NIBIB Workshop
on
Future Research Directions

National Institute of Biomedical
Imaging and Bioengineering

Crystal Ballroom
Bethesda Hyatt
Bethesda, Maryland

December 16-17, 2002

NIBIB WORKSHOP ON FUTURE RESEARCH DIRECTONS

Richard E. Swaja and Mariaileen D. Sourwine
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Executive Summary

A "Workshop on Future Research Directions" was conducted by the National Institute of Biomedical Imaging and Bioengineering (NIBIB) on December 16-17, 2002, at the Bethesda Hyatt Hotel in Bethesda, Maryland. This meeting represented a "NIBIB Futures Workshop" and was aimed at obtaining scientific community input on where the Institute can make a major impact on healthcare or biomedical research in the next five to ten years. To meet this objective, participants were requested to answer two questions:

1. What are the highest priority research focus areas for the NIBIB to consider that are appropriate for its mission and support national priorities, and

2. What are promising emerging technologies or high-impact projects that the NIBIB can consider to address these focus areas?

A total of 50 people attended this workshop including 23 invited extramural participants with expertise in a variety of areas associated with biomedical imaging and bioengineering research, 11 senior NIH (non-NIBIB) bioengineering and imaging program staff from other institutes and centers, 6 observers from other agencies and societies, and ten NIBIB program and science administration staff. Workshop results for NIBIB consideration were based on input from the extramural participants and senior NIH program staff.

The following topics are the ten highest priority research focus areas where participants believe that the NIBIB can have an impact on healthcare or biomedical research in the next five to ten years:

1. New imaging modalities and instruments
2. Biosensors, devices, and probes
3. Optical technologies
4. Systems approaches, engineering, and integration
5. Cellular- and molecular-level imaging
6. Image-guided interventions
7. Prosthetics and artificial organs
8. Regenerative medicine
9. Computational biology and predictive models
10. Minimally-invasive technologies

The list is presented in order of relative investment determined from a resource allocation exercise conducted during the workshop. High-impact projects and emerging

technologies associated with each of these areas were also identified during the workshop. These items provide definition for each of the focus areas and specific topics that can be addressed to realize the potential benefits. Related issues concerning multi-disciplinary research, inter-agency and inter-institute collaboration, technology translation, and the importance of information technology were also discussed.

Results were somewhat influenced by the areas of expertise included among the extramural participants. Although all major biomedical research areas were represented, many participants were associated with some aspect of imaging. Also, the list is based on relative allocation levels and does not represent chronological priorities; i.e., the workshop attendees did not recommend that higher priority areas be fully supported before lower priority topics are funded. Despite these caveats, the topics encompass current national biomedical research focus areas (nanotechnology, biomaterials, imaging, sensors, and computer applications) and reflect the consensus of the ensemble of extramural participants.

Participants recognized differences among the topics with regard to relative impact of potential benefits for healthcare and biomedical research. While some topics can possibly provide incremental advances, others have potential for transformational benefits which can produce radical improvements. Although this was a consideration in the allocation exercise, no attempt was made to prioritize the focus areas based solely on level of impact.

Results of this workshop will be used as input in the evaluation and development of the NIBIB's future research programs. Current plans are to post this report on the Institute's Web site.

Workshop Summary and Results

Background

The National Institute of Biomedical Imaging and Bioengineering (NIBIB), the newest of the research institutes at the NIH, was established by law on December 29, 2000. The broad mission of the Institute is to improve health by supporting the development and translation of technologies and methods that enable fundamental biological discoveries and facilitate disease diagnosis, management, and prevention. This involves supporting and conducting focused and multi-disciplinary research based on applying principles and methods from the allied disciplines to address problems in biology and medicine. To be optimally effective during the initial stages of development and to ensure that its programs are relevant and appropriate for national priorities, the NIBIB seeks input from the scientific community to consider in the formulation and evaluation of its research and training programs. To obtain this input, a "NIBIB Workshop on Future Research Directions" was held on December 16-17, 2002, at the Bethesda Hyatt Hotel in Bethesda, Maryland.

Program and Objectives

This meeting represented a "NIBIB Futures Workshop" and was aimed at obtaining scientific community input on where the NIBIB can make a major impact on healthcare or biomedical research in the next five to ten years. To meet this objective, participants were requested to answer two questions:

1. What are the highest priority research focus areas for the NIBIB to consider that are appropriate for its mission and support national priorities, and

2. What are promising emerging technologies or high-impact projects that the NIBIB can consider to address these focus areas?

The workshop program is included as Appendix A. An orientation dinner was conducted on the evening of December 16 to provide information to the participants on the mission and status of the NIBIB and the workshop objectives. On the morning of December 17, the participants were divided into three groups (each with equal representation of biomedical imaging, bioengineering, and NIH program expertise) to separately determine the highest priority research focus areas appropriate for the NIBIB for the next five to ten years. The groups then met in a plenary session to develop a consensus list of priority research areas. After the priority areas were determined, the three groups met separately during a working lunch to identify promising emerging technologies or high-impact projects that the Institute could consider based on the priority research areas determined during the morning session. Following these separate meetings, the groups met in a plenary session in the afternoon to develop a consensus list of projects and technologies. To prioritize the research focus areas, a "Director for Fifteen Minutes" (DFFM) event was conducted during which the participants could allocate $100 M in $10 M increments to the consensus focus areas developed during the morning session. Results were tabulated, and a prioritized list of research focus areas was developed for the workshop.

Participants

A list of workshop participants is given in Appendix B. A total of fifty NIH and extramural staff attended this workshop. The attendees consisted of 23 invited extramural participants with expertise in a variety of areas associated with biomedical imaging and bioengineering research, 11 senior NIH (non-NIBIB) bioengineering and imaging program staff from other institutes and centers, 6 observers from other agencies (National Science Foundation, National Institute of Science and Technology, and the Department of Energy) and societies (Academy of Radiological Research and the American Institute of Medical and Biological Engineering), and ten NIBIB program and science administration staff. Workshop results for NIBIB consideration were based on input from the extramural participants and senior NIH program staff.

Research Focus Areas, Emerging Technologies, and High-Impact Projects

The following list of ten high-priority research focus areas was developed during the morning plenary session and is based on input from the three separate groups. These topics represent areas where the participants believe that the NIBIB can have an impact on healthcare or biomedical research in the next five to ten years. This list is not presented in any priority order.

1. Biosensors, devices, and probes
2. Prosthetics and artificial organs
3. Regenerative medicine
4. Computational biology and predictive methods
5. Systems approaches, engineering, and integration
6. New imaging modalities and instruments
7. Optical technologies
8. Image-guided interventions
9. Cellular- and molecular-level imaging
10. Minimally-invasive technologies

During the afternoon breakout and plenary sessions, a list of high-impact projects or emerging technologies associated with each of these ten research focus areas was developed. This information provides definition to the above focus areas and specific topics that can be addressed to realize the potential advances. The following text summarizes the results of related discussion at the workshop.

1. *Biosensors, devices, and probes* – In general, the need to develop novel biosensors and measurement systems was identified. Examples of novel approaches include wireless, wearable sensors and new sensors based on physiological response. The development of biochips that integrate nano-level devices, biological systems, information technology, and cognition methods should be considered. Materials issues such as biocompatibility and longevity are also important for this topic.

2. *Prosthetics and artificial organs* – Among the most important projects to consider are the development of bioinspired and biomimetic materials for artificial organs and prosthetic devices, the development of "smart" artificial materials, and three-dimensional scaffolds for tissue engineering and reparative medicine.

3. *Regenerative medicine* – In general, the field of tissue engineering is a "high impact" area that needs to be considered. Stem cell engineering and the creation of functional, three-dimensional, heterogeneous tissue constructs (e.g., CV and MSK) are areas that need to be addressed in the next five to ten year time frame.

4. *Computational biology and predictive models* - This topic includes the development of quantitative predictive models of complex biological function and modeling and simulation from molecular to systemic levels. In addition to

simulating basic biological function, validated models can be used to extrapolate from animal to human response and across spatial and temporal scales.

5. *Systems approaches, engineering, and integration* – The need to develop a culture that uses engineering and systems (integrative) approaches to address biomedical problems was emphasized throughout the workshop. One aspect of this topic is to engineer and fully integrate components of systems for a wide range of imaging and bioengineering applications. Possible activities to support this need include developing (1) fundamental biological knowledge to provide bases for computational models, (2) methods to synthesize and analyze data from different disciplines, (3) techniques to integrate data and instruments across multiple platforms and systems, and (4) methods to integrate across spatial and temporal scales. Included with this topic is the development of standards and guidelines for optimizing and facilitating integration among vendors and investigators.

6. *New imaging modalities and instruments* - With regard to new imaging modalities, instruments, and probes, areas that need to be considered are the development of (1) new detectors (e.g., fast, photon-counting, energy-discriminating detectors for applications such as low-dose dynamic CT, PET, and radiography), (2) new systems and instruments for high-field or open-magnet MR, and (3) functional imaging systems for either single or multiple modalities. The application of computer technologies to improve imaging methods was highlighted as an area where support is needed. Included in this topic are the development of principles and foundations for (1) construction and analysis of images, (2) image data post-processing (i.e., segmentation), (3) quantitative measurements such as tumor or lesion volume, and (4) computer-assisted diagnosis.

7. *Optical technologies* - Optical technologies offer substantial promise to improve biomedical research and healthcare in areas associated with cellular- and molecular-level imaging, high-resolution *in-vivo* imaging (e.g., endoscopic and external sensors), non-invasive diagnostics, and chemical specificity (spectroscopy). Associated with this topic is the need for collaboration with the chemistry community to develop targeted agents and probes for specific applications.

8. *Image-guided interventions* - This item involves developing more accurate and less invasive interventions based on imaging technologies. For therapy guidance, the development of integrated anatomic and functional imaging systems could provide significant advances in non-invasive techniques. One example of this item is the use of MRI for guidance and functional imaging for percutaneous therapy of liver cancer including both ablative and regional techniques. Application of focused ultrasound as a therapeutic tool also offers significant promise.

9. *Cellular- and molecular-level imaging* – Substantial improvements in the quantification of physiology and metabolism could result from imaging molecular and genetic events *in-vivo*. Areas that need to be addressed include spatial and temporal scalability, fusion of data from multiple platforms, multi-organ and multi-disease integrated approaches (e.g., signal transduction cascades), and molecular target credentialing (comprehensive validation and modeling). To support applications at diagnostic levels, efforts to map the "imageable" proteosomes in mouse models of major human diseases should be pursued.

10. *Minimally-invasive technologies* – This item encompasses methods to conduct diagnoses and therapies based on novel technologies from the physical, engineering, and computational sciences. Areas that show promise for related improvements include robotics, micro- and nano-electrical and mechanical systems, and closed-loop control. Examples of areas where closed-loop control could be useful include glucose in diabetics and blood pressure in hypertensives.

Prioritized Research Focus Areas

A DFFM (Director for Fifteen Minutes) exercise was conducted in which the participants were provided the list of ten high priority research areas developed during the morning session and asked to allocated a total of $100 M in $10 M increments to areas that they considered be most important. The opportunity to "write-in" topic areas not included in the consensus list was provided. The results of the DFFM exercise in priority order based on total participant investment are given in the following list (total allocations in parenthesis):

1. New imaging modalities and instruments ($325 M)
2. Biosensors, devices, and probes ($300 M)
3. Optical technologies ($285 M)
4. Systems approaches, engineering, and integration ($270 M)
5. Cellular- and molecular-level imaging ($260 M)
6. Image-guided interventions ($260 M)
7. Prosthetics and artificial organs ($210 M)
8. Regenerative medicine ($190 M)
9. Computational biology and predictive models ($160 M)
10. Minimally-invasive technologies ($150 M)

Several caveats should be considered when interpreting this information. First, not all participants voted and some did not allocate their total $100 M allotment. Second, the priorities were somewhat influenced by the areas of expertise included among the extramural participants. Although all major biomedical research areas were represented, many of the attendees were associated with some aspect of imaging. Third, the above list is based on relative budget allocations and not chronological considerations; i.e., the workshop participants did not recommend that higher priority areas be fully supported before lower priority areas are funded. Despite these caveats, this list encompasses current national biomedical research focus areas (imaging, biomaterials, sensors,

nanotechnology, and computer applications) and reflects the consensus of the ensemble of voting participants.

The extramural attendees also recognized differences among the focus areas in the relative impacts of potential benefits for healthcare and biomedical research. While some topics have potential for incremental advances, others have potential for transformational advances that can provide radical improvements. No attempt was made to prioritize the focus areas relative to level of impact.

Other Issues

In addition to the lists of research focus areas and associated high-impact projects that were developed, several issues related to NIBIB research programs were also discussed. Topics receiving the most discussion include:

1. Support of inter-disciplinary research is essential to realize the potential benefits from biomedical research conducted in support of the mission of the NIBIB. The BECON bioengineering research partnership (BRP) program and some of the multi-organizational programs developed by the National Center for Research Resources are appropriate models that effectively encourage and support this type of research. The necessary inter-disciplinary projects will be facilitated if the NIBIB can develop a culture that promotes integration, innovation, and a systems approach to problem solving.

2. Both fundamental discovery and translation of technologies for biomedical applications are necessary to provide the maximum impact from NIBIB research programs. Integrating Institute efforts with other organizations inside (other institutes/centers) and outside (other federal agencies) the NIH can result in more effective and efficient programs.

3. While development and translation of technologies are important, validation, optimization, and assessment of these technologies must also be considered. These activities will ensure appropriate and cost-effective application of new technologies for research and clinical use.

4. The importance of information technology and computer applications in many of the future research focus areas was emphasized throughout the workshop. In addition to computer-assisted diagnosis, surgery, and interventions, computer technologies for analysis and display of imaging and medical information, data fusion, and enhancement of training programs through application of virtual reality techniques were identified as areas which should be considered.

5. The need for understanding and modeling the fundamental bases of disease and biological processes was emphasized several times during the workshop. In addition, the needs for appropriate and validated animal models and methods to extrapolate from animal to human response were also discussed.

Summary

A group of extramural participants with a broad scope of expertise in biomedical imaging and bioengineering identified ten consensus research focus areas that encompass current national biomedical priorities. These topics represent research areas appropriate for the mission of the NIBIB that can provide significant benefits to healthcare and biomedical research in the near-term. In addition, high-impact projects and emerging technologies were identified for each of the focus areas. These provide definition for the topics and specific issues that can be addressed to realize the potential benefits. This information will be considered by NIBIB program staff in the development and evaluation of the Institute's research programs. Current plans are to post this report on the Institute's Web site.

Acknowledgements

The valuable contributions of Mr. Stephen Green of the NIBIB in the planning, conduct, and evaluation of this workshop are gratefully acknowledged. In addition, Ms. Cheryl Fee and Ms. Stacy Wallick of the NIBIB are recognized for their dedicated and tireless efforts to record proceedings and results of the breakout session discussions during the workshop. The contributions of participants Dr's. Thomas Brady (MGH), Elliot Chaikof (Emory), Donald Giddens (Georgia Tech), William Hendee (Wisconsin), Beth McFarland (Washington University), and Thomas Skalak (Virginia), who effectively moderated the breakout sessions and summarized results, are also gratefully acknowledged.

APPENDIX A

NIBIB WORKSHOP ON FUTURE RESEARCH DIRECTIONS

AGENDA FOR DECEMBER 17, 2002

7:30 AM – Continental Breakfast – *Crystal Ballroom Foyer*

8:00 AM – Welcome and Charge – *Baccarat Suite*
Dr. Ruth Kirschstein (NIH/OD)
Dr. Roderic Pettigrew (NIH/NIBIB)
Dr. Richard Swaja (NIH/NIBIB)

8:30 AM – Breakout Sessions – NIBIB Research Focus Areas
Group 1 – LaLique Suite
Group 2 – Haverford Suite
Group 3 – Cartier/Tiffany Salons

10:00 AM – Break – *Crystal Ballroom Foyer*

10:30 AM – Plenary Session – *Baccarat Suite*

11:30 AM – Lunch – *Crystal Ballroom Foyer*

12:00 PM – Breakout Sessions – High-Impact Projects/Emerging Technologies
Group 4 – LaLique Suite
Group 5 – Haverford Suite
Group 6 – Cartier/Tiffany Suites

1:15 PM – Break – *Crystal Ballroom Foyer*

1:45 PM - Plenary Session – *Baccarat Suite*

3:00 PM – Adjourn

APPENDIX B

NIBIB WORKSHOP ON FUTURE RESEARCH DIRECTIONS

LIST OF PARTICIPANTS

Extramural Participants

Philip Alderson, MD
Professor and Chair – Department of Radiology
Columbia University
630 West 168 Street
Harkness 3-320
New York, NY 10032
TEL: 212-305-8994
FAX: 212-305-4835
EMAIL: poa1@columbia.edu

Thomas Brady, MD
Massachusetts General Hospital
CIMIT Suite 400
100 Charles River Plaza
Boston, MA 02114
TEL: 617-726-8313
FAX: 617-724-4152
EMAIL: tom@nmr.mgh.harvard.edu

Elliot Chaikof, MD, PhD
Emory University School of Medicine
Surgery Research – 5105 WMB
1639 Pierce Drive
Atlanta, GA 30322
TEL: 404-727-8413
FAX: 404-727-3396
EMAIL: echaiko@emory.edu

Carlo De Luca, PhD
Neuromuscular Research Center
Boston University
19 Deerfield Street
Boston, MA 02215
TEL: 617-353-9756
FAX: 617-353-5737
EMAIL: cjd@bu.edu

Richard Ehman, MD
Mayo Clinic and Foundation
Rochester, MN 55905
TEL: 502-284-7573
FAX: 507-284-9778
EMAIL: ehman.richard@mayo.edu

Laurie Fajardo, MD
Professor and Chair, Department of Radiology
University of Iowa Health Care
200 Hawkins Drive – 3966 JPP
Iowa City, IA 52242-1077
TEL: 319-356-3372
FAX: 319-331-4297
EMAIL: l-fajardo@uiowa.edu

Donald Giddens, PhD
Dean, College of Engineering
Georgia Institute of Technology
Atlanta, GA 30332-0360
TEL: 404-894-6825
FAX: 404-894-0168
EMAIL: don.giddens@coe.gatech.edu

William Hendee, PhD
Senior Associate Dean and Vice President
Dean of the Graduate School of Biomedical Sciences
Medical College of Wisconsin
Milwaukee, WI 53226
TEL: 414-456-4402
FAX: 414-456-6554
EMAIL: whendee@mcw.edu

Ronald Kikinis, MD
Director, Surgical Planning Laboratory
Brigham and Women's Hospital
Radiology, ASBI, L1-050
75 Francis Street
Boston, MA 02115
TEL: 617-732-7389
FAX: 617-582-6033
EMAIL: kikinis@bwh.harvard.edu

Robert Lenkinski, PhD
Department of radiology
Beth Israel Deaconess Medical Center
1 Deaconess Road
Boston, MA 02215
TEL: 617-754-2112
FAX: 617-754-2010
EMAIL: rlenkins@caregroup.harvard.edu

Beth McFarland, MD
Mallinckrodt Institute of Radiology
510 South Kingshighway Boulevard
St. Louis, MO 63110
TEL: 314-362-1053
FAX: 314-362-2976
EMAIL: mcfarland@mir.wustl.edu

Lawrence McIntire, PhD
E. D. Butcher Professor and Chair
Department of Bioengineering
Rice University
6100 Main Street – MS-144
Houston, TX 77005
TEL: 713-348-4903
FAX: 713-348-5154
EMAIL: mcintire@rice.edu

Bernhard Palsson, PhD
Department of Bioengineering
University of California – San Diego
La Jolla, CA 92093-0412
TEL: 858-534-5668
FAX: 858-822-3120
EMAIL: palsson@ucsd.edu

Hunter Peckham, PhD
Director – Rehabilitation Engineering Center (H601)
MetroHealth Medical Center
2500 MetroHealth Drive
Cleveland, OH 44109
TEL: 216-778-3480
FAX: 216-778-4259
EMAIL: pxp2@cwru.edu

Norbert Pelc, ScD
Professor and Associate Chair for Research
Department of Radiology
Stanford University
Lucas MRS Imaging Center – MC 5488 – P260
Stanford, CA 94305-5488
TEL: 650-723-0435
FAX: 650-723-5795
EMAIL: pelc@stanford.edu

David Piwnica-Worms, MD, PhD
Professor of Radiology
Washington University School of Medicine
510 South Kingshighway Boulevard – Box 8225
St. Louis, MO 63110
TEL: 314-362-9356
FAX: 314-362-0152
EMAIL: piwnica-wormsd@mir.wustl.edu

Anne Roberts, MD
Thornton Hospital/UCSD Medical Center
9300 Campus Point Drive
La Jolla, CA 92037
TEL: 858-657-6650
FAX: 858-657-6699
EMAIL: acroberts@ucsd.edu

Thomas Skalak, PhD
Professor and Chair
Department of Biomedical Engineering
University of Virginia
Box 800759, Health System
Charlottesville, VA 22908
TEL: 434-924-0270
FAX: 434-982-3870
EMAIL: tskalak@virginia.edu

Alan Snyder, PhD
Professor of Surgery and Bioengineering
Penn State College of Medicine
P.O. Box 850
500 University Drive – H151/C4864
Hershey, PA 17036
TEL: 717-531-7068
FAX: 717-531-4464
EMAIL: asnyder@psu.edu

Bruce Tromberg, PhD
Beckman Laser Institute
University of California – Irvine
1002 Health Sciences Road East
Irvine, CA 92612
TEL: 949-824-4713
FAX: 949-824-8413
EMAIL: tromberg@bli.uci.edu

Michael Viola, MD
Director, Medical Sciences Division
Office of Biological and Environmental Research
Department of Energy
19901 Germantown Road
Germantown, MD 20874-1290
TEL: 301-903-3213
EMAIL: michael.viola@science.doe.gov

Tuan vo Dinh, PhD
Group Leader and Corporate Fellow
Advanced Medical Science and Technology Group
Oak Ridge National Laboratory
P.O. Box 2008
Oak Ridge, TN 37831-6101
TEL: 865-574-6249
FAX: 865-576-7651
EMAIL: vodinht@ornl.gov

David Walt, PhD
Robinson Professor of Chemistry
Tufts University
Department of Chemistry
62 Talbot Avenue
Medford, MA 02155
TEL: 617-627-3470
FAX: 617-627-3443
EMAIL: david.walt@tufts.edu

NIH Participants

Eileen Bradley, DSc
Chief, Surgery, Radiology, and Bioengineering IRG
Center for Scientific Review
National Institutes of Health
6701 Rockledge Drive
Bethesda, MD 20892
TEL: 301-435-1179
FAX: 301-480-2241
EMAIL: bradleye@csr.nih.gov

James Cassatt, PhD
Director, Division of Cell Biology and Biophysics
National Institute of General Medical Sciences
National Institutes of Health
Building 45, Room 2AS-19C
45 Center Drive – MSC 6200
Bethesda, MD 20892-6200
TEL: 301-594-0828
FAX: 301-480-2004
EMAIL: cassattj@nigms.nih.gov

Laurence Clarke, PhD
Biomedical Imaging Program
National Cancer Institute
National Institutes of Health
6130 Executive Boulevard – Room 6054
Bethesda, MD 20852-7412
TEL: 301-435-9190
FAX: 301-496-9531
EMAIL: laurence_clarke@nih.gov

William Heetderks, MD/PhD
Program Director – Repair and Plasticity
National Institute of Neurological Disorders and Stroke
National Institutes of Health
Room 2207 – NSC
Bethesda, MD 20892
TEL: 301-496-1447
FAX: 301-480-1080
EMAIL: heet@mail.nih.gov

Michael Huerta, PhD
Director, Office of Translational Research and Scientific Technology
National Institute of Mental Health
National Institutes of Health
6001 Executive Boulevard – Room 7202 – MSC 9645
Bethesda, MD 20892-9645
TEL: 301-443-3563
FAX: 301-443-1731
EMAIL: mhuerta@helix.nih.gov

Warren Jones, PhD
National Institute of General Medical Sciences
Natcher Building
National Institutes of Health
Bethesda, MD 20892
TEL: 301-594-5938
FAX: 301-480-2802
EMAIL: jonesw@nigms.nih.gov

King Li, MD, MBA
Associate Director – Radiology and Imaging Sciences
Clinical Center
National Institutes of Health
10 Center Drive – MSC 1182
TEL: 301-435-5741
FAX: 301-480-0055
EMAIL: kingli@nih.gov

Lance Liotta, PhD
National Cancer Institute
National Institutes of Health
Building 10 – Room B1B41
Bethesda, MD 20892
TEL: 301-496-2035
EMAIL: liottal@mail.nih.gov

Michael Marron, PhD
Director, Division of Biomedical Technology
National Center for Research Resources
National Institutes of Health
6705 Rockledge Boulevard
Bethesda, MD 20892-7965
TEL: 301-435-0755
FAX: 301-480-3659
EMAIL: marron@nih.gov

Jeffery Schloss, PhD
Program Director – Technology Development Coordination
National Human Genome Research Institute
National Institutes of Health
Building 31 – Room B2-b07
31 Center Drive
Bethesda, MD 20892-2033
TEL: 301-496-7531
FAX: 301-480-2770
EMAIL: jeff_schloss@nih.gov

John Watson, PhD
Director, Clinical and Molecular Medicine
National Heart, Lung, and Blood Institute
National Institutes of Health
6701 Rockledge Drive – Room 9186
Bethesda, MD 20892-7940
TEL: 301-435-0555
FAX: 301-480-7971
EMAIL: jw53f@nih.gov

Observers

Wendy Baldwin, PhD
Deputy Director for Extramural Research
National Institutes of Health
1 Center Drive
Bethesda, MD 20892
TEL: 301-496-1096
FAX: 301-402-3469
EMAIL: baldwinw@od.nih.gov

Anna Barker, PhD
National Cancer Institute
National Institutes of Health
31 Center Drive – Room 10A52
Bethesda, MD 20892
TEL: 301-496-1550
EMAIL: barkera@mail.nih.gov

Bruce Hamilton, PhD
Director, Bioengineering and Environmental Systems Division
National Science Foundation
4201 Wilson Boulevard – Suite 565
Arlington, VA 22230
TEL: 703-292-7066
EMAIL: bhamilto@nsf.gov

Angela Hight-Walker, PhD
Physics Laboratory
National Institute of Standards and Technology
100 Bureau Drive – Stop 8441
Gaithersburg, MD 20899
TEL: 301-975-2155
FAX: 301-869-5700
EMAIL: angela.hightwalker@nist.gov

Edward Nagy
Executive Director
Academy of Radiology Research
Suite 505
1029 Vermont Avenue, NW
Washington, DC 20005
TEL: 202-347-5872
FAX: 202-347-5876
EMAIL: acadrad@aol.com

Kevin O'Connor
Executive Director
American Institute for Medical and Biomedical Engineering
1901 Pennsylvania Avenue NW - Suite 401
Washington, DC 20006
TEL: 202-496-9660
FAX: 202-466-8489
EMAIL: kwoaimbe@aol.com

NIBIB Staff

Roderic Pettigrew, MD, PhD
Director, National Institute of
Biomedical Imaging and Bioengineering
National Institutes of Health
6707 Democracy Boulevard – Suite 200
Bethesda, MD 20892-5469
TEL: 301-496-8859
FAX: 301-480-0679
EMAIL: rpettigrew@nih.gov

Marialieen Sourwine, MS
National Institute of Biomedical Imaging
and Bioengineering
National Institutes of Health
6707 Democracy Boulevard – Suite 200
Bethesda, MD 20892-5469
TEL: 301-451-4775
FAX: 301-480-4973
EMAIL: sourwine@nibib.nih.gov

Donna Dean, PhD
Deputy Director, National Institute of
Biomedical Imaging and Bioengineering
National Institutes of Health
31 Center Drive – Room 1B37
Bethesda, MD 20892-2077
TEL: 301-451-6768
FAX: 301-480-4515
EMAIL: deand@mail.nih.gov

Richard Swaja, PhD
National Institute of Biomedical Imaging
and Bioengineering
National Institutes of Health
6707 Democracy Boulevard – Suite 200
Bethesda, MD 20892-5469
TEL: 301-451-4779
FAX: 301-480-4973
EMAIL: swajar@nibib.nih.gov

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