NIH Funding for Novel Biomaterials Technologies

David Rampulla
Program Director

Biomaterials
Delivery Systems for Drugs and Biologics
Synthetic Biology for Technology Development
NIBIB/NIH
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The NSF-NIH Biomaterial Hand-off

• At the NSF…
  – Greater focus on developing material properties (in general)
  – Larger importance on ‘new’ materials and phenomena
  – Pushing properties toward biomedical relevance
  – Some basics… does it kill cells?

• At the NIH/NIBIB…
  – Greater focus on developing the material in a biomedical context
  – Larger importance on addressing an unmet medical need
  – Pushing properties toward clinical relevance
  – More in vivo (and in vitro) testing
NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.
NIH FY16 Budget

NIH Divides most of its investment according to the interests of the component parts (i.e. Institutes or Centers), with 5% allocated to trans-NIH initiatives.

Total = $32 B

About 85% distributed via Extramural grants, contracts, cooperative agreements
“Biomaterials” in the NIH Portfolio
(by percent of total investment, FY16)

Total Awards = 569

NIH average 1.2%
What Comes in the Door at NIBIB?

• First… contact a Program Director
  – There are occasionally subtle differences between the missions of the institutes

• NIBIB is the ‘engineering’ IC
  – Integrating the physical and engineering sciences with the life sciences to advance basic research and medical care
  – Strong focus on developing a technology
  – Disease agnostic

• Tissue sealant
• In vivo energy harvester
• Wound dressings
• A wide range of applications!

• Functional properties
• Biocompatibility

• Tends to be a ‘next step’ for biomaterials from NSF toward biomedical relevance
Biomaterials

This program supports the research and development of new or novel biomaterials that can be used for a broad spectrum of biomedical applications such as implantable devices; tissue engineering; imaging agents; and biosensors and actuators.

Research that is supported includes the design, synthesis, characterization, processing and manufacturing of these materials as well as the design and development of devices constructed of these materials and their clinical performance.

This program supports the design, development, evaluation and validation of medical devices and implants, vis-à-vis their interface to the host. This includes: exploratory research on modifications (especially of the implant surface) that increase device integration; development of tools for assessing host-implant interactions; development of predictive models and methods to assess the useful life of devices; and explant analysis.

<table>
<thead>
<tr>
<th>GRANT NUMBER</th>
<th>PROJECT TITLE</th>
<th>PRINCIPAL INVESTIGATOR</th>
<th>INSTITUTION</th>
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<tbody>
<tr>
<td>5-R21-EB018617-02</td>
<td>A new tool for measuring surface-biomolecule interactions</td>
<td>Kevin Plaxco</td>
<td>University of California Santa Barbara</td>
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<td>5-R21-EB019063-02</td>
<td>Augmentation of Hemostasis in Pediatric Cardiopulmonary Bypass</td>
<td>Nina Guzzetta</td>
<td>Emory University</td>
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<td>5-R21-EB016833-02</td>
<td>Catalytic Nitric Oxide Release Coating for Prolonged Anti-Clotting Catheters</td>
<td>Melissa Reynolds</td>
<td>Colorado State University</td>
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NIH GUIDE
NIH PARENT ANNONCMENTS
NIH SUBMISSION DATES
NIH RoRePORTER
NIBIB AND THE RECOVERY ACT
RESEARCH RESOURCES
Does NIH Already Support My Interest Area?

<table>
<thead>
<tr>
<th>Act</th>
<th>Project</th>
<th>Year</th>
<th>Sub #</th>
<th>Project Title</th>
<th>Contact PI/Project Leader</th>
<th>Organization</th>
<th>FY</th>
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<th>Funding FY</th>
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<td>R01</td>
<td>CA165111</td>
<td>01A1</td>
<td>TUMOR ANTIGEN-SPECIFIC T-CELLS AND HEPATOCELULAR CARCINOMA</td>
<td>KAPLAN, DAVID E</td>
<td>UNIVERSITY OF PENNSYLVANIA</td>
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<td>R01</td>
<td>AR055993</td>
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<td>TISSUE REGENERATION BY BIOPHYSICAL SIGNALING</td>
<td>KAPLAN, DAVID L et al.</td>
<td>TUFTS UNIVERSITY</td>
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<td>ELECTROTHERAPEUTIC STRATEGIES FOR CONNECTIVE TISSUE REPAIR</td>
<td>KAPLAN, DAVID L et al.</td>
<td>TUFTS UNIVERSITY</td>
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<td>P41</td>
<td>E002520</td>
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<td>TISSUE ENGINEERING RESOURCE CENTER</td>
<td>KAPLAN, DAVID L</td>
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<td>BIOMATERIAL APPLICATIONS OF RECOMBINANT BACTERIAL COLLAGENS</td>
<td>KAPLAN, DAVID L et al.</td>
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<td>MULTIFUNCTIONAL TROPONELASTIN-SILK BIOMATERIAL SYSTEMS</td>
<td>KAPLAN, DAVID L</td>
<td>TUFTS UNIVERSITY</td>
<td>2012</td>
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<td>MODELS TO PREDICT PROTEIN BIOMATERIAL PERFORMANCE</td>
<td>KAPLAN, DAVID L et al.</td>
<td>TUFTS UNIVERSITY</td>
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<td>IN VITRO BIOREACTOR SYS FOR PLATELET FORMATION</td>
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<td>TISSUE ENGINEERING CORNEA REPLACEMENTS</td>
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... of Useful Information.
Two roads diverged in a wood, and I—
I took the one less traveled by, 
and that has made all the difference.

- Robert Frost

R21  ($275K spread over 2 yrs, non-renewable)
  - High(er) risk and reward
  - Little/no supporting data

R03  (2 yrs, $50K per year, non-renewal)
  - Little/no supporting data
  - succinct task(s)

R01  (4-5 yrs, $250 - 400K+, renewable, a “real” grant)
  - Convincing preliminary data for each aim
  - Longer term questions
  - Multiple complexities
Relevant NIBIB Funding Opportunities

• MOST applications come in through the Parent Mechanisms... and that’s OK!

• PAR-16-390: NIBIB Trailblazer Award for New and Early Stage Investigators (R21)
• PAR-15-031: NIBIB Quantum Program (U01)
• PAR-17-083: NIBIB Biomedical Technology Resource Centers (P41)
• PAR-16-116: Bioengineering Research Partnerships (U01) and Related Grant (BRG [R01])

• NOTE: No specific biomaterials focused FOAs at NIBIB at this time
Conversation at the Study Section’s Mid-Morning Break

PD: I think I have this figured out. You guys have pretty much decided on an impact score by the time you finish reading the Specific Aims page, right?

Reviewer #1 (hesitantly): Well... yes, that’s right.

PD: And the rest is filling in the details, looking for confirmation of your opinion, scanning for fatal flaws...

Reviewer #2: That about sums it up, yes.
Cover Letters Help Target Your Review

Applicants can suggest

- Review Group assignment
- Expertise necessary for a full and fair review
- Primary (and secondary) Institute or Center (IC) assignment
- Reviewers with potential conflicts
- Do not suggest possible reviewers, they will be disqualified.

Other Important Information

- Reasons for a late submission
- Note eligibility for continuous submission
- Highlight this application as one of a set, if applicable
- Acknowledge NIH approval for acceptance of
  - A budget >$500K/yr
  - Conference grant

Suggested format and other information at

http://cms.csr.nih.gov/ResourcesforApplicants/CoverLet.htm
It’s an orderly universe.

Your application is reviewed by either …

- Chartered (Standing) Scientific Review Group (SRG), or “Study Section”
- Special Emphasis Panel (SEP)
  - organized by the Center for Scientific Review (CSR)
    - Conflicts on the panel (e.g. reviewer is a PI on the grant application)
    - Special review for a unique solicitation (e.g. PAR)
  - convened within a home IC of a highly specific initiative (e.g. RFA)
Your application may be REVIEWED by one of:

- Bioengineering Sciences and Technology (BST)
  - BDMA, BMBI, GDD, ISD, MABS, NANO

- Healthcare Delivery and Methodologies (HDM)
  - BCHI, BMRD, CIHB, CLHS, DIRH, HDEP, HSOD, NRCS

- Endocrinology, Metabolism, Nutrition and Reproductive Systems (EMNR)
  - MCE, ICER, CMIR, PN, CADO, IPOD, CICO, INMP, F06

- Immunology (IMM)
  - CMIA/B, HAI, IHD, III, IMM-M, TTT, VMD, F07

- Interdisciplinary Medical Sciences and Training (IMST)
  - EBIT, various training

- Emerging Technologies and Training in Neuroscience (ETTN)
  - MNG, BNVT, NOIT, F01/2/3

- Vascular and Hematology (VH)
  - AICS, ELB, HM, HP, MCH, VCMB, F10B

- Cell Biology (CB)
  - BVS, NCSD, CMAD, CRS, DEV1/2, ICI, MBPP, MIST

- Biology of Development and Aging (BDA)
  - International/Cooperative Projects

- Behavior and Behavioral Processes (BBBP)
  - APDA, BRLE, CP, CPDD, LCOM, MESH, MFSR

- Infectious Diseases and Microbiology (IDM)
  - BACP, CRFS, DRR, HIBP, PTHE, VB, VIRA/B, F13

- Molecular, Cellular and Developmental Neuroscience (MDCN)
  - BPNS, CMBG, CMND, DDNS, MNPS, NCF, NDPR, NOMD, NTRC, SYN

- Invasion and AIDS Related Research (AARR)
  - ACE, ADDT, AIP, AMCB, AOIC, BSCH, BSPH, NAED, VACC

- Brain Disorders and Clinical Neuroscience (BDCN)
  - ANIE, ASG, BINC, CDIN, CNBT, CNN, CNNT, DBD, DPVS, NPAS, PMDA

- Biological Chemistry and Molecular Biophysics (BCMB)
  - BBM, MSFA/B/D/C/D, SBCA/B

- Risk Prevention and Health Behavior (RPHB)
  - BMIO, PDRP, PRDP, RPIA, SPIP, F16

- Genes, Genomes and Genetics (GGG)
  - MGA/B, GCAT, GVE, GHD, PCMB, TAG

- Oncology 1 – Basic Translational (OBT)
  - CAMP, CE, CG, MONC, TCB, TME, TPM

- Oncology 2 – Translational and Clinical (OTC)
  - BMCT, CBSS, CDP, CII, CONC, DMP, DT, RTB

- >200 Standing Scientific Review Groups (SRGs or Study Sections) housed in 25 Integrated Review Groups at CSR
How to Identify the Best Study Section

Center for Scientific Review

CSR Home > Study Sections

Study Sections

Find a Study Section

Applications are reviewed in Study Sections (Scientific Review Group, SRG). Integrated Review Groups (IRGs) are clusters of Study Sections based on scientific discipline.

Enter Search Keywords

Integrated Review Groups (IRGs)

Review activities of the Center for Scientific Review (CSR) are organized into Integrated Review Groups (IRGs). Each IRG represents a cluster of study sections around a general scientific area. Applications generally are assigned first to an IRG, and then to a specific study section within that IRG for evaluation of scientific merit.

View Study Sections by Integrated Review Groups

Standing Study Sections

Policy Changes

» Notice of the National Center for Advancing Translational Sciences and Anticipated Implementation Plan

» Ruth L. Kirschstein National Research Service Awards (NRSA) and Other Fellowship Applications: New Policy on Post-Submission Information on Sponsor's Research

http://public.csr.nih.gov/StudySections/Pages/default.aspx
The Biomaterials and Biointerfaces Study Section (BMBI) reviews applications concerned with biologically relevant research in materials science and the interaction of materials surfaces with biological systems. Applications driven by bioengineering principles are typical. Areas of interest include the theory, principles, design and synthesis of biomaterials as well as characterization of new or existing materials. BMBI has related interests in the interactions of biomaterials with proteins, membranes, cells, and tissues.

Specific areas covered by BMBI are:

- Development and characterization of biomaterials; Self-assembled materials; Design principles, material processing, and combinatorial approaches to the synthesis of new biomaterials; Biocompatibility, toxicity, structure/property relationships, and biodurability.
- New biomaterials and fabrication techniques for tissue engineering, transport and perfusion aspects of tissue engineering, and bioreactors.
- Molecular/cellular interfacial interactions; Non-fouling and bioactive surfaces; Improved understanding of the biology-biomaterials interface; Biosurface characterization and technology characterization at the nano-scale.
- Chip- and micro-array-based microtechnologies and biosensors, with a focus on biocompatibility, nonfouling surfaces, and fouling mechanisms; Including cell and gene delivery systems, lithographic and microfluidic elements.
- Drug and gene delivery systems and nanoparticles, with a focus on the chemistry of drug, fabrication, biocompatibility, and toxicity.

Study sections with most closely related areas of similar science listed in rank order are:

- Gene and Drug Delivery Systems (GDD)
- Nanotechnology (NANO)
- Bioengineering, Technology, and Surgical Sciences (BTSS)
- Enabling Bioanalytical and Biophysical Technologies (EBT)
- Instrumentation and Systems Development (ISD)

Revised 12/6/2010
SOME Biomaterials Study Sections

• “Biomaterials and Biointerfaces Study Section (BMBI) - applications concerned with biologically relevant research in materials science...”
• “Nanotechnology Study Section (NANO)- research ... relating to the unique properties of nanomaterials.”
• “Bioengineering, Technology, and Surgical Sciences (BTSS) Study Section- applications in the interdisciplinary fields of surgery and bioengineering...”
Once You’ve Successfully Submitted...

**Receipt and Referral,**
Center for Scientific Review (CSR)

Electronic SF424 R&R submitted through grant.gov and the eRA Commons

Error free, warnings addressed

CSR Referral Office assigns the application...

Application assessed for completeness & eligibility

- to an NIH Institute (IC)
- to Integrated Review Group (IRG) and then a study section (SRG)
- a unique identifier (application number)

Notice of assignment available in eRA Commons in 4 weeks.

Check your eRA Commons account for updates!
New Directions at NIH/NIBIB

• **BRAIN!** [https://www.braininitiative.nih.gov/funding/index.htm](https://www.braininitiative.nih.gov/funding/index.htm)
  - Tools and technology development
  - Look for NIBIB on the FOA
New Directions at NIH/NIBIB

- Biomaterials at NIBIB... highly investigator driven... but...
- Immunomodulating
- Energy generation/storage
- More than just biochemical phenomena
  - Tribolological/mechanical
  - Electromagnetic
- Especially for...
  - Therapeutic agent delivery
  - Surgical Tools
  - Biosensors
  - Tissue engineering
  - Medical devices
David Rampulla, Ph.D.

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National Institutes of Health (NIH)

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