

Policy Harmonization Through Collaboration: The Interstate Alliance on Stem Cell Research

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The Interstate Alliance on Stem Cell Research (IASCR) is a voluntary body whose mission is to advance stem cell research by fostering effective interstate collaboration, by assisting states in developing research programs, and by promoting efficient and responsible use of public funds. The IASCR was formed in 2007 by the organizers of Connecticut's Stem Cell Research International Symposium. The original objective was to facilitate coordination among U.S. states that wish to advance stem cell research. The IASCR provides a forum for information exchange and collaborative planning in an attempt to facilitate the sharing resources and to support the efficient development of research programs. Because stem cell research is an international endeavor, the IASCR includes other affiliates jurisdictions and organizations that have established collaborations with U.S. states. The National Academies of Sciences serves as the secretariat.

Participating States

- California
- Illinois
- Massachusetts
- New York
- Rhode Island
- Connecticut
- Maryland
- New Jersey
- Ohio
- Wisconsin

Other Affiliates

- Canada
- The National Academies
- United Kingdom
- International Society for Stem Cell Research

Developing Practical Solutions

IASCR meetings and publications are designed to develop practical solutions to issues and challenges facing publically-sponsored research programs. Deliberations are specifically designed to generate solutions to regulatory and policy challenges. Topics for

in-depth analysis and deliberation have included:

- **Collaborative Funding Agreements:** Many states have developed bilateral collaborative funding agreements with other states, NGOs and other countries. Collaborative funding of research serves to optimize the use of resources and avoid duplication while creating a critical mass of excellence across a wide range of specialties both nationally and worldwide. Such agreements require detailed memorandum of understanding and implementation procedures. The IASCR provides a venue for sharing model language and developing consistent approach to collaborative agreements. As a result, the IASCR serves to speed research and economic development opportunities (see Maryland / Ohio & Wisconsin testimonials).
- **Regulatory Harmonization:** Variation in state and national policies might impede collaboration or the sharing of research materials or raise overall costs. As a result of detailed analysis published by IASCR,¹ policy makers have the tools to address sources of regulatory inconsistency. IASCR's analysis has utilized by decision-makers to harmonize policies thus supporting more effective collaboration and exchange.
- **National Policy Development:** The IASCR report, *Advancing the Promise*,² is one example of how the Alliance simultaneously supports effective state and national policy development. This report served to compile the views of the nations leading stem cell research institutions, funding organizations, state programs and scholars into a joint report to NIH. Themes and policy remedies identified in *Advancing the Promise* are reflected in the final *NIH Guidelines for Human Stem Cell Research*.
- **Policy Impacts on Research Institutions:** IASCR invites research institutions to share their experiences implementing stem cell research policies. Research institutions, such as Harvard and Stanford Universities and the Universities of Wisconsin and Massachusetts, described their experiences with implementing policies consistent with the National Academies' Guidelines for Human Stem Cell Research. These perspectives allow state funding agencies to perform regulatory impact evaluations, which ultimately serve to inform legislators, advisory bodies and related policy deliberations.

- **Policy Impacts on Stakeholders:** The IASCR also invites key constituencies to discuss critical needs for the field. IASCR has developed relationships with organizations advancing the interests of potential research donors (such as the National Infertility Association and the American Society for Reproductive Medicine) to nonprofit research organizations and foundations promoting the interests of patients who might benefit from research (such as the Juvenile Diabetes Research Foundation and the New York Stem Cell Foundation). Such interactions alert and connect IASCR members to the needs of a broad base of constituents and serves as a vehicle stakeholder involvement in state policy development.

Participant Testimonials

Facilitating State-State Collaboration: the Wisconsin Perspective

Since its inception in 2007, the Interstate Alliance for Stem Cell Research has led efforts to promote collaboration among disparate and disconnected state, and other non-profit, stem cell research support organizations. Between 2001 and 2009, Federal policies precluded coordinated U.S. government efforts in this promising area of human embryonic stem cell research so the IASCR stepped in to provide a venue for states to share strategies for funding and promoting this work. While Wisconsin and the WiCell Research Institute led early advances in human pluripotent cell research and development (for example the derivation of the first primate and human embryonic stem cell lines, the establishment of the National Stem Cell Bank, and the first patents protecting human embryonic stem cell rights that led to the approval of the use of these cells in clinical trials), the processes and experiences that led to these advances and advances that occurred in a few other states, such as California, were not being disseminated to other state and non-profit organizations prior to the formation of the IASCR. A testament to the success of the IASCR is the growth and success of stem cell programs in the states and organizations that have participated in the IASCR, including Wisconsin and WiCell. In 2010, Wisconsin Governor Jim Doyle and the Chair of the Governing Board of the California state stem cell agency, Robert Klein, signed a Declaration of Cooperation that aims to create a framework for joint funding between researchers in the two states and to accelerate the pace of development of cellular therapies to patients.

Hence, the mission of the IASCR to “advance stem cell research by fostering effective interstate collaboration, by assisting states in developing research programs, and by promoting efficient and responsible use of public funds” has achieved important milestones.

Advancing Economic Development: the Maryland & Ohio Experience

Maryland and Ohio are both members of the Interstate Alliance for Stem Cell Research, which has provided a forum for exchange and cooperation across state lines. The two states have taken different approaches to a similar goal of driving biotechnology economic development. The IASCR provided a unique forum for support during program development in both states.

Maryland emphasizes economic development through the

investment of stem cell funding to academic institutes as well as companies within the State. The management of the *Maryland Stem Cell Research Fund*, provided by the Maryland Technology Development Corporation (TEDCO), an independent entity established by the Maryland General Assembly in 1998, facilitates the creation of businesses and fosters their growth in all regions of the State through the development and commercialization of technology.

The MSCRF funded 181 different projects in a four-year period. According to several economic models,³ each scientific grant creates between seven to ten new jobs. Based on modeling, the grants made in the year 2007 and 2008 supported more than 500 jobs in Maryland statewide. These jobs were associated with more than \$34 million in income, which translates to more than \$64,000 per job.

In addition to job creation and again, in just the first two years, the industry was able to “return” nearly \$3 million to State and local governments through greater support for income generation, retail activity and property tax payments.

Ohio supports stem cell commercialization through its Ohio Third Frontier Program (“OTFP”) from the Ohio Department of Development. The OTFP provides financial incentives in the form of matching dollars, for companies to partner with non-profit research organizations in developing new technologies and products.

The Center for Stem Cell and Regenerative Medicine (CSCRM) is funded in part by OTFP and has refined an effective approach in the regenerative medicine technology space. The successful OTFP template includes providing financial incentives for companies to partner with non-profit research organizations to extend company development dollars. It also provides incentives to develop centers of excellence including academic and commercial capabilities, which feed into Ohio’s economy. CSCRM has effectively adapted this basic format by brokering a consortium of non-profit and for-profit members with mutual goals and vision.

The economic impact of CSCRM’s programs have provided a natural common ground for collaboration with biotechnology economic development organizations and chambers of commerce for business formation, recruitment, and clinical development acceleration initiatives. In addition to building the commercial and research elements of this technology sector, the success of CSCRM has fed into Ohio’s premier healthcare industry. There has been a 10-times leverage of state investment of \$32.4M over seven years and creation of 130 new jobs, seven new company start-ups, private equity investments to the partner companies of \$83M, and \$180M in additional research funding. IASCR plays an important role in allowing participants, such as Ohio and Maryland, foster collaborative agreements, exchange models to support economic development, and share methodologies for evaluating impact, thus building on the success of the Maryland and Ohio programs to other states’ initiatives.

A Source of Innovation: The New York Stem Cell Foundation

Stem cell research represents a vital resource for modeling disease pathology, developing therapies and testing the efficacy and safety of drugs that will advance to the clinic to cure and prevent diseases that affect millions of people worldwide. To realize the full potential of this groundbreaking field, it is essential that the private and public

sectors work together. Many states have worked hard to develop funding programs and ethical oversight to support this essential research independently of the federal system. The IASCR network has provided a forum for collaboration, communication and strategic planning to ensure private-public partnerships can move forward in a coordinated way that will maximize the potential of efforts nationwide. Private philanthropy supports the cutting-edge, proof of concept research that can then be scaled up through public funding.

The New York Stem Cell Foundation (NYSCF) is funded entirely by private philanthropy and was founded in 2005 to address the lack of funds and facilities available for stem cell research. Today, NYSCF is acknowledged as a leader in this field in advocacy, advising on policy/program development, and scientific research. NYSCF opened the first privately funded stem cell laboratory in New York City, where NYSCF researchers and collaborating scientists conduct advanced stem cell research free of federal restrictions. The organization supports scientists engaged in stem cell research through the NYSCF Fellowship Awards for Early Career Investigators programs; organizes the annual translational stem cell conference and other symposia; runs collaborative, state-of-the-art research facilities directly focused on curing disease; and educates the public about the importance and potential benefits of stem cell research. The NYSCF also interacts with stem cell networks worldwide and continues to explore opportunities to fulfill its mission and find cures for the major diseases of our time.

As an independent organization, the NYSCF has been intrinsically involved in the strategic development of New York State's stem cell program from the outset and is proud to continue to offer advice and support for the Empire State Stem Cell Board's NYSTEM stem cell research funding program. As part of the IASCR network, NYSCF is able to continue to make a significant contribution to this exciting field of research, to discuss policy issues and to learn about initiatives in other states that will move stem cell research forward in the most productive way.

A Catalyst for International Development & Exchange: The UK Experience

In March 2005, the UK Government launched The UK Stem Cell Initiative to provide a high-level review, in collaboration with public and private sector stakeholders, to formulate a ten-year vision for UK stem cell research from 2006 to 2016 and to create a platform for coordinated public and private funding of research. The UK Stem Cell Bank supports this initiative by supplying cell lines under accredited quality systems, both for basic research and the development of clinical applications. The first of its kind to be established worldwide, the Institute has become a centre of expertise that provides support to scientists and clinical projects through the provision of well-characterized and safety assured stem cell lines. Public/private research initiatives and the associated banking and distribution of research materials require a high degree of policy coordination. The UK has continually strives to build international collaborations and is a partner in many initiatives sponsored by U.S. states. Participation in the IASCR affords UK representatives the opportunity to gather valuable information concerning the direction of U.S. state-based research programs. IASCR provides a venue where

UK scientists and cell bank administrators can coordinate directly with their U.S. colleagues. The concentration of expertise during IASCR deliberations allows UK representatives to address policy challenges in a highly detailed and efficient manner.

A Roadmap for Policy Development the Massachusetts A Experience

Since the IASCR's inaugural meeting in May of 2007, Massachusetts has actively participated in the discussion and shared its legal and policy developments. Participation in the IASCR has not only provided Massachusetts with a forum to discuss complex policy issues, but has also provided Massachusetts with a veritable clearinghouse of information on state and national developments in the area of stem cell research oversight and policy as it navigates the regulatory waters since the passage of its own stem cell research authorizing legislation in 2005.

Massachusetts has passed a number of landmarks along the way. In June of 2007, Massachusetts Governor Deval Patrick filed a 10-year, \$1 billion Life Sciences Initiative to finance cutting-edge research within the Commonwealth. Within the same month, and pursuant to Governor Patrick's Life Sciences Initiative, the Board of the Massachusetts Life Sciences Center voted to approve more than \$8.2 million in funding to the University of Massachusetts Medical School for the establishment of the Massachusetts Human Embryonic Stem Cell (hESC) Bank and an International hESC Registry.

Throughout this period, Massachusetts policymakers have met with researchers and sought to address concerns and questions of interpretation raised by researchers seeking to comply with the statutory and regulatory framework surrounding stem cell research. A Biomedical Research Advisory Committee (BRAC), composed of scientists, academic leaders, researchers, ethicists, and others advise the legislature and Administration on implementation and potential amendments to the statute and regulations. Since 2005, the BRAC has reviewed and commented on the Department of Public Health's proposed regulations and advisory rulings interpreting. Pursuant to such review, the Massachusetts Department of Public Health (the Department) has implemented regulatory changes and issued interpretative guidance facilitating research within the Commonwealth. Participation in the IASCR provides a networking opportunity for Department staff to research the related technical and substantive issues surrounding such policy amendments and interpretations.

Conclusion

The IASCR strives to vertically integrate the policy needs within the dynamic domain of publically sponsored human stem cell research. Core participants bring a range of experience related to program administration and implementation. Affiliated members provide additional knowledge and expertise on an international level. As described in the participant testimonials, IASCR's efforts have served to:

- Identify policies that spur economic development.
- Facilitate inter-jurisdictional collaborative partnerships.

- Foster communication among a variety of stakeholders.
- Influence national stem cell research policy.

The collective knowledge and expertise that emerges from IASCR deliberations serves to support the efficient and responsible use of public funds towards the development of new stem cell therapies and cures.

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Geoffrey Lomax, Dr.PH.

Dr. Geoffrey Lomax is the Senior Officer for the Medical and Ethical Standards at the California Institute for Regenerative Medicine. He develops the CIRM's medical and ethical standards, performs compliance-related activities and facilitates the institutes Standards Working Group and advisory body to the Independent Citizens Oversight Committee. He worked previously as the Research Director with the California Environmental Health Investigations

Branch to publish and implement a strategic plan for the development of an Environmental Health Surveillance System in California. Through his professional career Dr. Lomax has continually work to bridge issues of scientific, policy and ethics in the development of state-based public health programs and research. His DrPH research and M.P.H. work were performed within the Division of Environmental Health Sciences at the University of California at Berkeley and his BS in Environmental Toxicology was conferred by the University of California at Davis.

Erik Forsberg, Ph.D.

Erik Forsberg is the executive director of the WiCell Research Institute in Madison, WI. Erik graduated from Kalamazoo College and earned a Ph.D. in pharmacology and physiology from the University of Chicago. Erik has worked as a staff scientist at the NIH, assistant professor of Physiology at the University of Wisconsin-Madison, vice president of Infigen, Inc., director of cloning technologies at Minitube of America, Inc., senior director of scientific development at Pharming Healthcare, Inc., and has maintained a part-time senior scientist

appointment in the Department of Surgery at the University of Wisconsin since 2004. Erik's vision is to build WiCell's collaborative R&D efforts with universities, non-profit organizations and companies to promote the translation of basic stem cell research into new therapies and diagnostics for unmet medical needs.



Dan Gincel, Ph.D.

Dr. Dan Gincel is the Director of the Maryland Stem Cell Research Fund (MSCRF) at the Maryland Technology Development Corporation (TEDCO). Dr. Gincel represents Maryland on the Inter-State Alliance on Stem Cell Research (IASCR), and also volunteers as a VP of Regional Managers in the Israeli

Foundation BioAbroad, building the Life Science field while reducing the Israeli "brain-drain". Dr. Gincel has over 15 years of extensive

experience in research and management that spans various areas in biochemistry, cell biology and stem cell research. Before joining TEDCO, Dr. Gincel completed four years of postdoctoral fellowships at Johns Hopkins University, Department of Neurology. Dr. Gincel published his research and opinions in many articles. He acquired his leadership, management and strategic skills as an officer in the Israeli armed forces and further developed those skills through his work in university environments. Dr. Gincel has a Ph.D. and a B.S. from the Ben-Gurion University in Israel.

Debra S. Grega, Ph.D.

Debra has extensive experience in the enhancing the value from collaborations of interdisciplinary research groups and biotechnology business and product development organizations.

Currently the Associate Director of Business Development in the University of Michigan Office of Research, prior to July 2010, Debra was the founding Executive Director of the Center for Stem Cell and Regenerative Medicine (CSCRM), a multi-institutional center composed of investigators from Case Western Reserve University, University Hospitals Case Medical Center, the Cleveland Clinic, Athersys, Inc., and Ohio State University, established in 2003.

Debra has seventeen years of international, commercial biotechnology experience. She has worked on both the scientific and business aspects of new biotechnology commercialization of research and FDA-regulated products. Prior to joining CSCRM, as Senior Manager Business Development at Athersys, Inc., Dr. Grega managed strategic alliances with key pharmaceutical partners such as Bristol Myers Squibb and

Pfizer, in addition to providing and facilitating program management and value realization.

Debra was employed for 14 years at Roche Diagnostics/ Boehringer Mannheim Corporation. After starting as a group leader in research and development, she moved into more business-oriented positions, such as Manager of Business Development, e-Commerce and Director of Global Marketing, contributing to many company successes including the launch and support of over 30 products.

Debra received her Ph.D. in Biology, from the University of Kentucky in 1982, and completed her postdoctoral studies at the University of Michigan, and Colorado State University and business administration at Anderson University. She was an adjunct Professor of Neurobiology at Indiana University School of Medicine from 1988 to 2001.



Melissa J. Lopes, J.D.

Melissa Lopes is Deputy General Counsel for the Massachusetts Department of Public Health. In the life sciences arena, Ms. Lopes has provided advisory rulings on egg donation in the human embryonic stem cell research context, and drafted Department regulations under the Massachusetts Stem Cell bill and the Pharmaceutical and

Medical Device Manufacturer Conduct bill. Further, Ms. Lopes works with the Biomedical Research Advisory Council and serves as Co-Chair of the Interstate Alliance on Stem Cell Research convened by the National Academies of Sciences. Ms. Lopes also serves on the Stem Cell Advisory Committee for the UMASS Medical School International Stem Cell Registry and the Massachusetts Human Embryonic Stem Cell Bank. Additionally, Ms. Lopes provides legal advice and guidance

to the Determination of Need program, the Office of HIV/AIDS, the Clinical Laboratories Program and on matters including blood banking and body art in the Commonwealth. Prior to joining the Department of Public Health, Ms. Lopes was a Kellogg Fellow with Community Catalyst, a national healthcare advocacy group. In this capacity, Ms. Lopes worked with grassroots community groups across the country to secure and preserve needed healthcare resources. Ms. Lopes also worked as an associate attorney with the law firm Choate, Hall & Stewart in the corporate and healthcare departments. Ms. Lopes is a graduate of Boston College and Boston University School of Law, where she was an editor for the American Journal of Law and Medicine. Ms. Lopes was named a "Hero From the Field" at the 2009 Rx for Excellence Awards and was a recipient of the 2009 Commonwealth Citation for Outstanding Performance.

Caroline J. Marshall, Ph.D.

Caroline is a stem cell biologist with extensive research experience in the fields of hematopoietic, neural and embryonic stem cells. Prior to relocating to the USA in 2007, she ran a research project at the Wolfson Centre for Gene Therapy, University College London and Great Ormond Street Hospital for Children in the UK (1996-2006). Her research focused on how blood cells are formed in human embryos and the identification of molecular pathways that could be used in the treatment of disease. She has a keen interest in the ethical and social issues surrounding stem cell research and the promotion of

communication between scientists, government and public. She now works as Scientific Program Director for The New York Stem Cell Foundation, overseeing research and Fellowship programs, grant management and liaison with state and government agencies to improve funding for stem cell research.





Stefan Winkler, Ph.D.

Dr. Stefan Winkler is the UK Industry Advisor for Life Sciences for North America. His responsibilities include the promotion and guidance of regulatory issues concerning the life science and healthcare sectors, as well as providing the British Government with information and advice on issues concerning policy and wealth creation. A second area is the support of inward investment and trade for the UK industry as well as providing scientific and technical advice to the UK's lifescience trade and investment teams in the US and Canada. Before taking this role, Stefan served as Consul and Chief Science Officer at the British Consulate-General in Boston where he represented the British Foreign and Commonwealth Office's Science and Innovation Network in New England, New York, New

Jersey and Pennsylvania.

Before joining the Consulate, Stefan was a Manager of Biotechnology Research and Development in Arthur D. Little's Technology and Innovation Directorate focusing on commercial biotechnology.

Prior to joining Arthur D. Little, Stefan was involved in academic research. Besides his research at Tufts University and MIT, Stefan has worked at the National Institute of Sericulture and Entomological Science in Tsukuba, Japan; the Kyoto Institute of Technology, Japan; the University of Bristol, England; the US-Army Laboratories in Natick, MA; and the Institute for Applied Cell Culture in Munich, Germany.

Stefan received his Dipl.-Ing. (M.E.) degree from the FH-Weihenstephan in Germany and the Massachusetts Institute of Technology, and his Ph.D. degree from Tufts University.

Warren Wollschlager, Ph.D.

As Chief of the Office for Research and Development in the Connecticut Department of Public Health (DPH), Warren Wollschlager is the architect of Connecticut's internationally recognized stem cell research grants-in-aid program. Mr. Wollschlager manages the Connecticut Stem Cell Research Advisory and Peer Review Committees, and in May 2007 he was named the founding Chair of the Interstate Alliance on Stem Cell Research. He also manages agency initiatives involving umbilical cord blood banking, tissue biobanking, and genomics. He chaired the Connecticut Umbilical Cord Blood Banking and Biobanking Feasibility Committees and serves as Vice Chair of the Connecticut External Advisory Panel on Genomics.

In October 2009, he was designated as the Acting Government Health Information Technology Coordinator for the State of Connecticut. He

manages the Connecticut Health Information Technology and Exchange Advisory Committee and is the Project Manager for the State Health Information Exchange Cooperative Agreement with the Office of the National Coordinator.

Prior to being named Chief of Research and Development, Mr. Wollschlager served for six years as Chief of Staff of DPH, overseeing an agency with 800 employees and a budget of \$160 million. He previously served as Chief of the Bureau of Regulatory Services, responsible for the licensure and regulation of all health care and environmental practitioners and providers in Connecticut.



References

1. See <http://www.iascr.org/docs/LomaxStayn2008.pdf>
2. See http://www.iascr.org/docs/IASCR_Summary_NIH_Draft_Guidelines.pps
3. See: <http://www.marylandtedco.org/pressroom/detail.cfm?urlid=202>