Multi-Agency Tissue Engineering Science (MATES) Interagency Working Group (IWG)

Advancing Tissue Science and Engineering: A Foundation for the Future

A Multi-Agency Strategic Plan

Presented to the

FDA/NIST Workshop on *In Vitro* Analysis of Cell/Scaffold Medical Products

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MATES IWG

Tissue Engineering

- Term first coined in 1985 – NSF Engineering Research Center Proposal
- Definition resulted from first Tissue Engineering Conference (Granlibakken – Lake Tahoe, 1988).

  (the application of principles and methods of engineering and the life sciences toward fundamental understanding of structure-function relationships in normal and pathological mammalian tissues and the development of biological substitutes to restore, maintain, or improve tissue functions.)

- NSF Call for Proposals and Awards for Tissue Engineering occurred shortly after the Granlibakken Conference.
- Interagency Contacts sprang from Biotechnology Research Subcommittee (BRS) Activities.

Regenerative Medicine

- An overlapping field, encompasses some of the knowledge and practice of tissue engineering
- Also includes:

  self-healing through endogenous recruitment or exogenous delivery of appropriate cells, biomolecules, and supporting structures…

- Differentiated from other disciplines by its focus on cures rather than treatments
- See U.S. Department of Health and Human Services 2005. *2020: A New Vision, A Future for Regenerative Medicine*. http://www.hhs.gov/reference/newfuture.shtml

Tissue *Science and* Engineering

- Expanded terminology reflects transdisciplinary technical scope, broader suite of applications, and wider Federal agency interest.
  (the use of physical, chemical, biological, and engineering processes to control and direct the aggregate behavior of cells.)

- Advances in complex biological applications requires input from the physical and chemical sciences.

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Participating Agencies/Departments

Centers for Medicare and Medicaid Services (CMS)
Environmental Protection Agency (EPA)
Department of Defense (DOD, i.e., DARPA, NRL, Army)
Department of Energy (DOE)
Food and Drug Administration (FDA)
National Aeronautics and Space Administration (NASA)
National Institute of Standards and Technology (NIST)
National Institutes of Health (NIH)
National Science Foundation (NSF)
Office of Science and Technology Policy (OSTP)

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- The MATES IWG was first established with a Five-Year Plan in 2000
- The MATES IWG Five-Year Plan was revised and renewed in 2002
- Terms of Reference (TOR) Approved July 2007
- Overarching goal: maximize the benefit to society of the Federal investment in tissue science and engineering, specifically to provide a means for Federal agencies to stay informed of each others' activities and better coordinate their efforts.

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Accomplishments (5 Years)

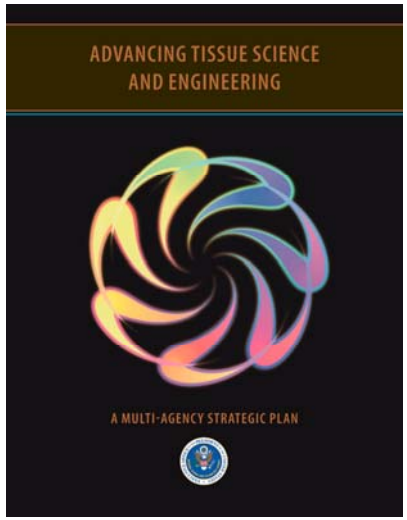
- Panel report, comparative international assessment of tissue engineering research (2002)
- Interagency website: http://www.tissueengineering.gov
- NIH-issued (multi-Institute) RFA for tissue engineering proposals based on information from the international assessment (2003)
- Report: “The Emergence of Tissue Engineering as a Research Field” (2003)
- Interagency Funding Opportunity Announcement (FOA) on “Enabling Technologies for Tissue Engineering and Regenerative Medicine” (2006)
- Workshop: “Stem Cell Research for Regenerative Medicine and Tissue Engineering” (2007)
- Strategic Plan issued through the Office of Science and Technology Policy (2007)

Tissue Science and Engineering

Why have a Multi-Agency Activity?

- Priority areas are not the purview of any one agency.
- Advances in tissue science and engineering will require the close collaboration between the physical sciences and the life sciences.
- Leadership is needed in the fields of bioethics, logistics, premarket review, standards development, and patient reimbursement.
- Tissue science and engineering addresses the OSTP/OMB FY2008 Guidance Memo on Interagency R&D Activities for a "…Deeper Understanding of Complex Biological Systems…"

Tissue Science and Engineering



Why a Strategic Plan Now?

- Persistent unfulfilled promise of generating an abundant supply of tissues and organs to replace those lost to disease, aging, and trauma
- Well-defined in vitro assay and screening systems could augment or substitute for less efficient animal testing
- Tissue culture “factories” could produce vaccines and other complex drugs
- A mechanistic understanding and better tools will accelerate the development commercially viable products
- Rapid progress will require integration across many scientific, engineering, and regulatory disciplines
- Fully-functional, tissue-based products and systems will depend on accurate, reliable measurements at many scales

MULTI-AGENCY TISSUE ENGINEERING SCIENCE (MATES) WORKING GROUP

Tissue Science and Engineering

Overarching Goals of the MATES Strategic Plan

- Understanding and Controlling the Cellular Response
- Formulating Biomaterial Scaffolds and the Tissue Matrix Environment
- Developing Enabling Tools
- Promoting Scale-Up, Translation, and Commercialization

Tissue Science and Engineering

Strategic Priorities in the MATES Strategic Plan

- Understanding the Cellular Machinery
- Identifying, Validating Biomarkers and Assays
- Advancing Imaging Technologies
- Defining Cell/Environment Interactions
- Establishing Computational Modeling Systems
- Assembling and Maintaining Complex Tissue
- Improving Tissue Preservation and Storage
- Facilitating Effective Applications Development and Commercialization

Tissue Science and Engineering

Implementation Plans

- Convene “State-of-the-Science” workshops targeted toward bringing new investigators with diverse backgrounds to the field (e.g., today’s workshop)
- Issue agency-specific and interagency funding opportunity announcements (FOAs)
- Promote interagency personnel “exchanges” -- research collaborations, postdoctoral programs, details and sabbaticals, cross training
- Foster technology transfer and translation via SBIR/STTR, centers of excellence, engineering research centers, joint R&D ventures, etc.
- Coordinate policy development, especially participation in development/adoption of industry-wide standards
- Exchange knowledge via a living database of funded projects and tissue science and engineering advances
- Track commercialization and R&D activity worldwide

Tissue Science and Engineering

Expected Outcomes

- Conferences with Academic and Commercial Communities
- Calls for Proposals and Grants Awarded
- Publications
- Patents
- Entry of New Companies into the Field
- FDA-Approved Products
- CMS Reimbursement Decisions
- Evaluations of the State of the Field Worldwide
- Interagency Collaborations

THANK YOU!

Comments, Questions?

Further Information: www.tissueengineering.gov