy, x-ray microscopy, acoustic microscopy, NMR and microscopic applications of MRI. Imaging principles may be developed, and proposals need not be hypothesis-driven.

Areas covered by MDI include:

- Development and Improvement of Instrumentation: major microscopic devices and accessories such as specimen holders and environmental chambers, high resolution and large pixel detectors, high-resolution film scanners, specimen preparative apparatus, computer automation of data collection and remote access.
- Improvement of Specimen Preparation Methodology: crystallization of membrane proteins and large assemblies, chemical and cryo specimen preservations, non-invasive preparative methods, chemical agents for contrast enhancement, molecular tagging, cell labeling, genetically expressed labels and studies of chemical and radiation damage effects.
- Image Analysis: Validation of image formation theory, data management, phasing methods, algorithm development including filtering, signal detection, data reduction, image enhancement, pattern recognition, restoration, reconstruction, segmentation, feature extraction, and visualization of multi-dimensional information, and high throughput, automatic data processing.
- Data mining: Integration of information derived from complementary imaging techniques and bioinformatics to derive functional mechanisms.

Shared interests within the IRG:

- MDI shares interests with the Gene and Drug Delivery Systems (GDD) study section in the areas of cellular imaging as a readout, e.g., activity dependent probes, expression patterns, interaction probes, single molecule reporters. Normally, applications focusing on imaging technology and development will be assigned to MDI.

- MDI shares interests with the Instrumentation and Systems Development (ISD) study section. If the focus is on the instrument per se then ISD is the appropriate home. However, if the focus were on imaging data analysis, then MDI would be the appropriate home for review.
- MDI shares interests with the Biodata Management and Analysis (BDMA) study section. If the focus is on image archiving then BDMA is the appropriate home. However, if the focus in on generation of images, then MDI would be the appropriate home for review.
- MDI shares interests with the Biomaterials and Biointerfaces (BMBI) study section in development of new materials for use as image enhancers and contrast agents. MDI will review applications emphasizing small molecule and soluble contrast agents; whereas BMBI will review applications emphasizing development of new polymeric or nanoparticle based contrast agents or where materials synthesis, characterization, biocompatibility, and toxicity are prominent.

Shared interests outside the IRG:

- Some shared interest in image analysis and instrumentation development is expected with Biomedical Imaging study sections in IRG21, i.e., Biomedical Imaging Contrast Agents and Probes (BMCAP), Biomedical Imaging Technology (BMIT), and Medical Imaging (MI). However, MDI will not cover studies involved with large animals and human subjects.
- Other potential shared interest is with Biological Chemistry and Macromolecular Biophysics IRG, which generally concerns specific biological systems whereas the proposed MDI is focused on general methodology and technology.

Modeling and Analysis of Biological Systems Study Section (MABS)

The Modeling and Analysis of Biological Systems (MABS) study section will review applications (R01 and SBIR/STTR) that develop modeling/enabling technologies for understanding the complexity of biological systems. The scope of interactions ranges from molecular to supramolecular to organelle and to tissue in prokaryotic and eukaryotic cells. The integration of interactions through levels and scales and the emergence of patterns that help to explain system behavior are the ultimate goals for applying these tools.

Specific areas covered by MABS:

- Modeling methods: Data integration into models; computational systems and tools for model construction, analysis, and simulation; sensitivity analysis; optimization techniques; dimensional analysis; structural analysis (topology); emergent properties of complex systems; model visualization; and multiscale/multilevel modeling.
- Specific models of important processes: signal transduction; biochemical networks; gene regulatory networks; intracellular dynamics; cell structural dynamics; analysis of large datasets.
- Integration of modeling and experiment: experimental validation of models; tools for analysis of assemblies, complexes, and networks; cell and molecular interactions; network reconstruction; high-throughput data integration; combinatorial approaches to genomics, proteomics and glycomics data.

- Development and adaptation of mathematical methods: stochastic, Boolean, continuous; dynamical systems analysis; timescale and spatial decomposition; stiff systems; sparse systems; finite difference and finite element approaches to spatial modeling.

Shared interests within the IRG:

- MABS shares interests with Biodata Management and Analysis (BDMA) study section in the areas of bioinformatics and large scale data collection efforts or “-omics” applications (genomics, proteomics, metabolomics, etc.). If the focus is modeling, review by MABS is appropriate. If the focus is large-scale data analysis, then BDMA would be appropriate.
- MABS shares interests with Instrumentation and Systems Development (ISD) study section in the area of high throughput technologies. If the focus is modeling, review by MABS is appropriate. If the focus is high throughput instrumentation, then ISD would be appropriate.

Shared Interests outside the IRG:

- MABS shares interests with IRG21 in the areas of biomedical computing and informatics as related to modeling physiological function. If the focus is modeling without a medical or clinical application, MABS would be appropriate. If the focus is modeling with a medical or clinical application, IRG 21 would be appropriate.
- MABS shares interests with basic IRG1 (Biological Chemistry and Macromolecular Biophysics), IRG2 (Molecular approaches to Gene Function), IRG3 (Molecular Approaches to Cell Function and Interactions), IRG4 (Fundamental Genetics and Population Biology), IRG5 (Biology of Development and Aging), and IRG 22 (Molecular, Cellular, and Developmental Neuroscience). If the focus is experimental investigation of interacting molecules, regulation of gene expression, cell physiological processes, genomics, development, differentiation, signal transduction, or neuronal cell physiology, then review by the IRGs identified would be appropriate. However, if the primary focus is combining modeling or related analysis, then review by MABS would be appropriate.
- MABS shares interests with IRG13 (Oncological Sciences), where review would be appropriate if cancer cell physiology, signal transduction, or therapy is the focus. If the focus is modeling or related analysis, then review by MABS would be appropriate.

Biodata Management and Analysis Study Section (BDMA)

The Biodata Management and Analysis (BDMA) study section will review applications (R01 and SBIR/STTR) involving the management and analysis of biological data, i.e., bioinformatics. This includes the review of data management technology in support of large-scale data collection efforts.

Specific areas covered by the BDMA study section include:

- Methods for data management including: Data representation, standards and ontology development, data capture, data integrity and validation, data archiving, data distribution, data query, and interoperation and federation of databases.
- Methods for data analysis including: Numerical, statistical and mathematical methods; visualization techniques that summarize and integrate data in meaningful ways, for example, graphical, auditory, tactile, and visual; summary and integration of data; and methods for data mining.

BDMA: Shared Interests Within IRG

Most of the study sections in this IRG will involve at some level the management of data generated by their projects. The BDMA study section focuses on basic methodology for data management and would be the appropriate home when that is the central scientific question. Specifically, the following shared interests merit highlighting:

- BDMA shares interests with the Multi-Dimensional Imaging (MDI) study section in the imaging area. If the focus is on generation of images, then MDI would be the appropriate home for review; however, if the focus is on image archiving, then BDMA is the appropriate home.
- BDMA shares interests with the Modeling and Analysis of Biological Systems (MABS) study section in the areas of bioinformatics and large scale data collection efforts or “-omics” applications (genomics, proteomics, metabolomics, etc.). If the focus were large-scale data analysis, then BDMA would be appropriate. If the focus is modeling, review by MABS is appropriate.
- BDMA has shared interests with the Instrumentation and Systems Development (ISD) study section in areas of data acquisition, analysis software, and hardware. If the focus were data storage and manipulation, then BDMA would be appropriate. If the focus were hardware or instruments for data collection, then ISD would be appropriate.

BDMA: Shared Interests With Other IRGs

- Most of the study sections in other IRGs will involve at some level the management of data generated by their projects. The BDA study section focuses on basic methodology for data management such that hybrid review situations may be necessary when creating databases and when engaging in large-scale collection efforts, as described below.
- Creation and maintenance of databases. The review of applications that propose the creation of databases will require expertise both from BDMA and the study section that deals with the subject domain. Therefore, in these cases dual review with the study section corresponding to the appropriate domain area is recommended.
- Large scale data collection efforts “-omics”. Large-scale data collection efforts require expertise in both data management and the subject domain as well as high throughput technologies. Therefore, in these cases review with expertise pooled from these areas is recommended.
- Statistical methods applications that are specific to clinical trial design/analysis or epidemiological study design/analysis would be reviewed by the appropriate study section in other IRGs, e.g., in the Health of the Population IRG, presently the SNEM-3

study section. All other statistical methodology applications would be reviewed by BDMA.

Instrumentation and Systems Development Study Section (ISD)

The Instrumentation and Systems Development (ISD) study section will consider research applications (R01 and SBIR/STTR) seeking to design and develop novel instrumentation and systems for biological research. Although a test biological problem may be used to provide context, proposals to this study section need not be hypothesis driven. Specific areas of interest include:

- Analytical instrumentation. The design and development of novel instrumentation for biological research. Examples are mass spectrometry, magnetic resonance spectroscopy, x-ray, neutron and electron crystallography, solution scattering, and 2D and 3D imaging technologies for fluorescence, scanning tunneling microscopy, atomic force microscopy, electron microscopy, and x-ray photoelectron spectroscopy.
- Sensing devices. Approaches to the detection and quantification of biologically important molecules, including both small molecule and macromolecular species. The development of such devices may require new surface chemistries and chemical, electrical, or other detection modalities, and may range in scope from devices for the analysis of a single analyte species to devices for the parallel analysis of thousand or millions of species. In addition, sensors of endogenous electric and magnetic fields in biological systems are of interest.
- Separation technologies. Improvements and variations to classical techniques such as electrophoresis and chromatography, as well as the exploration and development of novel approaches, including microfluidics.
- Robotics and automation. The design and development of both individual instrumentation modules and integrated robotic systems for the automation of chemical or biological reactions or processes. Systems for the large-scale acquisition of multivariate information from biological systems of interest.
- Synthesis. Instruments for the synthesis of biomolecules at various scales.
- Micro/nanofabrication. Microfabricated and/or nanostructured devices and systems for use in biological research.
- Single molecule/cell approaches. Techniques, approaches, and devices for the analysis of biological systems at the single molecule or single cell level.

ISD: Shared Interests Within IRG

Many of the study sections in this IRG will involve instrumentation at some level. With a focus on design and development of instrumentation and methods of analysis, the ISD study section would be the appropriate home when that is the central scientific or engineering question. Specifically, the following shared interests merit highlighting:

- ISD shares interests with the Gene and Drug Delivery Systems (GDD) study section in the area of instruments for gene and drug delivery. Applications on nano or microfabricated delivery vehicles and ballistic methods could be assigned to GDD.

Design and development of instrumentation to deliver samples and to monitor delivery could be reviewed by ISD.

- ISD shares interests with the Multi-Dimensional Imaging (MDI) study section. If the focus is on the design or development of imaging instrumentation per se then ISD is the appropriate home. However, if the focus were on imaging data analysis, then MDI would be the appropriate home for review.
- ISD shares interests with the Modeling and Analysis of Biological Systems (MABS) study section in the area of high throughput technologies. If the focus is modeling, review by MABS is appropriate. If the focus were high throughput instrumentation, then ISD would be appropriate.
- ISD has shared interests with the Biodata Management and Analysis (BDMA) study section in the areas of data acquisition, analysis software, and hardware. If the focus were data storage and manipulation, then BDMA would be appropriate. If the focus were hardware or instruments for data collection, then ISD would be appropriate.
- ISD has shared interests with the Biomaterials and Biointerfaces (BMBI) study section in the areas of development of microarray and nanoscale technologies and in sensing devices and associated surface chemistries. Applications with a principal focus on the materials and surface chemistry would be directed to BMBI; whereas applications with the major emphasis on instrumentation for materials fabrication or use would be directed to ISD.

ISD: Shared Interests With Other IRGs

Multiple study sections in other IRGs will involve adaptation of instrumentation and analytical methods to specific biological, medical, or organ situations. If the focus is on the specific situation, then other IRGs would be appropriate. However, if the focus were on design or development of the basic instrument or analytical method ISD would be appropriate. Specific shared interests are:

- IRG1 (Biological Chemistry and Macromolecular Biophysics) shares interests with ISD in the development and application of novel approaches for the study of molecular structure and interactions. In cases where the dominant emphasis of the application is the development of a novel technology or instrument, the application would be directed to ISD within BST. In cases where the dominant emphasis of the application is the science to be done with the new technology, rather than the technology itself, the application would be directed to IRG1.
- IRG21 (Surgery, Applied Imaging, and Applied Bioengineering) shares interests with ISD in the development of novel instrumentation that may have a clinical/medical rationale or focus. Specifically, BSMI (Biomedical Sensing, Measurement, and Development of Diagnostic Instrumentation) will share interests with ISD. In cases where the dominant emphasis of the application is the clinical application, the proposal would be directed to BSMI within IRG21. In cases where the dominant emphasis of the proposal is the technology or instrumentation itself, the proposal would be directed to ISD.

Biomaterials and Biointerfaces Study Section (BMBI)

The Biomaterials and Biointerfaces Study Section (BMBI) will review grant applications (R01 and SBIR/STTR) in materials science and the closely allied field of materials surfaces and their interactions with biological systems. The material aspects of biomaterials and surface science concerns the design, synthesis, characterization, and optimization of new or existing materials including polymers, composites, metals, ceramics, nanomaterials, hybrid systems of natural and synthetic polymers, and biomimetics. The biological aspects of biomaterials science concerns interactions of materials with proteins, cells, and tissues including studies related to scaffolds for tissue repair/tissue engineering, materials for bioreactors, biocompatibility issues, and microcirculation around implanted biomaterials.

Specific areas covered by BMBI include:

- Research and development of efficient methods to assess human acceptance of biomaterials including: Predictive, low-cost in vitro and in vivo models with a focus on reliability, accelerated testing, failure analysis, imaging, and improved understanding of the biology-biomaterials interface.
- Molecular/cellular interfacial interactions including: Protein adsorption, cell adhesion, differentiation and growth, biomolecule function at interfaces, nonfouling surfaces, and bioactive surfaces.
- New material development including: Synthesis of polymers, metals, ceramics, composites, glasses, carbons, biomimetic/bioinspired strategies for synthesis, structure-property relationships of biomaterials, bulk characterization of biomaterials, biodegradable and bioresorbable materials, material processing, and combinatorial approaches to synthesis of new biomaterials.
- Nanoscience and nanotechnology including: Nanoparticles, nanostructured surfaces, nanocomposites, nanodevices, and multifunctional nanoparticles.
- Biomaterials including: Biocompatibility, blood/material interactions, toxicity, healing, structure/property relationships, and biodegradability.
- Drug delivery systems including: Release kinetics, stimuli responsive delivery systems, mechanisms, targeting, bioadhesive delivery systems, fabrication of devices, pharmacokinetics and biodistribution, and bioavailability.
- Gene delivery systems including: Chemical, physical and mechanical methods of gene transfer and membrane recognition, fusion, and transport, cytoplasmic transport, endosomal disruption, and such biomaterials as antisense oligonucleotides.
- Chip- and microarray-based microtechnology including: Patterning, immobilization chemistry, nonfouling chemistry, detection modalities, MEMS, and microfluidics.
- Tissue engineering including: New biomaterials and fabrication techniques, cell-biomaterial interactions, transport and perfusion aspects of tissue engineering, bioreactors, cell and specific cell biology engineering, and tissue engineering.
- Self-assembled materials including: Block copolymers, surface assembly, protein assembly, biosignal delivery using self-assembled materials, biorecognition, liposomes, and tethered biomembrane mimics.

- Biosurface characterization and technology including: Surface analysis, surface modification, lubricity and tribology, and patterning.
- Biosensors including: Biorecognition, biocompatibility, nonfouling surfaces, and fouling mechanisms.

BMBI: Shared Interests Within the IRG

- Gene and Drug Delivery Systems (GDD). The GDD and BMBI study sections have shared interests in development and application of synthetic and biological materials for gene and drug delivery, including the incorporation of genetic material into bulk biomaterials, e.g., for enhancement of tissue engineering strategies. BMBI will review studies emphasizing synthesis, physical characterization, biocompatibility, and toxicity of new synthetic materials intended for use as gene vectors and as drug delivery vehicles.
- Multi-Dimensional Imaging (MDI). Both BMBI and MDI study sections share an interest in development of new materials for use as image enhancers and contrast agents. BMBI will review applications emphasizing development of new polymeric or nanoparticle based contrast agents or where materials synthesis, characterization, biocompatibility, and toxicity are prominent, whereas the Imaging study section will review applications emphasizing small molecule and soluble contrast agents.
- Instrumentation and Systems Development (ISD). Both BMBI and ISD share interests in the areas of development of microarray and nanoscale technologies and in sensing devices and associated surface chemistries. Applications with a principal focus on the materials and surface chemistry would be directed to BMBI; whereas applications with major emphasis on instrumentation for materials fabrication or use would be directed to ISD.

BMBI: Outside the IRG

Biomaterials and biointerfaces are relevant to a wide variety of biomedical devices that are utilized in biomedical science and clinical applications; therefore this IRG has extensive common interests with other IRGs. Where the issues are development of new materials or biocompatibility, the BMBI study section can take a primary role. Where tissue integration and application to medical devices and systems are primary foci, assignment to other IRGs might be appropriate. Common interests with other IRGs include:

- Surgical Sciences, Biomedical Imaging & Bioengineering (SBIB, IRG 21). Research on fundamental aspects of biomaterials and biocompatibility will be reviewed within BMBI, whereas research and development studies of medical devices, including clinical trials, will be reviewed in IRG21.
- Musculoskeletal, Oral and Skin Sciences (MOSS, IRG 17). Extensive use of medical implant materials in dental and orthopedic applications creates opportunities for synergism in studies on biocompatibility and new material development.
- Cardiovascular Sciences (IRG15). The fundamental role of surfaces in triggering thrombosis and other blood and tissue reactions makes the focus of BMBI a significant component of the development of cardiovascular devices, including stents, heart valves, vascular grafts, artificial hearts, ventricular assist devices and others.

- Other IRGs. Common biomaterials and biosurface interests are shared with other IRGs:

IRG1 Biological Chemistry and Macromolecular Biophysics
IRG2 Molecular Approaches to Gene Function
IRG3 Molecular Approaches to Cell Function and Interactions
IRG10 Immunology
IRG11 Infectious Diseases and Microbiology
IRG13 Oncological Sciences
IRG14 Hematology
IRG16 Endocrinology, Metabolism, and Reproductive Sciences
IRG18 Digestive Sciences
IRG19 Pulmonary Sciences
IRG20 Renal and Urological Sciences
IRG24 Brain Disorders and Clinical Neuroscience

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