MEDICAL IMPLANT INFORMATION, PERFORMANCE, AND POLICIES WORKSHOP

9630 Gudelsky Drive (Building 1)
University of Maryland, Shady Grove
Rockville, Maryland

September 19-20, 2002

FINAL REPORT

EXECUTIVE SUMMARY

The Biomaterials and Medical Implant Science (BMIS) Coordinating Committee convened a workshop entitled "Medical Implant Information, Performance, and Policies" on September 19-20, 2002, at the University of Maryland at Shady Grove in Rockville, Maryland. The purpose of the workshop was to evaluate the role of the Federal government in obtaining and disseminating data gained from medical implants to ensure safer health care. Workshop participants included representatives from clinical medicine, biomedical research, information technology, law, ethics, patient advocacy, and Federal program development.

For the purpose of this workshop, "implants are defined as having a minimum lifespan of 3 months, as penetrating living tissue, as having a physiologic interaction, and as being retrievable." This definition was used to exclude short-term devices that may be considered implants according to the FDA definition[1] (i.e., catheters).

The following recommendations outline the most important areas where the Federal government can impact the acquisition and dissemination of data related to medical implants to ensure safer heath care:

- Establish Internet-based medical implant information and data resources for patients, clinicians, researchers, designers, manufacturers, and other interested persons.
- Develop standard definitions and practices for recovering implants, conducting research, evaluating outcomes, and reporting results.
- Catalyze a scientific team approach involving stakeholders of the health care enterprise, including researchers, health care providers and payers, industry, and government.
- Educate stakeholders about research on retrieved implants.
- Publish a peer-reviewed law article that clarifies the medical implant property rights of patients, manufacturers, hospitals, insurers, and other interested parties.
- Create a central source of general information regarding the medical value, safety, lifetime, and adverse events associated with medical implants.

[1] Code of Federal Regulations for the Food and Drug Administration, Title 21, Volume 8

This report serves as a synopsis of the workshop proceedings and documentation of the resulting recommendations. Abstracts of each of the plenary presentations, a summary of the discussion and subsequent recommendations from each breakout session, and a description of the broad recommendations obtained from the workshop deliberations are included in this report. The Federal government will use these recommendations to evaluate and develop future programs.

BACKGROUND

It has been recognized by the scientific community that there is a need to acquire long-term performance data on medical implants. At the time that a new critical or life-sustaining device or technology is introduced into commercial distribution, data from the clinical trials, which demonstrate safety and efficacy of the device, extend only over a period of several months to possibly a couple of years. It is not until the device is in general distribution that post-market reporting and studies by the manufacturer can identify any long-term problems. Furthermore, the currently mandated information-gathering systems are designed to capture only serious adverse events. Information about how well an implant device or technology performs compared to other devices or treatment modalities is not required and not routinely captured. In order to improve the next generation of products, a mechanism is needed to retrieve devices once their useful lives are over and to evaluate their performance. Furthermore, the recent attention towards medical errors highlighted by the 1999 Institute of Medicine report raises the need to involve health care professionals, patients, and their families in the discussion of product performance to ensure that devices operate safely and effectively.

In 1997, in response to these emerging issues, Dr. Harold Varmus, then Director of the National Institutes of Health (NIH), formed the Biomaterials and Medical Implant Science (BMIS) Coordinating Committee. The BMIS committee serves as a trans-agency technical group, which coordinates research programs and develops joint initiatives and workshops in biomaterials and medical implant science. The committee has expanded to include representatives from other Federal agencies and public organizations, including the National Institute for Standards and Technology (NIST), the National Science Foundation (NSF), the Food and Drug Administration (FDA), and AdvaMed. These members bring additional scientific perspectives and represent the interests of the general public. Dr. John Watson, National Heart, Lung and Blood Institute, NIH, chaired the BMIS committee until September 2003. Dr. Christine Kelley, National Institute of Biomedical Imaging and Bioengineering (NIBIB), NIH, currently serves as chair.

Over the past 3 decades, numerous conferences have addressed issues associated with improving the performance of medical implants. These conferences have typically focused on the technical and procedural barriers, the development of an implant retrieval system, the creation of national databases, and the establishment of national and international standards.

In January 2000 the BMIS held its first conference entitled, “Improving Medical Implant Performance Through Retrieval Information: Challenges and Opportunities.” This technology assessment conference aimed to “provide researchers, health care providers, patients, and the general public with a responsible assessment of the opportunities for and challenges of developing a framework for independent research on explanted medical implants.” The conference represented a departure from the themes expressed in the earlier meetings because it focused on the barriers to establish generic implant retrieval databases and registries. Overall, the conference concluded that more attention needs to be directed towards clarifying the legal, economic, and patient education issues associated with implant retrieval and analysis. In particular, the conference highlighted the need to develop an aggressive educational program for teaching patients, policymakers, the medical community, and device manufacturers about the importance of device retrieval and analysis. The full report summarizing the recommendations of the meeting participants can be accessed at: http://odp.od.nih.gov/consensus/ta/019/019_statement.htm.

The workshop summarized in this report was organized in response to the 2000 NIH BMIS Technology Consensus Conference. This conference recommended that the NIH and FDA determine mechanisms for mitigating the effects of litigation on medical innovation. In 2000, it was estimated that 8 to 10 percent of Americans had a permanent medical implant. Since that time, the types and numbers of implanted devices continue to increase. As implanted devices become more prevalent and complex, the task of assuring their safety and efficacy is also increasingly difficult. An examination of the “Total Product Life Cycle” of a device (conception through manufacturing and use to obsolescence) reveals a number of points where the reliability of the device or process can potentially be compromised. It is important to examine this entire process to determine how useful data can be collected and distributed to all stakeholders. While the government can make some information available, it must rely on the health care providers, medical institutions, academic institutions, and the medical device industry to acquire the information and to disseminate it in an effective and useful manner.

SCOPE
The BMIS Coordinating Committee organized a workshop on September 19 and 20, 2002, in Rockville, Maryland, to evaluate the role of the Federal government in obtaining and disseminating data gained from medical implants to ensure safer health care. As a follow-up to recommendations identified through the BMIS workshop held in January 2000, this workshop focused on issues related to patient education and data about implants and implant retrieval.

PURPOSE
The purpose of this workshop was to consider the Federal government's role in providing medical implant information to ensure safer health care, and to evaluate the role for the Federal government in extracting and disseminating information gained from explanted medical implants.

GOALS
The goals of this workshop were to:

- Define the role of the Federal government to encourage the use of explanted medical devices for research.
- Design a structure for Federal programs to support the gathering and dissemination of data derived from medical implant retrieval.
- Design a Federal program to promote implant retrieval for use in research intended to ensure safer health care.

FORMAT
Attending the workshop were 86 representatives from a wide range of backgrounds, including clinical medicine, biomedical research, information technology, law, ethics, patient advocacy, and Federal program development. Ten invited speakers discussed topics pertinent to medical implant retrieval and provided an overview of current practices in implant research and education. Following the plenary presentations, attendees addressed the goals of the workshop in four breakout sessions: Education and Information, Medical Implant Research, Non-Technical Issues, and Dimensions of Health Informatics.

PLENARY SESSION SUMMARIES
Abstracts from the plenary presentations are presented below. The purpose of these presentations was to provide an overview of the most current practices in medical implant retrieval research and patient education.

Keynote Address
Patient Education: How Can It Be a Part of Medical Device Improvement?
Kenneth H. Keller, PhD (University of Minnesota)

In recent years, scientists and engineers have become increasingly aware of the need to think in "systems" terms, recognizing that the behavior of no single part of a complex physico-chemical device or organism can be understood in isolation. In the same way, medical technology development is embedded in a "system" that includes Federal policies and institutions as well as the social and economic environment within which those policies and institutions evolve. I argue here that:

1. For medical technology to achieve its potential in contributing to health care, the policies and institutions that support and regulate its development and use must be matched to the way in which the technology actually develops.
2. Despite the best hopes and dreams of scientists and engineers, the ways in which public policies and Governmental institutions develop depends on a complex interaction of political, economic, and cultural forces.

It has been traditional to view technology development as a fundamentally linear process, proceeding uni-directionally from basic research through various stages of application. However, the reality is quite different in that technology development occurs as an iterative process. For example, scientists learn from past experience and proceed to make devices that are more effective, safer, and less expensive. The rapidly changing landscape of scientific knowledge leading to new advances requires a nimble research and development process. Research and development must capitalize on multi-disciplinary and iterative approaches to maximize gains in technological applications. Device retrieval is an important aspect of this cyclical development process. Data obtained from explanted devices furthers understanding of the long-term, cumulative, and subtle effects of an implanted device. It is one of many examples of the importance of post-market data collection in a health care system increasingly dependent on medical technology and oriented to chronic therapies rather than short-term "cures."

Despite the rather broad consensus concerning these aspects of technology development, the public institutions and policies that regulate the introduction and use of medical technology are based on the fiction of the linear model with uni-directional regulatory and coverage gates and highly compartmentalized responsibilities that break up rather than integrate the system. Conditional coverage experiments, device registries, and now device retrieval efforts are valiant attempts to modify the system, but each has faced problems. Conditional coverage is slowed by conflicts over who pays for what. Registries have not garnered great support or cooperation from clinicians. Device retrieval faces a host of economic, legal, and social barriers.

Regulatory gates should be replaced with softer but more continuous regulation, extending over every stage of a device's development and use. The false dichotomy of "experimental" and "clinical" categories should be eliminated, recognizing that even in the clinical setting we must gather good quality data if we are to improve performance through design iteration. In practice, this means:

1. Lowering the bar for getting technology into clinical settings.
2. Expecting more from clinicians in data gathering as a condition of use for new technologies.
3. Raising the bar for clinicians to qualify to use new technologies.
4. Devoting more effort to educating patients and their families to encourage cooperation in the need to gather data, including the importance of device retrieval.

With respect to each of these changes, there are political, economic, and legal issues for Government agencies, medical technology companies, reimbursement agencies, practitioners, patients, their families, and the public. Many of these are affected or conditioned by social attitudes toward the therapeutic use of sophisticated

technologies in direct health care. These attitudes can be shaped or reinforced by the media. Because of these difficulties, it is important to have a clear vision for approaching the long-term task of educating the public on the need for and the promise of these changes. It can also help to identify the connections between various parts of the regulatory and reimbursement systems, and to recognize the opportunities for progress toward a more effective system in the future.

The progress in medical technology over the past several decades stands as a testament to the creativity and the energy of the scientists and engineers who have been a part of that history. I believe that if we are to continue to make progress in the proper and effective use of medical technology in health care, we have to devote the same energy and creativity to the "other part of the system," that intersection between technology and society where government policies play such an important role.

Medical Implant Devices: Data Available from NCHS and the Use of ICD-9-CM for the Coding of Diagnoses and Procedures
Donna Picket, MPH, RHIA (National Center for Health Statistics)

The National Center for Health Statistics (NCHS) is the Federal agency that is responsible for the coordination of all official disease classification activities in the U.S. There are two related classification systems of diseases used by the NCHS to track mortality and morbidity data. The International Classification of Diseases (ICD), published by the World Health Organization, is used internationally to code and classify mortality data from death certificates. The International Classification of Diseases, Clinical Modification (ICD-CM) is based on the ICD and is the official system in the U.S. for assigning codes to diagnoses and procedures associated with hospital utilization, including codes related to medical implants. The Federal government and the private sector have adopted ICD-CM for a number of purposes, including: statistical reporting, data collection, quality of care analyses, resource utilization, research, and reimbursement.

The ICD is periodically revised to incorporate changes in the medical field. The most current version, ICD-10, has developed a clinical modification of the classification for morbidity purposes and replaced ICD-9 as of January 1, 1999. The ICD-10-CM is currently under development and will be expanded to better capture clinical detail. There is not yet an anticipated implementation date for the ICD-10-CM. The ICD-9-CM includes diagnosis and procedural codes related to medical implants and devices. Diagnosis related codes include: mechanical complications, infections and inflammatory reactions, organ or tissue replaced by other means, post-surgical states, fitting and adjustment of prosthetic devices and implants, and fitting and adjustment of other devices. Procedural codes include: implantation, adjustment/revision, replacement, and removal.

Several NCHS surveys, using these classification systems, have collected data related to medical implants and devices. The NCHS National Health Interview Survey (NHIS) on Use of Selected Medical Device Implants in the United States was published in 1988. This survey generated reliable estimates of total number of medical devices implanted in U.S. population and provided specific, detailed information on selected generic classes of devices. The Ambulatory and Inpatient Procedures in the United States Survey, published in 1996, provided estimates on surgical and non-surgical procedures performed in the U.S. Finally, the National Hospital Discharge Survey (NHDS), which is conducted annually, provides estimates on the number of diagnoses and procedures discharged from non-Federal short-stay hospitals.

The NCHS is the Nation's principal health statistics agency. Statistical information compiled by the agency is an invaluable resource for evaluating public health and developing health policy. The data available from the NCHS is particularly useful for studying trends in medical implant and device use and prevalence.

Additional information, including NCHS data and ICD codes can be assessed at:
NCHS Classification of Diseases, ICD-9-CM, ICD-10 and ICD-10-CM, http://www.cdc.gov/nchs/icd9.htm; NCHS Surveys and Data Collection System, http://www.cdc.nchs/nchs.htm; Centers for Medicare and Medicaid Services, ICD-9-CM (Vol. 3), ICD-10-PCS, http://www.cms.gov/paymentsystems/icd9/default.asp.

Medical Devices: Current Information and Policies
William F. Regnault, PhD (Food and Drug Administration)

The world of medical devices is a rapidly expanding universe of diverse, high-tech products. Currently, there are more than 1,800 types of products marketed as medical devices with 60,000 to 80,000 brands and models from which consumers and clinicians can choose. These products span a wide spectrum of patient risks from bandages to heart valves. These products are managed by the FDA using classification panels as set forth in the Code of Federal Regulations (CFR) Part 21, Sections 862 to 892. The products within these classifications are further divided into classes by risk. Class I devices represent the lowest risk to patients and contain products whose safety and effectiveness is well established, such as bandages and scalpels. Class II devices represent a higher class of risk and are required to meet special controls such as guidance documents, standards, post-market surveillance, patient registries, and recommendations. These types of devices include contact lenses and powered wheel chairs. Class III devices represent the highest risk category and their safety and effectiveness must be demonstrated through laboratory testing and clinical trials. Class III devices include heart valves and cochlear implants. All products must adhere to general controls including registration and listing, pre-market notification, labeling, prohibition against adulteration and misbranding, and good manufacturing practices.

There are two mechanisms by which medical devices can receive FDA approval for market distribution depending on the risk classification. The first mechanism is the Pre-Market Notification, also known as the 510(k), which is typically used for low-risk devices. Products submitted under the 510(k) process must demonstrate substantial equivalence to products in commercial distribution prior to 1976 (when the Device Amendments were enacted). Most Class I devices, since they represent a low risk, are exempt from submitting a 510(k). A Pre-Market Notification must contain a device description, the proposed labeling, and any other information that the FDA needs to determine substantial equivalence. The second mechanism for device approval is the Pre-Market Approval, also known as the PMA, which is typically is used for high-risk devices. A PMA must contain sufficient and valid scientific evidence to provide reasonable assurance that the device is safe and effective for the intended use.

Once the FDA approves the device for use, it continues to be monitored by post-market surveillance. This process is important because pre-market testing may not always reveal long-term device durability issues, latent toxic effects, rare adverse events, or user-related problems. The sources of post-market information vary and may be obtained through routine and targeted inspections of a manufacturing firm and voluntary reporting by health professionals and consumers. There is also a mandatory reporting requirement for manufacturers in the case of serious injury, deaths, or certain malfunctions. The FDA receives approximately 100,000 adverse event reports each year. Depending on the number and severity of events reported, the FDA may alert health professionals and consumers about a use-related problem, recall the product, require that additional warnings or information appear on the label, or take regulatory action against the manufacturer. The FDA may also use in-house laboratories to diagnose the problem, develop testing standards, or work with the health care community and manufacturers on user education.

In addition to general post-market surveillance, the FDA may require tracking of a Class II or III device if failure is likely to have serious adverse health consequences, if the device is intended to be implanted in the human body for more than 1 year, or if the device is a life-sustaining or life-supporting product used outside a user facility. Such devices might be at risk for sudden, catastrophic failure, an adverse clinical outcome, or need prompt professional intervention. Currently there are twelve medical implants and five life-supporting or life-sustaining devices employed outside a user facility that are tracked.

While there is a plethora of information available from the FDA on medical devices, the information is maintained in separate databases that also contain proprietary and manufacturer-specific information. The development of a system that links the usable information in these databases and captures positive device outcomes would be extremely valuable. In addition, the development of a searchable “Device History Record” would allow new product developers to avoid mistakes that were encountered during the development and deployment of similar devices. Such systems would allow rapid epidemiological determination of background data when an adverse event occurs and would provide researchers, clinicians and manufacturers with critical information for device development and clinical decision-making. These are some of the challenges that face us today.

What Information Do Patients Need to Have?
Laura Quigley, MS, RN, ONC (Rush-Presbyterian-St. Luke's Medical Center)

Rush-Presbyterian-St. Luke's Medical Center maintains a comprehensive program for total hip and total knee replacement patients that integrates patient education, patient care and biomedical research that can serve as a model for other health care establishments. Patient education enables patients to make an informed decision about medical procedures and focuses on the role of the patient and family with regard to rehabilitation, long-term surveillance and research of artificial joints. A coordinated "team approach" of the orthopedic surgeons, orthopedic nurses, support staff, and research staff is one of the hallmarks of this successful program.

Prior to joint replacement surgery, patients and their families attend a class or receive individualized instruction regarding a variety of issues, including arthritis and its progression, treatment alternatives, risks and benefits of surgery, hospital care and routines, discharge care, and follow-up protocols. Patients are also provided with information that focuses on the special concerns of medically implanted devices, such as long-term local and systemic risks related to the device, the durability of the implant components over time, the life expectancy of the device, and the consequences of device "failure." In addition to oral educational sessions, patients receive an informational booklet and have an opportunity to examine and handle hip or knee replacement components.

In our experience, we have found that misconceptions regarding medically implanted devices are common. For example, many individuals believe that total hip and knee replacements are completely effective and predictable; that the artificial joint will be "better" than their natural joint, or that new technology is superior to older technology. The joint replacement team stresses to the patient the importance of research aimed at uncovering the truth about the safety and effectiveness of the artificial joint over time so that future patients will benefit from the experiences of others.

Prior to surgery, patients are invited to participate in the Institutional Review Board (IRB) approved "Orthopedic Tissue, Implant and Information Repository Study." This research involves the collection of clinical and radiographic information about the implant over time, as well as research involving the retrieval of any pre-existing implants at the time of a surgery. With few exceptions, patients are willing to participate in this study once they realize the importance of their contribution.

Approximately 1 year after surgery, patients receive a letter inviting their participation in research involving the post-mortem retrieval and analysis of their joint replacement. The joint replacement team encourages the patient to discuss their desires with their family since the family will ultimately determine whether the patient's wishes are followed after death. Research funds cover all expenses related to retrieval of the medically implanted device and the team strives to avoid any alterations in memorial plans. The information gained from such studies helps the clinicians, the research team, and device manufacturers to refine and improve patient care, the design of implants, and the patient education process itself.

This well-integrated program may be a model system that has the potential, if integrated with other leading clinical centers, to greatly advance the science, engineering, and art of medical implant therapy. Future efforts in this regard would need to address the uniformity of record keeping, the interoperability of data systems, data sharing and funding requirements.

What Information Can/Should the Federal Government Provide?
Arthur A. Ciarkowski, PhD (Food and Drug Administration)

When examining the issue of educating patients about implanted devices, there are three topics to review: the need for information about implants, the available resources of information, and the challenge of presenting information in a meaningful way.

Over the past few decades, the medical device industry has achieved unprecedented success. The industry has emerged out of the basements and garages of pioneers in the field to a rapidly growing and mature business. Today, medical implants compete with medical therapy as the primary treatment for many illnesses and injuries.

However, this growth in medical technology has created a complex environment where adequate information is essential for making responsible health care choices. In many cases, health care providers and patients are making decisions based on limited and incomplete information. For example, the FDA requires data from clinical studies on implanted heart valves where the patients are followed for at least 1 year post-surgery. Then, based on the combination of preliminary bench data and the 1year, post-surgery clinical data, physicians and surgeons must decide whether to implant future valves with the expectation that it will need to function for at least twenty years.

This does not mean that there are no resources for information about devices and their performance for an extended period of time. This information, however, resides in a variety of locations. The U.S. Patent Office retains design specifications, the NIH offers extensive clinical information, the NIST has information about device standards, and the FDA maintains files for each device that provides descriptions, performance data, manufacturing information, and labeling. In addition, the Centers for Medicare and Medicaid Services (CMS) may have additional information regarding reimbursement for the implant procedure, and the Agency for Healthcare Research and Quality (AHRQ) holds information about the practice of medicine required for implanting the device. It is cumbersome for patients and physicians to submit a Freedom of Information Request to obtain this information, or to search the Internet to find reliable sources before making treatment decisions.

The challenge for the Government, manufacturers, and the health care industry is to ensure the safety of health care. Reliable information is a crucial component of implant device safety. Information about implanted devices must provide the patient with specifics about device condition, lifespan, and related options in a form that is understandable to the general public, but sufficient to aide patients in making complex decisions.

How Can the Federal Government Provide Information?
Kevin O'Hara, JD (HealthStream, Inc.)

The Federal government can provide information by creating a fertile environment with standards, systems and services. With the right environment in place, the quantity and quality of information provided by the networked community of interest will greatly exceed what could be provided by the Government alone. Computerized databases and searches will play a crucial role in the sharing of this information, which makes the choice of the software infrastructure an important consideration. Although HTML-based web pages provide a means of making information widely available, this approach has drawbacks, such as a fixed layout format that is not easily modified in response to specific queries. New web-based technologies, such as XML and the Microsoft .NET software, provide a more powerful alternative based on a client-server model of information exchange. This would allow information stored in tagged database records to be provided in response to a specific query.

Value Gained from Implant Retrieval Research
Chuck Swanson, PhD (Medtronic, Inc.)

Medtronic is one of the world leaders in implanted medical technology. The company's products range from plates and screws for spinal applications to prosthetic heart valves and defibrillators. As a manufacturer, the company determines its level of effort regarding implant retrieval and analysis depending on device criticality, the device's inherent reliability and retrievability, and what other information sources are available. Two products that the company follows are pacemaker leads and stents. Pacemakers are an established technology. The few leads that are retrieved are analyzed to determine failure mechanisms, but not failure rates. The company reports pacer pulse generator and lead data to users and the FDA semiannually. Because there is less overall experience with stent grafts for treatment of abdominal aortic aneurysms, a research goal is to determine long-term clinical performance and disease progression. The few stent grafts that are retrieved are analyzed for mechanical/structural integrity. Long-term goals are to monitor device safety, improve patient follow-up and improve device designs.

A program to acquire and disseminate implant retrieval data should consider the following:

1. Manufacturers have regulatory responsibilities that require monitoring device performance and investigating complaints and failures to ensure the safety and effectiveness of their devices. This performance information is also valuable in improving the design of future generations of devices.

2. Federal programs need to complement rather than compete with existing industry systems. Third party researchers need product/technical expertise and related device information. Programs need clear goals and adequate funding.

Recommendations: (1) Focus on one or two devices for a pilot study to clearly define objectives and process, and (2) Promote the use of cooperative agreements with the industry segment to maximize success.

Patient Medical Implant History Record:
Department of Veterans Affairs: A Site for Medical Implant Device Research
Danielle Kerkovich, PhD (Department of Veterans Affairs)

The Veterans Administration (VA), as the largest health care system in the world, has one of the most comprehensive health care informatics systems. Therefore, the VA is a logical place for medical implant device informatics research, implementation, maintenance, and explant analysis. The VA provides medical care for over four million veteran's and is considered to be the largest single provider of health professional training in the world and one of the largest research organizations in the country. In order to manage this large patient population, the VA has developed a robust database including information on all persons treated within the VA Healthcare System. The database is accessible from all VA facilities and workstations and includes a variety of software and integrated data systems. To ensure a comprehensive dataset, core data elements from individual facilities are extracted and integrated into the national VA database. This information is used to analyze patient outcomes, quality of care, utilization patterns, performance assessment, and many other research applications. A national study is underway to analyze the use of medical implant devices in VA facilities. Pilot studies have begun in single VA medical centers and will expand to include other centers for longitudinal analyses. This evaluation will assess such parameters as: how the design, manufacture, and distribution compare across devices; how the "Total Product Life Cycle" varies with procedures and patient characteristics; and what are the costs of inpatient and outpatient services for management of medical implant devices and explant analysis. The results of this research will provide valuable information about device usage and management that will be important for the development of the next generation of devices. For more information, please visit the VA Information Resource Center at http://www.virec.research.med.va.gov/.

Medical Implant Research: Non-Technical Issues
David Smith, JD (Tissue Informatics, Inc.)

The evolution of medical implants from constructs of non-viable materials to bio-hybrids and engineered tissues will require a substantial re-examination of the challenges of and approaches to implant research. This evolution will render the implant progressively less removable in anything approaching an intact, discrete form (potentially increasing the consequence of implant failure and complicating failure analysis, absent substantial improvements in *in vivo* imaging), will incorporate some purposeful "remodeling" of the implant *in situ* (rendering the meaningful interpretation of implant failure more dependent upon greater access to patient medical information), and, through the active engagement of the host environment with the implant, expand the potential for remote effects (expanding the scope of the failure analysis). The clear, non-technical corollary to this biomedical evolution is heightened attention to the privacy of medical information and concern over exposure to liability.

Accurate understanding of the significance of these non-technical issues of privacy and liability for implant research is complicated by the penumbra of public perception that obscures their real boundaries. For example, the attention paid to preserving the privacy of medical information in the wake of the new HIPAA regulations has obscured the fact that the regulations do provide a fairly clear (if not always adequate) process for anonymizing and accessing information for research purposes. In fact, the HIPAA regulation creates a specific exception permitting certain disclosures of "individually identifiable health information" for "the purpose of activities relating to the quality, safety or effectiveness of [an] FDA-regulated product." [See 45 CFR §164.512(b)(1)(iii)] Likewise, fear of litigation can discourage manufacturers from engaging in implant research that could educate potential adversaries but is more likely to minimize potential liability – by identifying problems sooner and by demonstrating a continuing commitment to patient safety.

Access to relevant medical information can be complicated by the efforts of individual states to legislate protections in addition to those already provided under Federal law. Aside from the inevitable confusion and

conflict that can arise from multiple statutes governing the same activity, several state laws also suffer from a lack of clear definitions of key terms or impose particular burdens by conferring upon patients a potential economic interest in the use of their medical information. [See, e.g., Oregon Genetic Privacy Act, §659.700, et. seq.]

For the most part, access to medical information is a matter of compliance with Federal – and, increasingly, state – statutes and regulations, which more or less articulate "safe-harbor" processes enabling the release of that information for implant research. [An exception to this reasonably clear picture is the possible legislative or judicial re-interpretation of informed consent documents, where the consent was obtained many years before the removal of the implant.] By contrast, product liability is a matter of jury deliberation and court precedent, making the proper measure of and response to this non-technical issue much less objective. Significant clarity could be restored through judicial acceptance that FDA regulation of Class III Implants preempt state court civil actions. Among other things, the FDA's own disinclination to urge this acceptance provides a degree of disincentive to implant research.

If removed for premature failure, explants are essential exhibits in any personal injury lawsuit that may follow. When meaningful failure analysis must involve more than mere inspection of the explant, the fact and circumstances of any destructive testing can become evidence of concealment of defectiveness. Conversely, failure to conduct such analysis can expose the manufacturer under post-sale duty to warn theories. As much as possible, explant research should be conducted in a manner that enables the manufacturer to present it as a search for the truth, rather than for a defense to liability. To shield the research from the taint of litigation, it should be conducted on a programmatic basis and not limited to analysis of premature failures.

The introduction of viable, engineered human tissues as implants adds a further wrinkle to the liability issue, as many state "blood shield" laws may be read to declare that such tissues cannot be "products" subject to rules of strict product liability. If this interpretation survives judicial scrutiny, the introduction of engineered tissues may complicate the technical challenges of implant research but ease at least one of the non-technical ones.

Concluding Thoughts and Recommendations:

Privacy – HIPAA now favors medical information gathering for explant research, but state concerns for privacy may impede access to relevant data (requiring vigorous support of preemption). The evolution to "Living Implants" requires greater attention to informed consent (to enable greater access to information) and effective post-implantation monitoring.

Liability – This issue will remain a factor for implant research. Consideration should be given to a programmatic approach to explant collection/analysis to "neutralize" research (consider building an academic/industry legal team to develop intellectual basis and protocol for "neutral" research).

The Future – Start now to plan long-term "Living Implant" research; support technologies for *in vivo* analysis.

Medical Implant Research
Frederick J. Schoen, MD, PhD (Brigham and Women's Hospital)

Problem-oriented medical implant research has yielded important insights into deficiencies and complications limiting the success of implants.[2] Implant research has guided the development of new and modified implant designs and materials, assisted in decisions of implant selection and management, and permitted *in vivo* study of the mechanisms of biomaterials-tissue interactions, both local and distant from the device. Implant retrieval research is applicable to both the clinical environment and preclinical (i.e., *in vitro* functional and animal) investigations.

Preclinical implant research using modified designs and materials is crucial to developmental advances. These investigations include *in vitro* functional testing (such as fatigue studies at accelerated rates) and implantation of

[2] Schoen, FJ. Role of Device Retrieval and Analysis in the Evaluation of Substitute Heart Valves, in Clinical Evaluation of Medical Devices: Principles and Case Studies, K.B. Witkin, ed., Humana Press, Inc., Totowa, NJ, 1998, pp. 209-231.

functional devices in the intended location in an appropriate animal model. Relative to clinical studies, animal investigation permits more detailed monitoring of device function, enhanced observation of morphologic detail, frequent assay of laboratory parameters and *in situ* observation of fresh implants following elective sacrifice at desired intervals. Advantageous technical adjuncts may be available in animal but not human investigations, such as injection of radiolabeled imaging markers. Animal studies often facilitate observations in an accelerated time frame, such as calcification of bioprosthetic valves, in which a 5 to 10 year period in humans is simulated in just 4 to 6 months in juvenile sheep. Moreover, concurrent control implants are often possible in animal, but not human studies.

Clinicopathologic analysis of cohorts of patients who have received a new or modified prosthesis is crucial to evaluate device safety and efficacy. Analysis of rates and modes of failure and characterization of the morphology and mechanisms of specific failure modes contributes to the development of methods for enhanced failure recognition, guides future development of improved prosthetic devices, and stimulates diagnostic and therapeutic management strategies to reduce the clinical impact of complications. For individual patients, demonstration of a propensity toward certain complications could impact greatly on management. Moreover, some medical devices have demonstrated important complications only during clinical trials or post-market surveillance (complications that were not predicted by animal investigations). An important future goal is the effective integrated use of data derived from implant research (along with other clinical and experimental data) to influence both regulatory decisions and device improvements in an ongoing, incremental and iterative fashion throughout the product life cycle.

Clinical implant research has several additional benefits. Implant retrieval studies have demonstrated that success of a material or design feature in one application may not necessarily translate to another. Detailed analysis of removed implants can yield an understanding of specific failure modes and structural correlates of favorable performance. Implant research can be used to educate patients, their families, physicians, residents, students, engineers, biomaterials scientists, and the general public. As a basic research resource, the process of implant retrieval and evaluation yields data that can be used to develop and test hypotheses and to improve protocols and techniques.

Research based on implant retrieval and evaluation will continue to be critical for investigation of bioactive materials/devices and tissue engineered medical devices, in which the interactions between the implant and the surrounding tissue are complex. In such instances, novel and innovative approaches must be used in the investigation of *in vivo* tissue compatibility. In such implant types, the scope of the concept of "biocompatibility" is much broader and the approaches employed in implant retrieval and evaluation require identification of the phenotypes and functions of cells and the architecture and remodeling of extracellular matrix.[3,4] These are circumstances in which individual patient characteristics (for example, genetic polymorphisms in molecules that mediate matrix remodeling) could have a profound influence on outcome (potentially yielding a new area of study--"biomaterio-genomics"--analogous to pharmacogenomics). Thus, a critical role of implant retrieval will be the identification of tissue characteristics (biomarkers) that will be predictive of, and serve as surrogates for, success and failure. A most exciting possibility is that such biomarkers may be used to non-invasively image/monitor the maturation/remodeling of tissue engineered devices *in vivo* in individual patients.[5]

[3] Schwartz, RS and Edelman, ER. Drug-eluting stents in preclinical studies. Recommended evaluation from a consensus group. *Circulation* 2002; 106:1867-1873.

[4] Rabkin E, Hoerstrup SP, Aikawa M, Mayer JE Jr, and Schoen FJ. Evolution of cell phenotype and extracellular matrix in tissue-engineered heart valves during *in vitro* maturation and *in vivo* remodeling. *J Heart Valve Dis* 2002; 11:308-314.

[5] Rabkin E and Schoen FJ. Cardiovascular tissue engineering. *Cardiovasc Pathol* 2002 11:305-317.

BREAKOUT SESSIONS - SUMMARY and RECOMMENDATIONS
The breakout sessions addressed four broad topics related to medical implant retrieval research and education: Education and Information, Medical Implant Research, Non-Technical Issues, and Dimensions of Health Informatics. The objective of each session was to develop a set of recommendations relating to these topics and addressing the three overall goals of the workshop.

Education and Information
Chair: Denise Wilson, PhD (University of Washington)
Facilitator: Hilary Sigmon, RN (NIH/CSR)
Terrie Cowley, PhD (TMJ Association)
Jack Lemons, PhD (University of Alabama at Birmingham)

This group discussed a broad range of topics that centralized on educational benefits and the need to develop and transfer information on a timely basis. Experience over past decades has elucidated both opportunities and limitations specific to information gained from device retrieval and analysis, plus the need for enhanced education for professionals, patients, and the public. Recommendations were coordinated at the summary session with a central focus on potential benefits to all stakeholders.

1. **Develop and make available evidence-based information about implant device treatment outcomes.**

   This information should be related to the patient, the clinical aspects of the procedure, and the device (including retrieval and analysis). Information is needed prior to and during the time of implantation, the functional lifetime, the time of explantation, and the post-explantation period. Independent peer-reviewed assessments should be developed for the various categories of information with a focus on the value(s) of device retrieval and analysis.

2. **Initiate government and other programs to minimize existing restrictions while maintaining patient, health care provider and manufacturer rights.**

   This recommendation may require a focused working group meeting to evaluate the issues and goals for developing such programs.

3. **Establish educational programs to disseminate the appropriate information to professionals, patients and the public.**

   These programs should be supported within each of the stakeholder groups, including Government agencies, providers and payers, and manufacturers.

4. **Develop mechanisms to support device retrieval programs.**

   Such mechanisms should include vehicles for professional and patient education with extensions to the general public through appropriate professional organizations.

Medical Implant Research
Chair: Renu Virmani, MD (Armed Forces Institute of Pathology)
Facilitator: Nancy Shinowara, PhD (NIH/CSR)
Michael J. Lysaght, PhD (Brown University)
Clare M. Rimnac, PhD (Case Western Reserve University)
Regine Sitruk-Ware, MD (Rockefeller University)

There is substantial value in research on medical implants following retrieval or removal (explants). Explant analysis is the embodiment of the translation of biomaterials research to clinical care. This activity evaluates the safety and confirms the efficacy of implants and innovations through a complex interactive process that encompasses basic science research, applied research, medical research, and engineering materials and design. Ideally, it also determines the rates, modes, causes and mechanisms of implant failure, as well as early surrogate markers for failure. Patient and prosthesis factors in implant performance (both success and failure) can be identified. Moreover, sophisticated and informed implant analysis elucidates mechanisms of tissue-biomaterials interactions, which can also be utilized to inform implant innovation and enhance patient care.

1. **Encourage the use of information acquired from implanted and explanted medical devices.**

   The Federal government can play an important role by supporting five major areas: device access, tracking, and clinical outcomes; quality of explant research; enabling research initiatives; education of key constituencies; and explant research.

2. **Develop a nationally-linked clinical implant and explant registry.**

   Such registries would have a substantial impact on the ability to obtain valuable data on the performance of explanted medical devices, including device access, tracking, and clinical outcomes. For this type of system to be effective, it would require participation, acceptance, and cooperation of key constituencies (clinicians, patients, industries, Government agencies, and scientists).

3. **Enhance the quality of implant and explant research.**

   Specifically, the Federal government should support programs that would:

   - Stimulate hypothesis-driven research on well-defined cohorts.
   - Develop peer-reviewed “best practice” protocols and standards/guidelines for explant analysis.
   - Stimulate explant research as collaborative efforts of pathologists, manufacturers, scientists, engineers, and clinicians.
   - Support programs that seek to obtain retrieved devices from “lost” sources (e.g., community hospitals, retrieval of devices at autopsy and partial autopsy).
   - Support multi-center collaborations through targeted funding solicitations.
   - Address future, as well as existing, devices and implanted materials.
   - Consider implant research that identifies factors in device success as well as failures.
   - Stimulate training of implant retrieval scientists (e.g., NIH training grants, NSF education grants, industrial support, etc.).

4. **Support initiatives that will advance implantable device technology.**

   In the 21st century, three generations of medical devices are available: bioinert implants, bioactive implants, and cell-scaffold systems designed to regenerate functional tissues. To achieve the full potential of these mature and emerging generations of implantable devices, the following initiatives are recommended:

   - Develop targeted NIH solicitations focused on the analysis of patient factors in implant performance (e.g., proteomics, genomics, immune response).

- Identify early surrogate markers for implant failure through imaging techniques (e.g., Roentgen Stereophotogrammetric Analysis (RSA), calcification), clinical symptoms, sensors, and telemetry.
- Validate biomarkers and develop techniques for imaging tissue-engineered implant function and tissue quality.

5. Educate key constituencies to enhance medical device research.

Major initiatives should:

- Educate patients, pathologists, surgeons, clinicians, scientists, and engineers of the value of explant research following revision and at autopsy.
- Inform key constituencies that adverse reactions may occur (analogous to pharmaceuticals).
- Educate patients about normal implant function and expected outcomes, potential adverse events, and value of explant research.
- Link medical and research society web-pages to Federal (FDA, NIH, NIST) and corporate websites.
- Make implant retrieval research results available to patients to facilitate their pre-operative decision-making.

6. Obtain funding and support from multiple stakeholders.

Successful explant research is predicated upon obtaining funding from multiple stakeholders. Support should be sought from:

- Medical societies (e.g., American Academy of Orthopaedic Surgeons, American College of Cardiology) and research societies (e.g., Orthopaedic Research Society, Society for Vascular Surgery, Society for Biomaterials, American Heart Association).
- Payers for patient care (e.g., insurance companies, Medicaid, Medicare, and other government agencies). This would require a demonstration that explant research promotes cost-effective patient care.

Non-Technical Issues
Chair: Barbara H. Anderson (Dow Corning, Corp.)
Facilitator: Bernie Liebler (AdvaMed)
E. Haavi Morreim, PhD (University of Tennessee)
Jur Strobos, MD, JD (Olsson, Frank and Weeda PC)

The non-technical issues relevant to explant research are generally related to patient knowledge and the question of device ownership. To absolve the involved parties of potential legal liabilities, it is necessary to clarify who is the legal owner of an implanted medical device. It is also critical to ensure that patients understand the informed consent process. They will more likely agree to device explantation, particularly post-mortem explantation, when they understand the complete process. The Federal government can play a critical role by ensuring that information related to implant procedures and expected performance is easily available to the public.

1. **Prepare a document that clarifies the property rights of patients, manufacturers or other interested parties (e.g., insurers) in the device.**

   To promote research on explants and to resolve legal liability concerns of researchers, issues relating to ownership of an explanted device must be resolved. This need can be met though a legal memorandum or law review article addressing the current state of the law on ownership of the explant and its use for research *via* bequest, donation, or other contractual transfer (e.g., sale or lease) upon explantation either as a result of revision surgery or after death.

2. **Develop a Model Informed Consent Process.**

   A model informed consent process that guides the patient through signing the consent form, implantation and explantation, would maximize patient understanding of the value of research on devices and increase the probability of consent to explant the device.

3. **Help patients understand the value of explant research by providing an easy mechanism to obtain information.**

   Patients will be more likely to participate in research if they are able to read and understand the results of research conducted on devices. Therefore, publication of summaries of research in layperson's terms in readily accessible media, such as the Internet, would be one way for patients to obtain information.

4. **Convey a balanced story about research on explanted devices.**

   Newsworthy information tends to be focused more on adverse events relating to devices rather than the benefits. A more balanced publication of information, positive and negative, *via* med guides or stakeholder meetings could encourage more participation in research.

5. **Prepare a document that answers the question of whether an implant is personal health information under HIPAA.**

   Agency guidance on this question would address privacy concerns of patients and allow researchers and manufacturers to meet HIPAA requirements.

Dimensions of Health Informatics
Chair: Henry Heffernan (NIH)
Facilitator: Christine Kelley, PhD (NIH/NIBIB)
C. Martin Harris, MD, CIO (Cleveland Clinic Foundation)
Richard E. Ward, MD, MBA (Reward Health Sciences, Inc.)

Closer cooperation between Federal agencies, professional societies and clinical services organizations will be important for improving the acquisition and dissemination of implant information. In addition to the clinical trials information needed for regulatory approval of implant devices and the data derived from research on explants, the experience of clinicians providing clinical implant services for patients is a significant source of information. The correlation of this clinical implant care experience and data can be achieved by establishing consortia of clinical centers providing clinical implant services, and harmonizing the clinical data systems of the consortia institutions so they can conduct an ongoing series of collaborative performance improvement projects. The information on improved practices developed in these collaborative projects will provide evidence-based data for improving the implant device technology refinement and development process, the curriculum design of continuing education programs for physicians, and the dissemination of up-to-date implant information for patients. The Internet offers one way of disseminating this evidence-based information. Utilizing the full potential of the Internet will require a cooperative effort of government agencies, medical societies, and the clinical implant service institutions participating in the consortia.

1. **Facilitate the acquisition and use of retrieved medical implant information.**

   The role of the Federal government is to provide the initiative, encouragement, and support required for medical implant information retrieval to be economically feasible and to generate implant performance information for the education of patients, pathologists, physicians, surgeons and scientists. For example, key constituencies including patients, need information on normal implant function and expected outcomes, potential adverse events, and the value of explant research.

2. **Structure Federal programs to assist gathering and disseminating information.**

   Federal programs supporting the acquisition and dissemination of medical implant information should work toward:

   - Establishing consortia of institutions providing clinical implant services.
   - Establishing standards for data collection, testing methods, and record-keeping.
   - Establishing an Internet reference database to disseminate information and innovations developed by the consortia institutions.
   - Improving existing systems for the automated exchange of performance information, analytical algorithms, and implanted device status.
   - Facilitating development of long-term data archiving systems.

3. **Catalyze a scientific team approach to gather and disseminate life cycle data on implant performance and thus improve health care.**

   The data acquired from clinical trials of a novel but critical device may demonstrate safety and efficacy over a limited time period, ranging from several months to a few years, before the device is released into commercial distribution. The currently mandated information gathering systems are designed to capture only the serious adverse events that may become evident during general distribution and extended periods of use.

   To improve the next generation of products, a mechanism to retrieve and evaluate more subtle aspects of device performance is also needed. While the government can make some information available, it must rely on the health care providers, health care payers, researchers, and the medical device industry to acquire information derived from clinical populations and to make it understandable.

OVERALL WORKSHOP RECOMMENDATIONS

The Federal government has an important role in facilitating and disseminating data gained from medical implant and explant research to ensure safer health care. Reoccurring themes emerged in the breakout sessions and the overall recommendations reflect this consensus and other crucial areas in which the Federal government should provide support. Specifically, the Government should:

1. **Establish Internet-based medical implant information and data resources for patients, clinicians, researchers, designers, manufacturers, and other interested persons.**

   It is in the public interest to study retrieved implants and acquire systematic data on the performance of implants throughout their life cycle and in a variety of patients. These data will improve the design, fabrication, quality, and reliability of these implants and ensure enhanced safety and performance of future implants.

2. **Develop standard definitions and practices for recovering implants, conducting research, evaluating outcomes, and reporting results.**

   Agreement is needed on evaluation, research protocols, standards, and guidelines for retrieved medical devices. This will facilitate the creation of a reference source of aggregate data on implant device characteristics and allow electronic data exchange for long-term safety improvement and technical innovation for medical implant products. In addition, these definitions will provide input to the international standards development process.

3. **Catalyze a scientific team approach to gather and disseminate a comprehensive description of implant performance and thus provide improved healthcare.**

   The data acquired from clinical trials of a novel but critical device may demonstrate safety and efficacy over a limited time period, ranging from several months to a few years, before the device is released into commercial distribution. The currently mandated information gathering systems are designed to capture only the serious adverse events that may become evident during general distribution and extended periods of use.

   To improve the next generation of products, a mechanism to retrieve and evaluate more subtle aspects of device performance is also needed. While the Federal government can make some information available, it must rely on the healthcare providers, healthcare payers, researchers, and the medical device industry to acquire the information derived from clinical populations and to make it understandable.

4. **Educate key stakeholders about research on retrieved implants.**

   Establish programs that disseminate appropriate information to professionals, patients, and the public. Education about normal implant function and expected outcomes, potential adverse reactions (analogous to drug therapy), and the value of explant research all play an important role in enhancing medical device research. Possible approaches include: linking medical and research society Internet pages to Federal and corporate sites, maximizing the use of multi-media formats (e.g., videos, audio, text), and making implant retrieval research results available to patients to facilitate pre-operative decision-making.

5. **Publish a peer-reviewed law article that clarifies the medical implant property rights of patients, manufacturers, hospitals, insurers, and other interested parties.**

   This document will outline the legal liability concerns of researchers and coroners involved in retrieved implant research. The article will address the current state-of-the-law on ownership of both synthetic and natural retrieved implants and their use *via* bequest, donation, or other contractual transfer (e.g., sale or lease) upon explantation as a result of revision surgery or death.

6. **Create a central source of general information regarding the medical value, safety, lifetime, and adverse events associated with medical implants.**

   It is important to provide the general public with valid and reliable information about medical implants. Internet-based resources are an effective means for communicating accurate and up-to-date information in a format that is understandable to patients. This information should be derived from a standardized aggregate reference dataset that would provide consistent and dependable information.

APPENDIX A

WORKSHOP FINAL AGENDA

WORKSHOP CO-CHAIRS : Julia Weertman (Northwestern) and Y.C. Fung (UCSD*)*

PURPOSE

1. Consider the Federal government's role to provide medical implant information to ensure the safety of health care.
2. Evaluate the role of the Federal government to extract and disseminate information gained from explanted medical implants.

GOALS

1. Define the role of the Federal government to encourage the use of information acquired from implanted and explanted medical devices for research.
2. Design of a possible structure for Federal programs to support gathering and dissemination of information derived from medical implant retrieval.
3. Design of a Federal program to promote implant retrieval for use in research intended to achieve safer health care.

DAY 1 – September 19
(Building I, Auditorium)

8:00 a.m. **Purpose and Goals of Workshop**
Julia Weertman and Y.C. Fung

8:15 a.m. **Current Demographics**
"Medical Implant Devices: Data Available from NCHS and the Use of ICD-9-CM for the Coding of Diagnoses and Procedures"
Donna Picket (Center for Health care Statistics)

8:35 a.m. **Medical Devices: Current Information and Policies**
Bill Regnault (FDA)

8:55 a.m. **Keynote Address**
"Patient Education: How Can It Be a Part of Medical Device Improvement?"
Ken Keller (University of Minnesota)

9:25 a.m. **What Information do Patients Need to Have?**
Laura Quigley (St. Luke's Medical Center)

9:45 a.m. **What Information Can/Should the Federal Government Provide?**
Art Ciarkowski (FDA)

10:05 a.m. **Break**

10:30 a.m. **How Can the Federal Government Provide Information?**
Kevin O'Hara (HealthStream, Inc.)

10:50 a.m. **Value Gained from Implant Retrieval Research**
Chuck Swanson (Medtronic, Inc.)

11:10 a.m. **Patient Medical Implant History Record**
"Department of Veterans Affairs: A Site for Medical Implant Device Research"
Danielle Kerkovich (Department of Veterans Affairs)

11:30 a.m. **Medical Implant Research: Non-technical Issues**
David Smith (Tissue Informatics)

11:50 a.m. **Medical Implant Research**
Fred Schoen (Harvard)

12:10 p.m. **Lunch**

12:30 p.m. **Breakout Sessions:**

Education and Information
(Building I, Room 101)
Denise Wilson, Chair (University of Washington)
Terrie Cowley (TMJ Association)
Jack Lemons (University of Alabama at Birmingham)
Facilitator: Hilary Sigmon (NIH/NINR)

Non-Technical Issues
(Building I, Room 108)
Barbara Anderson, Chair (Dow Corning,)
E. Haavi Morreim (University of Tennessee)
Jur Strobos (Olsson, Frank and Weeda PC)
Facilitator: Bernie Liebler (AdvaMed)

Medical Implant Research
(Building I, Room 102)
Renu Virmani, Chair (Armed Forces Institute of Pathology)
Mike Lysaght (Brown University)
Clare Rimnac (Case Western Reserve University)
Regine Sitruk-Ware (Rockefeller University)
Facilitator: Nancy Shinowara (NIH/CSR)

Dimensions of Health Informatics
(Building II, Room 1012)
Henry Heffernan, Chair (NIH)
C. Martin Harris (Cleveland Clinic Foundation)
Rick Ward (Reward Health Sciences, Inc.)
Facilitator: Christine Kelley (NIH/NIBIB)

5:00 p.m. **Adjourn for the Day**

DAY 2 – September 20
(Building I, Room 220)

7:30 a.m. **Registration**

8:00 a.m. **Breakout Session Chair Reports**

10:00 a.m. **Break**

10:30 a.m. **Discussion of Recommendations and Development of Executive Summary**

1:00 p.m. **Adjourn**

APPENDIX B

Medical Implant Information, Performance and Policies

SPEAKERS AND PARTICIPANTS

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NON-TECHNICAL ISSUES

Chair:
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Panelists:
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APPENDIX C

Medical Implant Information, Performance and Policies

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