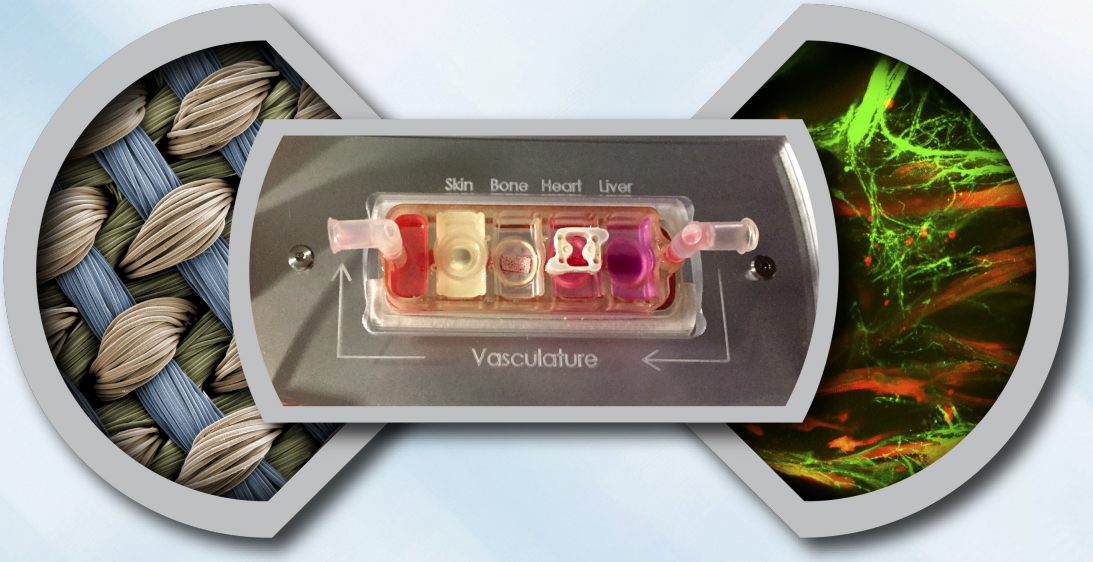
National Institutes of Health

Workshop on Tissue Chip Platforms as Tools for Testing Biocompatibility and Biotoxicity of Biomaterials

October 24 – 25, 2019
Washington, DC



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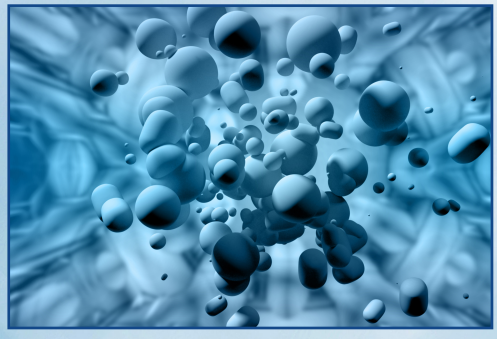
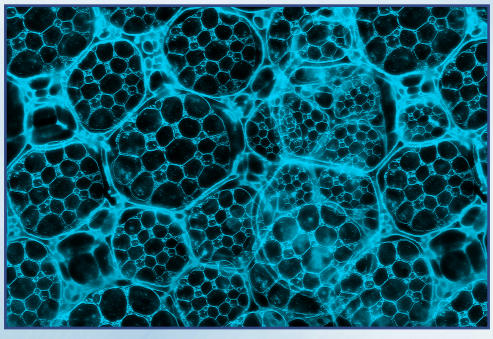
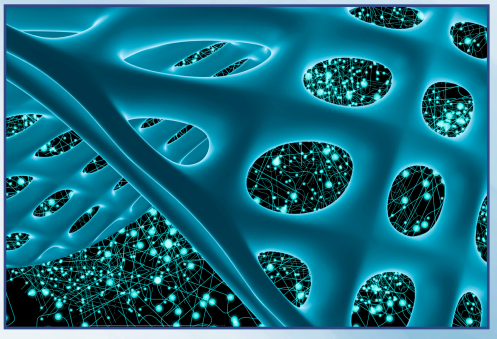


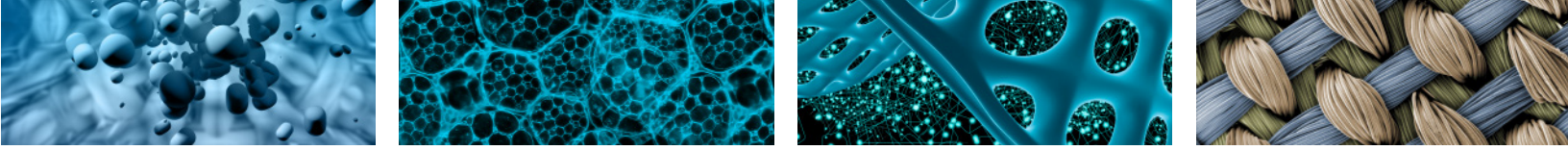




U.S. Department of Health and Human Services

Table of Contents

Agenda



Workshop on Tissue Chip Platforms as Tools for Testing Biocompatibility and Biotoxicity of Biomaterials

October 24 – 25, 2019

National Institutes of Health Sponsors:
National Institute of Environmental Health Sciences
National Institute of Dental and Craniofacial Research
National Heart, Lung, and Blood Institute
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Agenda

Thursday, October 24, 2019

8:00 a.m. **Registration**

8:30 a.m. **Welcome and Introductions**
Les Reinlib, Ph.D., National Institute of Environmental Health Sciences
Nadya Lumelsky, Ph.D., National Institute of Dental and Craniofacial Research
Richard Paules, Ph.D., National Institute of Environmental Health Sciences

9:00 a.m. **Keynote: Tissue Chips and Their Potential for Evaluating Biomaterials**
Gordana Vunjak-Novakovic, Ph.D., Columbia University

Session One: The Biomaterials Perspective

9:30 a.m. **Tissue Engineered Systems to Assess Materials Biocompatibility – Gaps and Opportunities**
David Kaplan, Ph.D., Tufts University

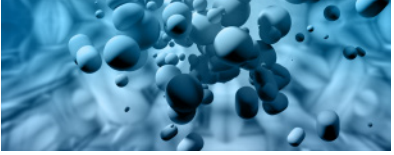
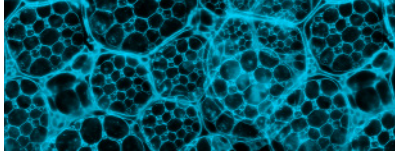
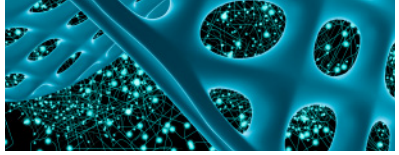
9:50 a.m. **Biomaterial Surfaces and Surface Byproducts: Understanding Their Effects on Biology as Assessed in a Physiologically Relevant Environment**
Carmem Pfeifer, D.D.S., Ph.D., Oregon Health and Science University

10:10 a.m. **Interfacing Degradable Biomaterials and in vivo: From Tissue Regeneration to Cancer**
Fan Yang, Ph.D., Stanford University

10:30 a.m. **Biocompatibility of Biomaterials in Tissue Chips and Tissue Chips for Assessing Biomaterial Biocompatibility**
Buddy Ratner, Ph.D., University of Washington

10:50 a.m. **Panel Discussion**

11:20 a.m. **Lunch Break**


Session Two: The Tissue Chips Perspective

12:50 p.m. **Biowire Models of Healthy and Diseased Myocardium**
Milica Radisic, Ph.D., University of Toronto, Toronto General Research Institute

1:10 p.m. **Human Organs-on-a-Chip: Microengineered Biomimicry of Human Physiological Systems**
Dan Huh, Ph.D., University of Pennsylvania

1:30 p.m. **Exploiting Microphysiological Systems for Assessing Biological Performance of Materials**
Kevin Healy, Ph.D., University of California, Berkeley

1:50 p.m. **Of and About Biomaterials: Tissue Chip Bioreactors and Perfusion Control Systems**
John Wikswo, Ph.D., Vanderbilt University

2:10 p.m. **Panel Discussion**

2:40 p.m. **Break**

Session Three: Evaluating and Monitoring Biocompatibility

3:00 p.m. **Biomaterials to Control Cell Fate**
Sharon Gerecht, Ph.D., Johns Hopkins University

3:20 p.m. **Tissue Models of Host Responses to Biomaterials**
Andres Garcia, Ph.D., Georgia Institute of Technology

3:40 p.m. **Tissue Chips and Materials: Cross-Pollination or Cross-Contamination?**
Christopher Chen, M.D., Ph.D. Boston University, Harvard University

4:00 p.m. **Biomaterial-based Fibrous Models of Connective Tissue Growth and Healing**
Helen Lu, Ph.D., Columbia University

4:20 p.m. **Panel Discussion**

4:50 p.m. **Day One Closing Remarks**

5:15 p.m. **Adjourn for the Day**

Friday, October 25

Session Four: Summary Discussions and Recommendations

8:30 a.m. **Introduction: Goals of the Summary Session**

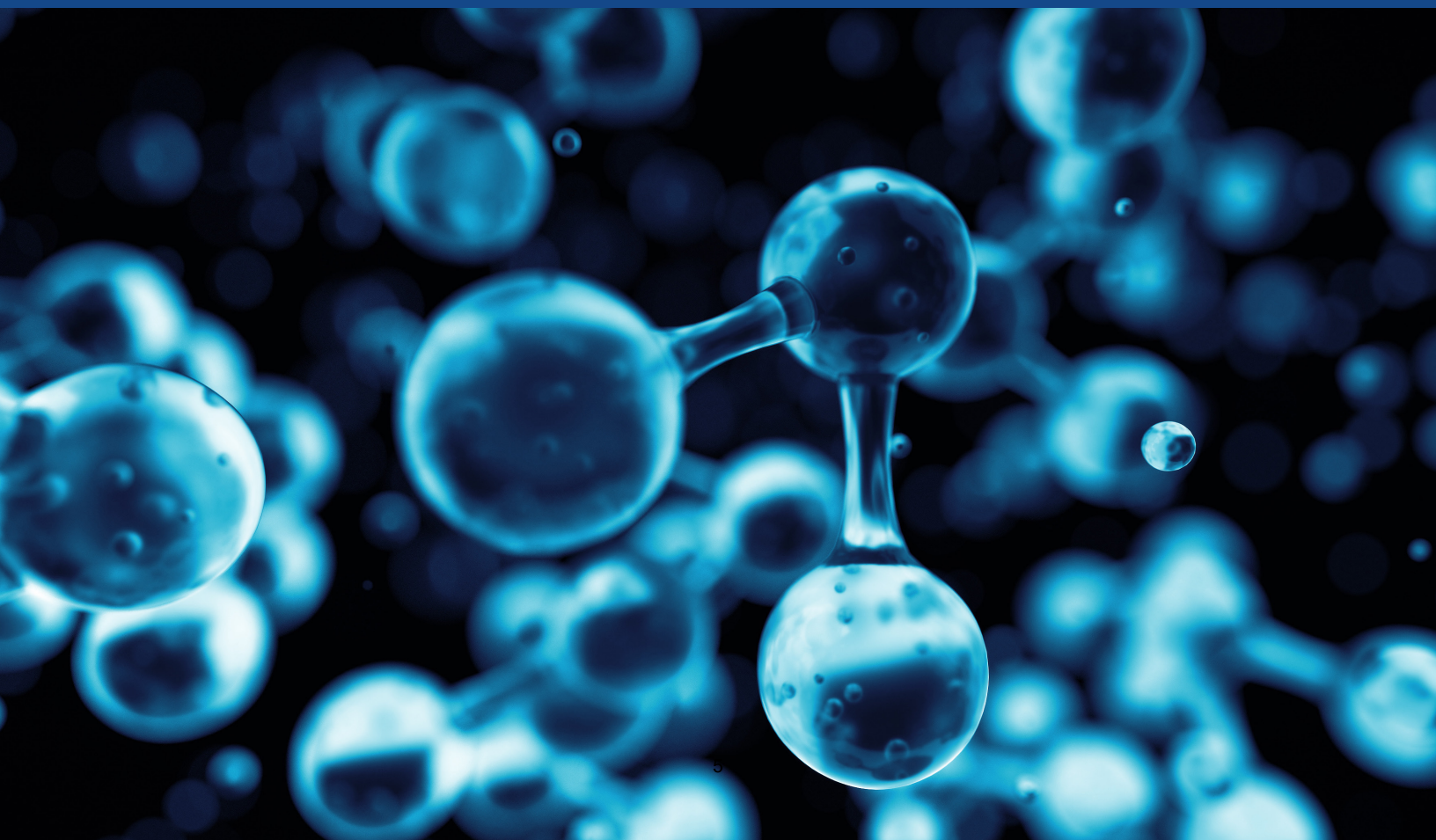
8:45 a.m. **Summary of Sessions by the Discussion Leaders**

10:15 a.m. **Break**

10:30 a.m. **Summary of Recommendations, Priorities, and Next Steps**

11:30 a.m. **Adjourn**

Abstracts



Keynote

Tissue Chips and Their Potential for Evaluating Biomaterials

Gordana Vunjak-Novakovic, Ph.D.
Columbia University

Modeling integrated human physiology in vitro is a formidable goal that is becoming increasingly plausible by the emergence of human "tissue chips" and "organs on a chip" platforms. Advances in stem cell biology and tissue engineering [e.g., 1-3] are now enabling the formation of micro-sized human tissues and organs that are grown *in vitro*, matured, and functionally integrated to emulate human physiology in health and disease [4]. Over the last decade, these platforms have increasingly demonstrated ability to recapitulate important aspects of human physiology, and enable predictive testing of the mechanisms of disease and drug action. In contrast to tissues grown for transplantation, the "tissue chips" provide fast-track opportunities for tissue engineering [4], with immediate impact on biological research and human medicine.

This Workshop is exploring an entirely new direction in the use of "tissue chips": assessment of the biocompatibility, immunogenicity, and toxicity of various types of materials that are on contact with the human body. The areas of highest interest include biomaterials for application in tissue engineering, regenerative medicine, oncology, dentistry, cardiology, and drug screening as well as the commodity materials and environmental agents. This talk will focus on the potential of "tissue chips", individually and connected to each other by vascular perfusion for testing of biocompatibility. To this end, we describe a configurable, modular microphysiological platform in which the individual human tissue modules (such as heart, liver, bone, skin, innervated skeletal muscle) are connected by perfusable vasculature. The functional integration is achieved by (*i*) maintaining a local regulatory niche for each tissue, (*ii*) connecting tissue units by a vascular perfusion containing circulating cells, and (*iii*) establishing endothelial barrier between the intravascular and interstitial compartments. We established methods for maturation of the component tissues, and the maintenance of stable tissue phenotypes over 4 weeks of culture, with real-time measurements of cell and tissue function. Notably, all tissues are derived from the same human iPS cells, allowing individualized studies of responses to biomaterials. To illustrate the utility, we describe studies of physiology and responses to drugs.

Session I: The Biomaterials Perspective

Tissue Engineered Systems to Assess Materials Biocompatibility – Gaps and Opportunities

David Kaplan, Ph.D.
Tufts University

3D tissue systems as in vitro tools have progressed at a remarkable rate over the past 20 years; escaping the confinements of 2D plastic, inclusion of accessible cell sources, incorporating highly engineered biomaterial matrices, and exploiting more complex bioreactor systems to house the systems. Key challenges ahead include further human physiological relevance, noninvasive imaging and assessments, scaling, incorporation of immune components, integrated innervation and related themes. Examples of opportunities and needs will be reviewed in the context of screening biomaterials using in vitro tissue systems, as predictors of in vivo responses for biocompatibility.

Biomaterial Surfaces and Surface Byproducts: Understanding Their Effects on Biology as Assessed in a Physiologically Relevant Environment

Carmem Pfeifer, D.D.S., Ph.D.
Oregon Health and Science University

The field of biomaterials, including dental restorative materials, has undergone a significant evolution in the past decade. Technological advances allowed for the production of stronger, more stable and less toxic materials. With those big hurdles out of the way, the future of the field lies in better understanding the biological interactions of such materials in environments much more complex than a petri dish, and at the same time much more streamlined than animal studies. This will ensure that there is bench-to-bedside translation of all those scientific advances to our patients. The concept of precision medicine has introduced the demand for fast, personalized diagnostics, which need to come at a cost that is attractive enough to make this accessible universally. Miniaturized, microfluidic devices, also known as organs on a chip, have certainly brought us one step closer to this goal, allowing for two types of cells to be cultured in close proximity, or even eukaryotic cells in the vicinity of bacteria. In this talk, I am going to focus on the dental application of this technology, with emphasis in what needs to be measured and when, to allow for the improvement of current materials. One example that is very relevant to my own line of research is the interaction between materials and host enzymes, such as MMPs present in the dentin and excreted by pulp cells. Another example is the interaction of materials with bacterial enzymes, specifically GTFs from cariogenic bacteria. If we can measure enzyme activity on the chip, in the presence of both bacteria and pulp cells, for example, it would be possible to assess the complex interactions between surface moieties introduced in the polymer, for example, and the GTF present in the cell wall of *S. mutans*. This would ultimately allow for the development of targeted therapies, in which the dysbiotic bacteria would preferentially be eliminated, while keeping the population of commensal organisms healthy, ultimately providing a protective mechanism for the tooth surface. While this example is very narrowly focused on the dental applications, this same rationale can certainly be applied to broader biomedical applications where infections are a concern, such as in hip implants.

Interfacing Degradable Biomaterials and in vivo: From Tissue Regeneration to Cancer

Fan Yang, Ph.D.
Stanford University

Biomaterials have been implanted or injected in vivo and into the human body for medical applications for a long time. The conventional medical devices are implantable and mostly based on non-degradable materials like metal/plastic or non-degradable polymers. With the advances of the field of biomaterials, more degradable biomaterials have been developed and widely used for various biomedical applications. Biomaterials can serve in various functions such as biomimetic cell niche, enhancing cell delivery, serving as in situ drug delivery depot, or providing physical/biochemical cues to modulate desirable cell fates. Applications of biomaterials have also been expanded from promoting tissue regeneration, to targeted therapy for cancer, as well as serving as implantable traps for detecting cancer cells or modulating cancer immunomodulation. In this talk, I will focus on degradable biomaterials and use specific applications from tissue regeneration to cancer to guide discussions on what key factors we should consider for assessing biocompatibility. These considerations will help define the needs of customized design biocompatibility tests, as well as guiding future design of tissue chips to help predict biocompatibility of biomaterials.

Biocompatibility of Biomaterials in Tissue Chips and Tissue Chips for Assessing Biomaterial Biocompatibility

Buddy Ratner, Ph.D.
University of Washington

Tissue chips are fabricated from materials (biomaterials) and tissue chips can be used to assess biointeractions of materials (biomaterials). This talk will consider key issues in biomaterials as they pertain to tissue chips. The working consideration for the materials/tissue chips interface is their biocompatibility. The standard definition of biocompatibility, *"the ability of a material to perform with an appropriate host response in a specific application,"* though totally accurate, is focused on in vivo implants and offers no insights for testing or optimizing biocompatibility. ISO10993 tests provide a starting point for assessing biocompatibility. In particular, most tests involve observations of the interactions of living cells with extracts from biomaterials. These tests can be useful to determine if components leaching from the materials of chips will poison or alter cells and tissues. It is straightforward to develop tissue chip biomaterials that are not toxic to cells. However, tissue chips accrue real value when they accurately replicate the normal physiologic functionality of tissues and organs. Cells in culture on tissue culture plastic rarely function in a physiologically accurate manner. Three considerations for biomaterials in "high-functioning" tissue chips are (1) control of protein conformation and orientation, (2) ensuring protein is present where you want it, and absent where it is not wanted and (3) ensuring cells and tissue can function in a 3D environment, rather than 2D cell layers on plastic. Once a tissue chip accurately models the in vivo tissue or organ, then it can be used as a screening to tool to assess the suitability for various biomaterials in medical devices and implants.

Session II: The Tissue Chips Perspective

Biowire Models of Healthy and Diseased Myocardium

Milica Radisic, Ph.D.
University of Toronto, Toronto General Research Institute

Tissue engineering using cardiomyocytes derived from human pluripotent stem cells holds a promise to revolutionize drug discovery, but only if limitations related to cardiac chamber specification and platform versatility can be overcome. I will describe a scalable tissue-cultivation platform that is cell source agnostic and enables drug testing under electrical pacing. The plastic platform enabled on-line non-invasive recording of passive tension, active force, contractile dynamics, and Ca2+ transients, as well as endpoint assessments of action potentials and conduction velocity. By combining directed cell differentiation with electrical field conditioning, we engineered electrophysiologically distinct atrial and ventricular tissues with chamber-specific drug responses and gene expression. Engineering of heteropolar cardiac tissues containing distinct atrial and ventricular ends is also achieved using this approach and the spatially confined responses to serotonin and ranolazine were validated in these tissues. I will also present modelling of polygenic left ventricular hypertrophy starting from iPSC-cardiomyocytes derived from patients with hypertension and illustrate that electrical conditioning for up to 8 months was necessary to observe the phenotypic and functional changes in comparison to the non-affected controls. In addition, work on the use of patient-derived iPSC to model critical aspects of heritable arrhythmias underlying a sodium channel mutation, SCN5a R222Q will be presented. Relying on these advances, I will describe our efforts to develop the next generation of miniaturized heart tissue models situated in an inert plastic platform similar to a 96-well plate, compatible with microscopy and high-content screening. New 3D printing and multimaterial processing methods are used to scale up and automate manufacturing.

Human Organs-on-a-Chip: Microengineered Biomimicry of Human Physiological Systems

Dan Dongeun Huh, Ph.D.
University of Pennsylvania

Remarkable progress in life science and technology in the past century has advanced our fundamental understanding of the human body beyond our imagination. The ever-increasing knowledge of human anatomy and biology, however, has done surprisingly little to improve the way we emulate and probe the complex inner workings of the human body. Even today, our ability to model human physiological systems relies on the century-old practice of cell culture or animal experimentation that has raised significant scientific and ethical concerns. The paucity of predictive and human-relevant model systems is emerging as a critical impediment to our scientific endeavors for a wide variety of biomedical applications. This talk will present interdisciplinary research efforts in my laboratory to develop microengineered in vitro models that can emulate the structural and functional complexity of human organs. Specifically, I will talk about i) bioinspired microsystems that mimic the alveoli and airways of the human lung during health and disease, ii) microengineering of vascularized and perfusable 3D human tissues, iii) a blinking eye-on-a-chip microdevice that emulates the ocular surface of the human eye, and iv) microengineered physiological models of human reproductive organs.

Exploiting Microphysiological Systems for Assessing Biological Performance of Materials

Kevin Healy Ph.D.,
University of California, Berkeley

Our work has emphasized creating both healthy and diseased model organ systems, we call microphysiological systems or 'organ chips', to address the costly and inefficient drug discovery process. While organ chips are poised to disrupt the drug development process and significantly reduce the cost of bringing a new drug candidate to market, organ chip technology is much more robust and creates a whole new paradigm in how to conduct biological science, and advances medicine in revolutionary ways. An emerging use of microphysiological systems is in the evaluation of biomaterials to assess either their function or compatibility. This presentation will discuss examples of exploiting microphysiological systems and human induced pluripotent stem cells (hiPSC) derived tissue specific cells as unique testbeds for rapidly assessing the performance of biomaterials.

Of and About Biomaterials: Tissue Chip Bioreactors and Perfusion Control Systems

John P. Wikswo, Ph.D.
Vanderbilt University

Tissue chips utilize microfluidic bioreactors that are typically constructed from a wide variety of elastomeric or rigid materials, from polydimethylsiloxane (PDMS) or styrene-ethylene-butylene-styrene (SEBS), to glass, polyurethane (PU), polystyrene (PS), and cyclic olefin copolymer (COC). Chips alone do not comprise an assay -- the perfusion system might use stainless-steel needles; polyetheretherketone (PEEK), Tygon™, Teflon (PTFE), or PharMed BPT tubing; polypropylene (PP) or glass syringes; PDMS or SEBS pumps and valves; and polyethylene (PE), PS, or glass reservoirs, with a variety of gaskets or seals throughout the system. Pipette tips and analytical instruments can interact with drugs and metabolites. None of these materials are totally inert biologically, all have different properties for cellular adhesion and molecular absorption, adsorption, and leaching, and each can contribute to adverse outcomes in a toxicology assay. One can argue that there are no biologically inert materials. Many things should be considered when creating a tissue-chip platform for evaluating biomaterials for research and clinical applications: 1) how to quantify the toxicological effects manifest in the cellular phenotype and cellular and secretory multi-ome; 2) what assays can detect interactions of drugs, metabolites, and toxins with the materials utilized; 3) what are the appropriate ratios of cellular-to-perfusion volume and recirculation fraction consistent with both physiology and detectability; 4) the best means to correct for the native properties of the platform that is used to support a particular materials assessment; 5) the differences between mechanical and fluid contact between the tissues and the material under test; 6) assay duration; and 7) validated in vitro to in vivo extrapolation (IVIVE). While there are significant reasons to move away from PDMS, one must be careful that the replacements do not introduce new problems. This talk will provide examples of progress in each of these areas.

Session III: Evaluating and Monitoring Biocompatibility

Biomaterials to Control Cell Fate

Sharon Gerecht, Ph.D.
Johns Hopkins University

Stem cell differentiation and tissue formation (morphogenesis) takes place in an intricate milieu. The extracellular matrix provides critical support for cell adhesion, proliferation, migration, and morphogenesis. Biomaterials can be designed to mimic key physicochemical cues that drive cellular processes. In this talk I will present our efforts to design and synthesize biomaterials that enable us to understand how physicochemical cues and downstream signaling pathways regulate cell fate and tissue assembly. I will focus on the challenges to define biocompatibility for specific usage and how we envision using "tissue chips" to develop and test such biomaterials.

Tissue Models of Host Responses to Biomaterials

Andrés J. García, Ph.D.
Georgia Institute of Technology

Tissue chips provide powerful platforms to model host responses to implanted biomaterials. These approaches, however, are limited by challenges regarding the incorporation of relevant components of complex in vivo responses to materials and lack of predictive power. This presentation will discuss key elements of the biological performance of materials (e.g., biocompatibility) and design criteria for biomaterials engineered to elicit targeted responses. Examples will be provided illustrating tissue chips and models in which engineered biomaterials play critical roles in recapitulating in vivo responses. In one application, synthetic hydrogels (highly hydrated cross-linked polymer networks) have been engineered to support the in vitro generation of 3D organoids from human pluripotent stem cell-derived cells and mimic their engraftment and reparative activities in vivo. In a second example, we have developed a microfluidic tissue-on-a-chip model to assess the reparative activities of human mesenchymal stem cells and predict in vivo potency.

Tissue Chips and Materials: Cross-Pollination or Cross-Contamination?

Christopher Chen, M.D., Ph.D.
Boston University, Harvard University

Tissue Chips have been rapidly emerging from the scientific community as potential testing platforms for a variety of applications. While still evolving, these tissue chips have been designed and demonstrated to recapitulate many functions and sub-functions of native tissues, organs, and multi-organ processes. In parallel, an unprecedented explosion in new materials, nano- and microstructures, and manufacturing processes is occurring, and some of those advances are having important enabling roles in the development of tissue chip systems. Simultaneously, in other fields and industries, new materials have found their way into a wide array of applications in foods, packaging, coatings, aerosols, creams, drugs, and implants, as well as unintentional exposures via the larger ecosystem. Tissue chips could not only provide an important mechanism to assess the safety of such materials in a wide variety of exposure routes, but also more clearly define biocompatibility especially for medical use materials, for example in terms of foreign material accumulation, clearance, fibrosis, inflammation, and integration. This presentation will discuss the opportunities and challenges in this complex interplay between materials and tissue chips.

Biomaterial-based Fibrous Models of Connective Tissue Growth and Healing

Helen H. Lu, Ph.D.
Columbia University

Physiologically relevant models of the extracellular matrix (ECM) of connective tissues are essential for understanding the biology of tissue repair and healing, as well as the mechanism of cell-matrix interaction. Moreover, these 3-D models offer an opportunity to identify key cellular processes and matrix characteristics critical for tissue healing and regeneration. We have explored the design of synthetic and biopolymer-based matrices that mimic the growing, healing or repaired collagenous matrix, focusing on generating a fiber-based platform with controlled fiber diameter, stiffness and architecture. Using these high-fidelity models, we have investigated the contribution of ECM to soft tissue repair. Given that heterotypic and homotypic cellular interactions regulate both tissue repair and homeostasis, we have also studied the interplay between fibroblasts, stem cells and macrophages during the wound healing. Findings from these studies will be highlighted and it is clear that the relative simplicity of the fiber-based models allows the distillation of key matrix parameter driving healing, immune-modulation and their interplay in directing heterotypic cellular response.

Biographies

Christopher Chen
Boston University, Harvard University

Christopher S. Chen, M.D., Ph.D., is Founding Director of the Biological Design Center, and Professor of Biomedical Engineering at Boston University and the Wyss Institute for Biologically Inspired Engineering at Harvard University. Chen has been an instrumental figure in the development of engineered cellular microenvironments to understand how cells build tissues. He has used these approaches to demonstrate a role for cell adhesion, shape, and cytoskeletal mechanics in regulating cell proliferation, differentiation, and apoptosis, and patterning tissue architecture. He serves as a member of the American Institute for Medical and Biological Engineering, Faculty of 1000, editorial board for Annuals Reviews of Cell and Developmental Biology, and Developmental Cell, and editor for Journal of Cell Science, Cell and Molecular Bioengineering, and Technology. He has been awarded the Presidential Early Career Award for Scientists and Engineers, the Angiogenesis Foundation Fellowship, the Office of Naval Research Young Investigator Award, and the Herbert W. Dickerman Award for Outstanding Contribution to Science. He received his Ph.D. from M.I.T., and M.D. from Harvard Medical School. He was the Skirkanich Professor of Innovation at the University of Pennsylvania and founding director of the Penn Center for Engineering Cells and Regeneration before his current appointment.

Andrés Garcia
Georgia Institute of Technology

Andrés J. García, Ph.D., is the Executive Director of the Petit Institute for Bioengineering and Bioscience and Regents' Professor at the Georgia Institute of Technology. García's research program integrates innovative engineering, materials science, and cell biology concepts and technologies to create cell-instructive biomaterials for regenerative medicine and generate new knowledge in mechanobiology. This cross-disciplinary effort has resulted in new biomaterial platforms that elicit targeted cellular responses and tissue repair in various biomedical applications, innovative technologies to study and exploit cell adhesive interactions, and new mechanistic insights into the interplay of mechanics and cell biology. In addition, his research has generated intellectual property and licensing agreements with start-up and multi-national companies. He has received several distinctions, including the NSF CAREER Award, Arthritis Investigator Award, Young Investigator Award from the Society for Biomaterials, Georgia Tech's Outstanding Interdisciplinary Activities Award, the Clemson Award for Basic Science from the Society for Biomaterials, and the International Award from the European Society for Biomaterials. He has been recognized as a top Latino educator by the Society of Hispanic Professional Engineers. He is an elected Fellow of Biomaterials Science and Engineering (by the International Union of Societies of Biomaterials Science and Engineering), Fellow of the American Association for the Advancement of Science, Fellow of the American Society of Mechanical Engineers, and Fellow of the American Institute for Medical and Biological Engineering. He served as President for the Society for Biomaterials in 2018-2019.

Sharon Gerecht
Johns Hopkins University

Sharon Gerecht, Ph.D., is Professor of Chemical and Biomolecular Engineering, Director of the Institute for NanoBioTechnology, and Kent Gordon Croft Investment Management Faculty Scholar, at Johns Hopkins University. Gerecht's research group studies the interactions between stem cells and their microenvironments with the long-term goal of engineering artificial cell microenvironments capable of guiding vascular differentiation, delivery, and regeneration. The research program is based on the integrated and advanced use of tissue engineering system components and is grounded in the fundamentals of interfacial science and engineering and stem cell biology. Gerecht is the recipient of several awards including the Established Investigator Award from the American Heart Association and the Johns Hopkins' Inaugural President's Frontier Award. Gerecht is an elected Fellow of the American Institute for Medical and Biological Engineering (2016). She is the author of more than 150 papers, book chapters, and patents in her field. Gerecht is a co-founder of Gemstone Biotherapeutics, LLC, a spin-off company based on technologies developed in her lab, focusing on wound healing.

Kevin Healy
University of California, Berkeley

Kevin E. Healy, Ph.D. is the Jan Fandrianto and Selfia Halim Distinguished Professor in Engineering at the University of California at Berkeley in the Departments of Bioengineering, and Materials Science and Engineering. He served as Chair of the Department of Bioengineering from 2011 to 2015. He is a thought leader and innovator working at the interface between stem cells and materials science to develop dynamic engineered systems to explore both fundamental biological phenomena and new applications in translational medicine. His group currently conducts research in the areas of: bioinspired stem cell microenvironments to control stem cell lineage specification and self-organization into microtissues or organoids; bioinspired systems for regenerative medicine; biological interfaces; and, microphysiological systems for drug development, gene editing, and environmental toxicity screening. Professor Healy is an elected Fellow of AIMBE, AAAS, FBSE, BMES, and recently received an Alexander von Humboldt Foundation Award. He has chaired the Gordon Research Conference on Biomaterials and Biocompatibility, and has been honored with the 2011 Clemson award for outstanding contributions to basic biomaterials science. He is a named inventor on numerous issued United States and international patents relating to biomaterials, therapeutics, stem cells, and medical devices, and has founded several companies to develop these systems for applications in biotechnology and regenerative medicine.

Dan Dongeun Huh
University of Pennsylvania

Dan Huh, Ph.D., is an Associate Professor and Wilf Family Term Endowed Chair in the Department of Bioengineering at the University of Pennsylvania. He is a pioneer of organ-on-a-chip technology, and his research group at Penn focuses on developing microengineered models of human physiological systems for a wide variety of biomedical applications. Huh has won several honors and awards including the Bernard Langer Distinguished Lectureship, Lush Prize, the McPherson Distinguished Lectureship, CRI Technology Impact Award, John J. Ryan Medal, Design of the Year Award and Best Product of the Year Award from London Design Museum, NIH Director's New Innovator Award, Analytical Chemistry Young Innovator Award, TEDx Fellow, NC3Rs Annual Award, Lifetime Membership from the MoMA, SLAS Innovation Award from the Society for Lab Automation and Screening, Scientific Breakthrough of the Year Award from American Thoracic Society, Best Publication Award and Best Postdoctoral Award from the Society of Toxicology, Wyss Technology Development Fellowship from Harvard, Distinguished Achievement Award from Michigan, Widmer Award from microTAS, and Horace H. Rackham Predoctoral Fellowship.

David Kaplan
Tufts University

David Kaplan, Ph.D., is the Stern Family Endowed Professor of Engineering at Tufts University and a Distinguished University Professor. He is Professor and Chair of the Department of Biomedical Engineering, with a joint appointment at Tufts Medical School and in the Department of Chemistry. His research focus is on biopolymer engineering to understand structure-function relationships for biomaterials, tissue engineering and regenerative medicine. Since 2004, he has directed the NIH P41 Tissue Engineering Resource Center (TERC) that involves Tufts University and Columbia University. He has published over 800 peer reviewed papers. He is the editor-in-chief of ACS Biomaterials Science and Engineering and serves on many editorial boards and programs for journals and universities. His lab has also been responsible for over 100 patents issued or allowed, and numerous startup companies. He has also received a number of awards for his research and teaching.

Helen Lu
Columbia University

Helen H. Lu, Ph.D., received her undergraduate and graduate degrees in Bioengineering from the University of Pennsylvania. She is currently the Vice Chair and Professor of Biomedical Engineering and the Director of the Biomaterials and Interface Tissue Engineering Laboratory at Columbia University. Lu's research focuses on Interface Tissue Engineering and the formation of complex tissue systems, with the goal of achieving integrative and functional repair of soft tissue injuries. Additionally, her research group is active in the design of novel biomaterials for driving stem cell differentiation. Her research has been recognized with many awards, including the Early Faculty Career Awards in Translational Research (Phase I and Phase II) from the

Wallace H. Coulter Foundation and the Young Investigator Award from the Society for Biomaterials. Lu was honored with the Presidential Early Career Award for Scientists and Engineers (PECASE) at the White House in 2010, and was elected as a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) in 2011. Her group has published over 90 original research articles, invited reviews and book chapters in biomaterials and tissue engineering, and she is the inventor and co-inventor of more than a dozen patents and applications. Lu has given over 150 invited lectures at national as well as international conferences and institutions. She serves on the editorial board of leading journals of the fields, including Tissue Engineering, Journal of Biomedical Material Research A, Journal of Orthopaedic Research, Regenerative Biomaterials, Regenerative Engineering and Translational Medicine, and as Associated Editor for Science Advances as well as IEEE Transactions on Biomedical Engineering. Lu's research has been supported by the Whitaker Foundation, the Wallace H. Coulter Foundation, the Musculoskeletal Transplant Foundation, the New York State Stem Cell Initiative, the National Football League (NFL) Charities, the Department of Defense and the National Institutes of Health.

Nadya Lumelsky
National Institute of Dental and Craniofacial Research

Nadya Lumelsky, Ph.D., is a Chief of Integrative Biology and Infectious Diseases Branch and a Director of Tissue Engineering and Regenerative Medicine Program at the National Institute of Dental and Craniofacial Research (NIDCR) at the National Institutes of Health (NIH). Prior to joining NIDCR in 2006, Lumelsky was an investigator at the intramural NIH Program at the National Institute of Neurological Disorders and Stroke and a Section Chief at the National Institute of Diabetes and Digestive and Kidney Diseases. Earlier in her career, Lumelsky conducted research at the University of Wisconsin/Madison and Yale University. She has a wide-ranging expertise in stem cell and developmental biology, cell biology, and bioengineering, and has been a leading and senior author on publications in Science, Nature, Diabetes, Stem Cells, Molecular and Cellular Biology, Tissue Engineering, Trends in Molecular Medicine and other high impact Journals.

Martha Lundberg
National Heart, Lung, and Blood Institute

Martha Lundberg, Ph.D., is an NIH Program Director in the Advanced Technologies and Surgery Branch. Lundberg has proven success in building solid, trusting relationships with key stakeholders to stimulate targeted National Heart, Lung, and Blood Institute (NHLBI) investment in over a dozen research programs. She brings nearly 20 years of experience and management of cell-based systems for cardiovascular regenerative medicine, including smart polymer systems and biodegradable matrices. Lundberg represents the NHLBI and the NIH at Congressional meetings, National and International scientific conferences, and other Trans-governmental activities. She is a key member of the NHLBI Production Assistance for Cellular Therapies Program since 2015. She co-chairs the Multi-Agency Tissue Engineering Science Working Group and is a member of the BioManufacturingUSA Federal Stakeholders Council and the

HESI Global Cell Therapy – Tracking, Circulation and Safety Committee, whose mission is to collaborate and share knowledge, experience and resources with an international network of experts in the rapidly evolving field of cell therapy. Lundberg has received many distinguished awards as a medical researcher and during her public health career. These include two NIH Director's Awards for her collaboration with the NIH Tissue Chip Project Team and the MATES Federal Strategic Plan, as well as the NHLBI Director's Special Act of Service Awards for work with the National Academies Regenerative Medicine Forum and Implementation of the 21st Century Cures Act.

Richard Paules
National Institute of Environmental Health Sciences

Richard S. Paules, Ph.D., is the Acting Chief of the Biomolecular Screening Branch (BSB) in the Division of the National Toxicology Program at the National Institute of Environmental Health Sciences, NIH. The BSB develops and carries out programs in medium and high throughput screening of environmental substances for rapid detection of biological activities of significance to toxicology and administers NTP programs designed to implement its vision for toxicology in the 21st century. In support of this program, BSB members represent the NTP in the U.S. Toxicology in the 21st Century, or Tox21, Federal Collaboration between members of the NTP, U.S. EPA, U.S. FDA and the National Center for Advancing Translations Science (NCATS) at NIH. The research interests of Paules include integrating conventional studies of environmental exposures and toxicity with studies utilizing novel model systems to rapidly assess exposure effects, including global systems or "omics" approaches. He also holds adjunct faculty appointments as Professor in the Department of Pathology and Laboratory Medicine and Member in the Lineberger Comprehensive Cancer Center at the University of North Carolina at Chapel Hill. Paules received his Ph.D. from the Department of Pathology at UNC-CH and then received postdoctoral training with George F. Vande Woude at the National Cancer Institute, NIH, before joining NIEHS in 1990. He has authored 136 peer-reviewed articles, invited articles and book chapters. Since joining the NIEHS, he has been recognized with several awards, including four NIH Merit Awards and an NIH Director's Award, as well as the Society of Toxicology's Leading Edge in Basic Science Award at the 2010 SOT Annual Meeting.

Carmem Pfeifer
Oregon Health and Science University

Carmem Pfeifer, D.D.S., Ph.D., F.A.D.M., is Associate Professor in the Division of Biomaterials and Biomechanics at OHSU School of Dentistry, and in the Department of Biomedical Engineering at OHSU School of Medicine. Pfeifer is a dentist by training (D.D.S., 2001), with a Ph.D. (2007) and post-doctoral fellowships (2008-2011) in the field of Dental Materials, and Polymer Chemistry. Pfeifer has published over 85 research articles in the field (H-factor of 24) and serves as the reviewer for over 40 journals in polymer science and biomaterials, as well as a standing member of the DSR study section for the NIH-NIDCR. She has held leadership positions in the IADR/Dental Materials Group (currently president-elect), Academy of Dental Materials (currently treasurer) and as a member-at-large of the board of directors of AADR. Her

research focuses on the development of innovative polymeric materials for restorative dentistry, to address the challenge of dental restoration degradation over time by bacterial and host factors. Her most recent project is based on polymerizable antimicrobials, targeting EPS-disruption specifically in dysbiotic bacteria, to avoid or significantly alter the formation of biofilms on the surface of biomedical devices and dental restorations. She has received funding for her research and career development from the National Institutes of Dental and Craniofacial Research, Oregon Medical Research Foundation, National Science Foundation, as well as industry partners. She has received the inventor of the year award from OHSU for the commercial potential of her patented inventions. More details at www.biomaterials-pfeiferlab.com

Milica Radisic
University of Toronto

Milica Radisic, Ph.D., is a Professor at the University of Toronto, Canada Research Chair (Tier 2) in Functional Cardiovascular Tissue Engineering and a Senior Scientist at the Toronto General Research Institute. She is also the Associate Chair-Research for the Department of Chemical Engineering and Applied Chemistry at the University of Toronto and Director of the NSERC CREATE Training Program in Organ-on-a-Chip Engineering and Entrepreneurship. She obtained B.Eng. from McMaster University, and Ph.D. form the Massachusetts Institute of Technology. She is a Fellow of the Royal Society of Canada-Academy of Science, Canadian Academy of Engineering and the American Institute for Medical and Biological Engineering. She received numerous awards and fellowships, including MIT Technology Review Top 35 Innovators under 35. She was a recipient of the Professional Engineers Ontario-Young Engineer Medal in 2011, Engineers Canada Young Engineer Achievement Award in 2012, Queen Elizabeth II Diamond Jubilee Medal in 2013 and NSERC E.W.R Steacie Fellowship in 2014. The long-term objective of Radisic's research is to enable cardiovascular regeneration through tissue engineering and development of new biomaterials. Her research interests also include microfluidic cell separation and development of in vitro models for drug testing. Currently, she holds research funding from CIHR, NSERC, CFI, ORF, NIH, and the Heart and Stroke Foundation. She is an Associate Editor for ACS Biomaterials Science and Engineering, a member of the Editorial Board of Tissue Engineering, Advanced Drug Delivery Reviews and Regenerative Biomaterials. She serves on review panels for Canadian Institutes of Health Research and the National Institutes of Health. She is actively involved with BMES (Cardiovascular Track Chair in 2013 and 2014) and TERMIS-AM (Council member, Chair of the Membership Committee). She was a co-organizer of a 2017 Keystone Symposium, "Engineered Cells and Tissues as Platforms for Discovery and Therapy". Her research findings were presented in over 160 research papers, reviews and book chapters with h-index of 56 and over 11,000 citations. She is a co-founder of a New York-based company TARA Biosystems, that uses human engineered heart tissues in drug development and safety testing for major pharmaceutical companies. She serves on the Board of Directors for Ontario Society of Professional Engineers and TARA Biosystems.

Buddy Ratner
University of Washington

Buddy D. Ratner, Ph.D., is the Director of University of Washington Engineered Biomaterials (UWEB21) Engineering Research Center, co-director of the Center for Dialysis Innovation (CDI) and the Darland Endowed Chair in Technology Commercialization. He is Professor of Bioengineering and Chemical Engineering, University of Washington. Ratner received his Ph.D. (1972) in polymer chemistry from the Polytechnic Institute of Brooklyn. He is a fellow of the American Institute of Medical and Biological Engineering (AIMBE), AVS, AAAS, American Chemical Society, ACS-POLY and the International College of Fellows Biomaterials Science and Engineering. In 2002 Ratner was elected to the National Academy of Engineering, USA. He has been involved in the launch of seven companies and won numerous awards including the AVS Welch Award (2002), Society for Biomaterials Founders Award (2004), the BMES Pritzker Distinguished Lecturer Award (2008), the Acta Biomaterialia Gold Medal (2009), the Galletti Award (2011) the George Winter Award of the European Society for Biomaterials (2012) and the University of Washington School of Medicine Lifetime Innovator and Inventor Award (2014). He served as President of Society for Biomaterials in 1998 and AIMBE in 2002. His research interests include biomaterials, medical devices, tissue engineering, regenerative medicine, biocompatibility, polymers, surface analysis and plasma thin film deposition.

Les Reinlib
National Institute of Environmental Health Sciences

Les Reinlib, Ph.D., is a Health Scientist Administrator at the National Institute of Environmental Health Sciences, NIH. He develops and leads scientific programs in molecular and experimental carcinogenesis, tissue chips and stem cells, genomic integrity, and Breast Cancer and the Environment Research. Reinlib received a B.S. and M.S. in Biology from the University at Albany and a Doctorate in Natural Sciences and Biochemistry from the Swiss Federal Institute of Technology in Zurich, Switzerland. He was on the faculty of Tufts University – New England Medical Center and later the Johns Hopkins University School of Medicine before joining the NIH in 1990. Throughout his career, Reinlib has worked with laboratory and clinical investigators focusing on cellular mechanisms of disease. He has published reports on stem cell biology and therapy, genome integrity, breast cancer, circadian rhythm disorders, environmental origins of lupus, mechanisms of heart failure, and second messenger regulation underlying health disorders.

Gordana Vunjak-Novakovic
Columbia University

Gordana Vunjak-Novakovic, Ph.D., is a bioengineer appointed University Professor, the highest academic rank at Columbia University reserved for only 16 professors out of 4,000, as the first engineer in the history of Columbia to receive this highest distinction. She is also the Mikati Foundation Professor of Biomedical Engineering and Medical Sciences, and a faculty in the Irving Comprehensive Cancer Center, College of Dental Medicine, Center for Human Development, and the Mortimer B Zuckerman Mind Brain Behavior Institute. She received her

Ph.D. in Chemical Engineering from the University of Belgrade in Serbia where she was a faculty until 1993 (full professor), holds a doctorate *honoris causa* from the University of Novi Sad, and was a Fulbright Fellow at MIT. The focus of her research is on engineering functional human tissues for regenerative medicine and studies of development and disease. She published 3 books, 60 book chapters, 400 journal articles (including those in Nature, Cell, Nature Biotechnology, Nature Biomedical Engineering, Nature Communications, Nature Protocols, Science Advances, PNAS, Cell Stem Cell, Science Translational Medicine) that were cited 44,000 times, with an impact factor h=120. She also has 101 licensed, issued or pending patents. With her students, she co-founded four biotech companies: epiBone (epibone.com), Tara Biosystems (tarabiosystems.com), Xylyx Bio (xylyxbio.com), and Immplacate (immplacatehealth.com).

Among her many recognitions, Vunjak-Novakovic was elected to the Council of the National Institute for Biomedical Imaging and Bioengineering (NIBIB), HHMI Scientific Review Board, American Institute for Medical and Biological Engineering (AIMBE) where she was the Chair of the College of Fellows (2016-17), inducted into the Women in Technology International Hall of Fame, and received the Clemson Award of the Biomaterials Society (2009), the Pritzker Award of the Biomedical Engineering Society (2017) and Shu Chien Achievement Award (2018). She gave the Director's lecture at the NIH, as the first woman engineer to receive this distinction. Her team received the 2019 TERMIS award for innovation and commercialization. She was also elected to the New York Academy of Sciences, Academia Europaea, and the Serbian Academy of Sciences and Arts. She is a Fellow of the Biomedical Engineering Society, a Fellow of the AAAS, a Founding Fellow of the International Society for Tissue Engineering and Regenerative Medicine, and one of the Foreign Policy's 100 Leading Global Thinkers for 2014. Vunjak-Novakovic is a member of the National Academy of Engineering, the National Academy of Medicine, the National Academy of Inventors, and the American Academy of Arts and Sciences.

Fei Wang
National Institute of Arthritis and Musculoskeletal and Skin Diseases

Fei Wang, Ph.D., is the Program Director for the Musculoskeletal Tissue Engineering and Regenerative Medicine Program (https://www.niams.nih.gov/grants-funding/supported-scientific-areas/musculoskeletal-tissue-engineering-and-regenerative) in the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH). Wang has long been an advocate for Tissue Chip research and her interest in this area began when she was working in the National Institute of Biomedical Imaging and Bioengineering (NIBIB) in 2005.

John Wikswo
Vanderbilt University

John P. Wikswo, Ph.D., is the Gordon A. Cain University Professor, the A. B. Learned Professor of Living State Physics, and Professor of Biomedical Engineering, Molecular Physiology and Biophysics, and Physics at Vanderbilt University, and the founding Director of the Vanderbilt Institute for Integrative Biosystems Research and Education (VIIBRE). Trained as a physicist, he

received his B.A. degree from the University of Virginia and his Ph.D. from Stanford University. He has been a member of the Vanderbilt faculty since 1977. His research has included superconducting magnetometry, the measurement and modeling of cardiac, neural, and gastric electric and magnetic fields, and non-destructive testing of aging aircraft. Since 2001, VIIBRE has developed a breadth of optical instruments and software for studying how living cells interact with each other and their environment and respond to drugs, chemical and biological agents, and other toxins, thereby providing insights into systems biology, physiology, medicine, and toxicology. For the past decade, Wikswo has been guiding VIIBRE engineers and scientists in the development of microfabricated organ-on-chip bioreactors that include an NCATS-funded neurovascular unit / blood-brain barrier and the associated perfusion controllers, microclinical analyzers, and other devices that are required to integrate multiple organs-on-chips to create an in vitro micro-homunculus. His group's most recent innovations include the ongoing development of 96-channel microformulator, funded by AstraZeneca, and a smart well plate for organs-on-chips and high-throughput biology, funded by an NCATS SBIR to CFD Research Corporation. VIIBRE is also the home of the Systems Biology and Bioengineering Undergraduate Research Experience (SyBBURE), a year-round, multi-year program funded by Gideon Searle. Wikswo has published more than 200 peer-reviewed papers, is a fellow of seven professional societies, holds 28 patents, several of which have been licensed, has multiple patents pending, and nurtures innovation among his trainees. He loves teaching and learning and sharing his enthusiasm for research and inventing with high school students, undergraduates, and graduate students.

Fan Yang
Stanford University

Fan Yang, Ph.D., is currently an Associate Professor with tenure at Stanford University in the Departments of Bioengineering and Orthopaedic Surgery, and Director of Stanford Stem Cells and Biomaterials Engineering Laboratory. Her research seeks to develop novel biomaterials and cell-based therapeutics for tissue regeneration, with special focus on treating musculoskeletal diseases, cardiovascular diseases and cancer. Prior to joining Stanford, Yang received her Ph.D. in Biomedical Engineering at the Johns Hopkins University, and then completed a postdoctoral fellowship in the laboratory of Prof. Robert Langer at MIT. In recognition of her innovation, she was selected to be one of the TR35 Global list honorees by MIT's Technology Review in 2011, which recognizes the world's 35 most outstanding innovators in that year who are younger than 35. Yang has published over 90 journal articles and her research lab has been awarded 27 research grants from both federal agencies and private foundations including NIH R01s, NSF CAREER Award, and Tools and Technologies Development Award from California Institute of Regenerative Medicine. She has also been recognized by numerous awards including Young Investigator Award from Society for Biomaterials, Biomaterials Science Lectureship Award, Young Investigator Award from Alliance for Cancer and Gene Therapy, Ellen Weaver Award by the Association for Women in Science, National Scientist Development Award from American Heart Association, Rising Star Award from BMES-CMBE, Mission for Learning Faculty Scholar Award in Pediatric Translational Medicine, Donald E. and Delia B. Baxter Faculty Scholar Award, the McCormick Faculty Award, Stanford Asian American Faculty Award, the 3M Nontenured Faculty Award, and the Basil O'Connor Starter Scholar Research Award.

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Workshop on Tissue Chip Platforms as Tools for Testing Biocompatibility and Biotoxicity of Biomaterials