Access to, Sharing and Retention of Research Data: Rights & Responsibilities

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ACCESS TO, SHARING AND RETENTION OF RESEARCH DATA:

RIGHTS & RESPONSIBILITIES

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INTRODUCTION

Scientific and technical data generated by research and other scholarly activities are the currency of the intellectual capital that researchers and scholars create and share to advance the research enterprise. Both investigators and research institutions have rights and responsibilities with respect to research data. This holds true whether or not outside support, with its attendant compliance requirements, contributed to creating the data.

Among the responsibilities of institutions and investigators are shared obligations regarding retention of and providing access to research data. Research sponsors are the primary sources of these obligations, generally documented in the grant and contract agreements through which funding is provided. Additional obligations regarding access to data may be imposed by journals as a condition of publishing a manuscript describing results of primary research.

Because research data are the most valuable property of our investigators it is not surprising that tensions may arise between the investigator, the institution and the sponsor regarding the issues of ownership, control and externally imposed management processes of data. This guide is written as a brief review for the researcher and as guidance for research administrators and their institutions to provide clarity on questions they may have regarding access to and sharing and retention of research data.

IN THIS GUIDE: THE CONTEXT

In this guide, we deal with data in the most comprehensive sense. While the federal government has not developed a uniform definition of "research data" or "scientific data," we have based our definition on the guidance provided by the US Office of Management and Budget (OMB) in its grants management circular, Circular A-110/2CFR 215. OMB defines research data

The Guide is accompanied by companion documents:

- Definition of Research Data and Research Materials;
- Case scenarios

The sidebar on each page will note when a topic is featured in a checklist or case scenario.

The definition of "research data" and "research materials" is distinctly different depending on the sponsor and by discipline. As a companion to this Guide, the authors have prepared a brief paper that begins the exploration of how you define "data" and "materials" and its affect on the policies and procedures designed for access and retention.
See Appendix A

as "the recorded factual material commonly accepted in the scientific community as necessary to validate research findings." It is important for investigators to recognize their rights, responsibilities and the protections which cover their research results, beyond the government's rights to intellectual property generated by the research.

IN THIS GUIDE: THE CONTENT

This guide complements the COGR brochure on rights in technical data that deals primarily with federal requirements for intellectual property rights in agreements.[1] This guide examines the broader context of data stewardship beyond the specific procurement or agreement process, using case scenarios to illustrate various data management questions and offering suggestions for addressing these questions. While the technical data brochure focuses on federal agency expectations, this guide examines the institution's obligations irrespective of the outside funding source and regardless of the type of funding mechanism selected.

The Guide begins with general guidelines for retention and access and then examines unique Federal agency policies or regulations and special circumstances that affect the access to and sharing and retention of data.

Some institutions have begun to develop formal policies and procedures for access to and sharing and retention of research data. This guide and its component case studies can assist this process and help stakeholders recognize situations where roles or policy need to be clarified, to

[1] A detailed description of these responsibilities is found in the COGR online publication entitled "*Technical Data and Computer Software – A Guide to Rights and Responsibilities Under Federal Contracts, Grants and Cooperative Agreements*" (October 2009). http://www.cogr.edu/Pubs_intellectual.cfm

identify issues that may need to be addressed, and to review options for defining responsibilities with respect to access to and sharing and retention of research data.

As with other COGR guidance documents, it is important to recognize that missions and cultures of research institutions vary. Of specific relevance to these discussions are varying state open records statutes which dramatically and differentially impact access to research data generated and held by researchers in public institutions relative to private institutions in the same state. As a result, this guidance must be placed into the context of individual institutions. While policies must be clear when sponsored funding dictates regulations or requirements, institutional standards with respect to access to and sharing and retention to scientific data will vary widely.

USING THE GUIDE:

This guide, a paper examining the definitions of research "data" and research "materials," and the companion case scenarios are available to the community in two formats: on paper and on line. A complementary institutional policy checklist that combines information highlighted in the sidebars throughout the guide is only available online. The case scenarios are presented as a separate set of documents online as well. We will provide additional resources online including links to the principal regulatory websites. Generally the web links are to main or home pages and the user will need to search for a specific document. These external links will be checked periodically. Users may print the entire text as a single file and each group of case scenarios individually, or the entire set of scenarios as single file. See the *Access to and Sharing and Retention of Research Data* opening page on the COGR website for more information.

COGR appreciates the contribution of all its members in providing information that strengthened these documents and acknowledges the contributions of Peter Dunn, Todd Guttman and Gunta Liders as authors of the 2006 edition of this document. The 2011 edition working group's unfailing dedication and commitment benefits all the members.

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I. DEFINITION & OWNERSHIP OF "RESEARCH DATA"

Both the rights and responsibilities surrounding ownership, access and retention of data as well as the definition of research data, may vary based upon sponsorship of the project, nature of the funding instrument implementing the award, and general context of the situation. Research and technical data may consist of a set of numbers recorded manually or digitally, resulting from measurements, computations and statistical analyses, or it may consist of materials such as micrographs, molecules, cells, integrated circuits, genetically-modified plants or animals, etc. Data can also be "raw," "preliminary" and "final." Thus, the very definition of research data poses problems in attempting to delineate the overall responsibilities of the research institution and its researchers.

A broader institutional definition and policy provides a more comprehensive and useful foundation upon which to apply the sponsor's specific requirements. The investigator and institution should review the agency's particular definition and expectations for the purposes of a specific research agreement.

The meaning and management of "research data" and "research materials" are important for meeting the obligations of a particular sponsored agreement but also must address potential future use of the data and materials. The question of future use is particularly important in pre-clinical research that may be needed to support clinical research activities.

A. DEFINITION

In the Office of Management and Budget's (OMB) Circular A-110/2CFR 215, *Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*, research data

Investigator Check:

The Investigator needs to understand the meaning of "data" for a particular sponsor as well as understand potential future uses of the research data and materials. For example, pre-clinical and clinical studies that will fall under HIPAA and/or FDA requirements need to be managed in compliance with those regulations from the start of the study.

Data management and/or sharing requirements may affect how data is collected and stored. Any requirements for management and sharing should be reviewed with all members of the research team to ensure consistent collection and treatment.

are "defined as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues." [2] This definition uses the context of dissemination and validation to explain the meaning of research data.

The National Institutes of Health (NIH) Grants Policy Statement defines "data" as "recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data." This approach frames the definition on how the information is recorded.

The Federal Acquisition Regulations (FAR) refers to "recorded information, regardless of form or the media on which it may be recorded," and includes technical data and computer software. The Department of Defense Acquisition Regulations (DFARS) defines "technical

Investigator and Institution Check:

The provisions or requirements for data access and retention linked to a specific agreement should be reviewed before executing the agreement.

Institution Check:

If the agreement proposes restrictions on or limits to the use of data or requires review and approval of research results/publications, the institution must make a determination on whether the agreement's provisions conflict with institutional policies.

[2] The circulars are available on OMB's website at: http://www.whitehouse.gov/omb/circulars/a110/a110.html. In May 2004, OMB established a new Title 2 of the Code of Federal Regulations (2CFR) for policy guidance for grants and other financial assistance and non-procurement agreements. OMB Circular A-110 is located at 2CFR 215. Subtitle A includes government-wide guidance to Federal agencies for grants and agreements; subtitle B includes related agency implementation regulations. The definition provides the following exclusions: "This recorded material excludes physical objects (e.g., laboratory samples). Research data also do not include: (A) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and (B) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."

data," as "recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation but not software programs, source code, etc.)." The Environmental Protection Agency (EPA) defines raw data as "any laboratory worksheets, memoranda, notes or exact copies thereof that are the result(s) of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study." NASA defines "data" as "recorded information, regardless of form, the media on which it may be recorded, or the method of recording, created under the grant. The term includes...data of a scientific or technical nature, and any copyrightable work in which the recipient asserts copyright, or for which ownership was purchased, under the grant." [3]

Thus, it is important for institutions and investigators to be knowledgeable about the definition of the term "research data" in the context of specific federal regulations, institutional policy and sponsor requirements.

This guide relies on the OMB definition because it applies across Federal agencies and, thus, is the framework for discussing federal requirements for access to and retention of research data. In OMB's definition, preliminary or "raw" data without analysis is not included for the purposes of access by the general public. However, investigators must retain this raw data in laboratory notebooks or records for purposes of validating research findings. The raw data serves other purposes as well, such as patent applications, investigations of misconduct, or if the research results are used for public policy or regulatory purposes.

[3] FAR 27.401; DFAR 252.227-7013(a)(15); EPA 40 CFR Subpart A §792.3; NASA 14 CFR Part 1260

B. OWNERSHIP

Past scholarly practice may have presumed that the investigator owned the data that resulted from his/her research. In the context of sponsored programs and the related award requirements, institutions are required to assert ownership over data resulting from research. Confusion and potential conflict among investigators, institutions and their sponsors may result when an institution's policy is silent on the issue of data ownership.

In general, federal policy and guidance supports institutional claims of data ownership for federally funded research. Under OMB Circular A-110/2CFR215, the rights to "intangible property" belong to the institution as the grantee. The NIH Grants Policy Statement states that "grantees own the data generated by or resulting from a grant-supported project." The National Science Foundation gives grantees rights to their data as well. While federal sponsors have recognized grantees' ownership rights in the data and research results, they retain a broad right or license to use the research results.

On the other hand, some federal and a growing number of private sector contracts, as opposed to grants, now require that sponsors be granted ownership and/or unlimited, sometimes exclusive, rights in data as a condition of the award.[4] Research institutions generally refuse to relinquish ownership and rights in data because such limits on ownership or access conflict with the goal of sharing research results to advance the field. At a minimum, most institutions retain rights to use the data for research and educational purposes; some institutions

[4] The Federal Acquisition Regulations (FARs) generally give the government unlimited rights in data but allow research institutions to claim copyright. http://www.arnet.gov/far/ Not all agencies, however, follow the FAR guidance. For example, the Department of Defense takes a different approach (see COGR *Technical Data and Computer Software – A Guide to Rights and Responsibilities Under Federal Contracts, Grants and Cooperative Agreements*" (October 2009).

Investigator Check:

The distinction between research "data" and research "materials" from which data is extracted will be important for managing data and materials in the laboratory to meet the sponsor requirements.

Institution Check:

The ownership of and rights to use data (and/or materials) should be clearly defined in institutional policy to ensure the institution, as grantee, can meet its obligations. The applicability of the policy in terms of which members of the community are covered should be clearly defined.

The institution's policy with regard to allowable limitations or restrictions on data produced under a sponsored agreement should be clearly defined in policy.

Institution and Investigator Check:

The party responsible for management or custodianship of the data and material itself should be clearly specified.

narrowly limit the rights assigned to research sponsors through such mechanisms as the nature of the report to be provided to the sponsor or a limit to the field of use. Before agreeing to any limits on rights and ownership, the research administrator should discuss the implications with the investigator and consider the impact on the institution's teaching and research missions and agreement with institutional policies.

In its role as the grantee, the research institution is required to hold title to or own the data through its contractual obligations. Most states impose a similar ownership obligation on their state-assisted universities and research institutions.

By tradition and for practical reasons, investigators, as creators of the data, retain possession of the data on behalf of the institution.

As custodians of the data, investigators must be thoughtful about any assignments of copyrights made without consultation with the institution. Investigators should review copyright assignments usually required for the publication of journal articles or books. These assignments generally give the publisher all rights to the article or manuscript – not the data – which will limit the author's ability to use the publication in future works. The author should retain the rights to use the publication for research and educational purposes and to meet the obligations in sponsored agreements.

One principle is clear – as institutions consider creating a research data policy, a broad, clear definition of data will provide the greatest flexibility for the institution. The policy should acknowledge the broad context of the institution's research program and yet address the specific situations spawned by individual programs and existing sponsor requirements.

II. GRANTEE OBLIGATIONS UNDER OMB CIRCULAR A-110/2CFR 215

The Office of Management and Budget (OMB) Circular A-110/2CFR215 , *Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations*,[5] establishes uniform administrative requirements for Federal grants and agreements and prohibits Federal awarding agencies from imposing additional or inconsistent requirements, except for special classes of grants or recipients or for an applicant or recipient whose performance, financial or management systems do not conform to the standards outlined in the Circular.

Thus, OMB Circular A-110/2CFR215 serve as the most useful general standard for articulating Federal requirements for the administration of research and research-related programs. This guide uses OMB Circular A-110 and the policies of the principal Federal research agencies and research institution partners, the National Institutes of Health (NIH) through the Public Health Service (PHS) and the National Science Foundation (NSF) as the best general framework for discussing the access to and sharing and retention of research data. While the OMB Circular sets uniform requirements, institutions and investigators should carefully review the requirements of each individual award to identify any special access or retention requirements.

A. DATA RETENTION

1. GENERAL OBLIGATIONS

OMB Circular A-110/2CFR215 sets forth the expectations for the grantee's retention of research and administrative records produced under federal grants and

Institution Check:

Institutional policy should be clear about the meaning of data and materials and define the roles and responsibilities of the institution and the investigator.

Institutions should consider how to incorporate the definition and ownership of data and materials, the obligations for data access and retention, etc., into faculty and staff orientation programs and education in the responsible conduct of research.

Investigator Check:

In submitting data for publication, investigators must be alert to the assignment of copyrights.

[5] The circular is available on OMB's website at: http://www.whitehouse.gov/omb/circulars/a110/a110.html

cooperative agreements. Section C._.53 of Circular A-110 requires that all records – financial records and the supporting documentation, scientific data including notebooks, etc. – be maintained for three years or, in the case of litigation started before the end of the original three-year period, until any claim or audit is resolved and final action taken.[6] Thus, a three-year period is the minimum amount of time that research data should be kept by the grantee. Many institutions insist upon a longer period of time given varying sponsors' agreements, regulatory requirements (e.g., FDA regulations), obligations created under a data sharing or data management plan and to respond to allegations of research misconduct.

In addition, institutions should specify other retention periods for special circumstances such as:

a. When the data are in support of a patent or other protected intellectual property, retention should extend at least through the life of the patent or as long as necessary to protect the intellectual property;

b. When the data in question are linked to any inquiries or investigations with respect to research, such as allegations of scientific or financial misconduct or conflict of interest, the data should be retained until all charges, appeals and litigation are fully resolved;

Institution Check:

Institutional policy should set a minimum retention requirement. Institutions must be alert to the varieties of types of data and/or materials that are produced in research activities and address the roles, responsibilities and resource needs to meet the institution's policy.

Institutions should identify mechanisms that ensure communication between/among institutional components to preserve data, materials and other research records in special circumstances, e.g., patent applications, misconduct allegations, etc.

Investigator Check:

Some agencies require the development of data management plans and/or data sharing plans. If the award pleges to meet specific access or sharing obligations, investigators should alert the institution and ensure that laboratory practices are put in place to meet these obligations.

[6] OMB, A-110. C. _53. Retention and Access Requirements for Records: Financial records, supporting documents, statistical records, **and all other records pertinent to an award** shall be retained for a period of three years from the date of submission of the final expenditure report or, for awards that are renewed quarterly or annually, from the date of the submission of the quarterly or annual financial report, as authorized by the Federal awarding agency. There are four non-research related exceptions to these requirements.

c. If a student is involved, research data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work;

d. When the nature of the research data prohibits a three year retention period, e.g., biological materials that cannot be stored for a long time period. In these cases, the investigator should be required to document the characteristics of the samples by some other means.

2. DATA STORAGE

As the grantee and formal owner of the data, the research institution is responsible for retaining research data, materials and documentation as required by its agreements. However, it will not be practical or reasonable from the perspective of the investigator for the institution to assume primary responsibility for custody. As a result, it is common for institutions to indicate in policy that the principal investigator serves as the custodian of data, materials and other research documentation for their projects and as responsible agent for their preservation and retention. While often the only reasonable approach, this solution often raises the question of who (the investigator, the department, the college or school, or the institution) provides the resources to maintain the facilities required for proper preservation and retention of all the data generated in modern federally funded research. Institutions need to establish policies and procedures to support the retention of research data, material and documentation. This support can be in the form of centralized facilities for retention or assistance in the transfer of information to electronic formats. An institution should develop flexible records management strategies to accommodate the needs of its investigators.

Institution Check:

Sponsors may have different requirements or policies concerning records. Institutions will want to have a process to identify and comply with exceptions to general rules.

Questions of ensuring confidentiality, particularly in light of other data requirements, notably HIPAA, should be reflected in institutional policy.

Investigator and Institution Check:

Policies and practices should be identified to ensure that custodianship can be managed, as necessary.

Institution Check:

Institutions should address their obligations to manage data storage. The allocation of time and resources to support storage centrally versus distributing those responsibilities to either the investigator or another unit, e.g., department or college, must be considered.

3. DIGITAL STORAGE OF DATA

As the management of records and information at institutions has changed from paper to electronic, Federal policy and regulation has not necessarily kept up with these changes. OMB Circular A-110 allows the substitution of copies for original documents without addressing specifically the use of electronic records.[7]

The US Department of Health and Human Services (HHS) will authorize the use of electronic imaged records as substitutions for paper records for those institutions for which it is the cognizant agency.[8] The authorization makes it clear, however, that the use of electronic storage media requires procedures to provide for the security of the stored records including secure transmission and dissemination of the records and a process to validate the authenticity of the record. The Federal Acquisition Regulations require retention of the paper record for validation for one year after imaging.[9] Whether records are electronic or on paper, the requirements for retrieval and access by the federal government are the same. HHS still retains the requirement that it should be notified when substituting electronic copies of original records, but not when the records are created electronically. Other agencies have adopted similar policies to permit substitution of electronic records.

[7] OMB, A-110. C. _53. (c) Copies of original records may be substituted for the original records if authorized by the Federal awarding agency.

[8] The authorization was issued by the HHS Office of Grants and Acquisition Management as OGAM AT 99-1). http://www.hhs.gov/grantsnet/gps/ogamat.pdf

[9] FAR 4.703 (c)(3). Most academic institutions have interpreted this requirement as applying to notification of institutional or "system-wide" substitution of electronic copies for original paper records - not notification of the substitution of individual records held by investigators and departments.

Not all records in digital medium are copies of paper records. Research data and research materials today are both created and stored in digital media. Thus, the establishment of institutional standards for digital record storage, as well as archives for digital and other media should be considered.

B. DATA ACCESS BY FEDERAL AGENCIES

1. ALL DATA

The provisions of OMB Circular A-110, Section C._ .53 retain the right of "timely and unrestricted access" for the awarding agency, inspectors general, and the US Controller General as a condition of all grants and cooperative agreements.[10] Similarly, federal contracts assure access to the data by means of requirements contained within the Federal Acquisition Regulations (FARs).[11]

Access does not mean confiscation of documents. As a general rule, research institutions that receive a request for access make the original documents available for review at an institutional site or provide copies of documents requested by the agency.

2. DATA USED TO FORMULATE FEDERAL REGULATIONS – ACCESS VIA FEDERAL FREEDOM OF INFORMATION ACT (FOIA)

Prior to the 1999 revision to OMB Circular A-110, the Freedom of Information Act (5 USC, Section 552) allowed for interested persons to seek documents and records in the possession of the federal agencies, such as material in grant applications, progress reports, and other information sent by the grantee to an agency.

Investigator and Institution Check:
The mechanisms for responding to FOIA requests should be clearly defined and broadly conveyed. Requests for information can be received by various stakeholders and the institution should ensure that the entire organization understands how and who will respond.

Institution Check:
Institution should design mechanisms that ensure consistent responses to Federal requests for access to data and materials and other documents related to Federal awards. Similar access mechanisms may be implemented for non-Federal sponsors.

[10] OMB, A-110. C. _53 (e).

[11] Federal Acquisition Regulations., **FAR 52.215-2, Audit and Records – Negotiation**, allows the Contracting Officer or an authorized representative the right to examine and audit supporting records and materials, including research data. **FAR 52.227-14, Rights in Data - General, Alt. V**, allows the contracting officer or agency to have the right to inspect certain data at a contractor's facility

Federal agencies do not require grantees to provide raw data as part of their technical reporting responsibilities, nor could FOIA requirements previously reach into the institution for such records.[12] The 1999 revision of OMB Circular A-110, otherwise known as the "Shelby Amendment," opened the door for interested persons to obtain federally sponsored information and raw data that are only in the possession of the grantee institution. The instances of when this can be done are narrowly defined; the request is limited to research data related to published research findings, developed under an award, that were used by the Federal Government in developing an agency action that has the force and effect of law.[13] In 2009, the US Attorney General established new practices for responding to FOIA requests. Agencies are directed to not withhold information simply because it can demonstrate, as a technical matter that the records fall within the scope of a FOIA exemption; consider partial disclosures; and understand that the Department of Justice would defend the denial of a FOIA request in a very limited set of circumstances. Institution should review their FOIA obligations under the prevailing Department Of Justice provisions.

[12] The Freedom of Information Act, 5 U.S.C. § 552, As Amended By Public Law No. 104-231, 110 Stat. 3048FOIA can be found at http://www.usdoj.gov/oip/foia_updates/Vol_XVII_4/page2.htm

[13] OMB, A-110. C. _ . 36 (d) (1) In addition, in response to a Freedom of Information Act (FOIA) request for research data relating to published research findings produced under an award that were used by the Federal Government in developing an agency action that has the force and effect of law, the Federal awarding agency shall request, and the recipient shall provide, within a reasonable time, the research data so that they can be made available to the public through the procedures established under the FOIA.[11] Federal Acquisition Regulations., FAR 52.215-2, Audit and Records – Negotiation, allows the Contracting Officer or an authorized representative the right to examine and audit supporting records and materials, including research data. FAR 52.227-14, Rights in Data - General, Alt. V, allows the contracting officer or agency to have the right to inspect certain data at a contractor's facility

Most institutions have established procedures for responding to FOIA requests when these requests involve data from funded federal proposals and awards (grants, cooperative agreements and contracts). A copy of a FOIA request will normally be sent to an institutional official and the investigator. Typically, the institutional official will work with the investigator to ensure that any private or protected information is identified to the federal agency so that it can be protected from release. Federal agencies normally consider two exemptions to FOIA requests. Exemption 4 permits withholding of "trade secrets and commercial or financial information."

Exemption 6 permits withholding certain information, the disclosure of which "would consider a clearly unwarranted invasion of personal privacy." Through these exemptions, certain sensitive institutional data may be shielded from FOIA access.

C. DATA AND INFORMATION QUALITY

In February 2002, OMB's Office for Information and Regulatory Affairs (OIRA) issued regulations to ensure the quality of data and information distributed by federal agencies and to allow individuals and entities to challenge the quality of government data under certain circumstances. The "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" are designed for federal agencies to use in implementing agency-level procedures for ensuring the quality of information. These guidelines were supplemented in December 2004 with additional guidance for the peer review of influential scientific information.[14]

Institution Check:

The Federal Funding Accountability and Transparency Act of 2006 (FFATA, as amended) and Federal Awardee Performance and Integrity Information System (FAPIIS, Sec. 872 PL 110-417 as amended) reporting requirements release data concerning the institution and its principals. Institutions will want to establish mechanisms for maintaining accurate information within these systems particularly ensuring required updates to Central Contractors Registration (CCR) which collect this information.

Consider modifications to sub-agreements requiring subrecipients to register in the CCR and to provide access to information needed for FFATA and FAPIIS reporting.

[14] The Guidelines for Ensuring Quality and related Peer Review Guidelines are available on OMB's OIRA web site at: http://www.whitehouse.gov/omb/inforeg/infopoltech.html

In 2009, the President directed agencies to develop plans to ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions. This Memorandum on Scientific Integrity (March 2009) relies on the use of the agencies' Guidelines for Data and Information Quality.

It's important to recognize that the guidelines apply to information that agencies represent as fact or agency opinion and that is an agency-initiated or sponsored distribution of information. While the focus of these regulations is to ensure the quality of federal information and data and does not apply directly to data distributed by research institutions, there may be situations in which an agency wishes to disseminate data generated by a research institution – either funded by the agency, or not. If an agency chooses to distribute the research institution's information "as fact or agency opinion" or use it in developing "influential scientific, financial or statistical information," e.g., as justification or supporting information for a new regulation or recommendation, the research results or publication falls under the guidelines. In such cases, investigators may be asked to provide access to the underlying data used in publications or reports.

Most institutions would respond to these requests in a manner similar to a FOIA request. Investigators can temper the impact of these information quality guidelines and potentially qualify for the general exclusion from the provisions by including the clear, standard disclaimer on all publications and presentations of federally supported research results – "The findings and conclusion in this [report, publication, presentation] are those of the author(s) and do not necessarily represent the views of the [funding agency]."

Institution and Investigator Check:

With increased emphasis on scientific integrity of Federal information, research data used in the formulation of policies and regulations will receive greater attention. All publications resulting from research supported by Federal agencies should include a disclaimer noting the publication does not represent the views of the agency. This disclaimer provides a buffer for the investigator and the agency.

III. GRANTEE OBLIGATIONS FOR DATA SHARING

Under some federal agency and foundation guidelines for grant funding, institutions and investigators have very clear and definitive responsibilities for the sharing of research data. These responsibilities echo the overall mission of a research institution, namely to disseminate research findings to benefit the public at large. Some examples from Federal sponsors are provided below. This list is not exhaustive but provided to demonstrate that institutions and investigators will want to review the requirements included in any agreement governing the sharing of data, materials, etc., and access to research results.

A. NATIONAL INSTITUTES OF HEALTH

NIH has a number of policies that govern sharing of data, model organisms, and the dissemination of research results. According to the NIH Data Sharing Policy and Implementation Guidance,[15] NIH believes that data "should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data." To facilitate this view, since October 1, 2003, NIH has required a data-sharing plan (or an explanation of why data sharing is not possible) be included in NIH applications seeking $500,000 or more per year in direct costs. This plan should describe how the "timely release and sharing"[16]

Investigator Check:

Investigators should review with the institution any data sharing or data management plan incorporated into an application for support from a sponsor, particularly NIH and NSF. Laboratory mechanisms should be established to ensure that obligations for data sharing and management can be met.

Investigators must ensure that data collected under confidentiality provisions of human subjects protections, HIPAA, CIPSEA (with regard to statistical information) and any other confidentiality provisions are respected and complied with in any data sharing or data management plan.

Investigator Check:

Data and materials used to support applications for patents, FDA-regulated products or that carry other limited restrictions should be protected under any data and/or materials sharing plan.

[15] http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

[16] This is defined as "no later than the acceptance for publication of the main findings from the final dataset. However, the actual time will be influenced by the nature of the data collected." http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#time2

of "final research data[17] from NIH-supported studies for use by other researchers will be achieved. Given the wide variability in the nature of science that NIH supports, minimum standards for compliance with the data-sharing policy have not been articulated and have instead been left to the particular scientific disciplines to define.

NIH supports the sharing of unique research resources or research tools under reasonable terms and conditions for dissemination and acquiring the tools. The agency believes that "the sharing of synthetic compounds, cell lines, DNA sequences, etc., enhances the value of the NIH-sponsored research." This 1999 policy embodied in NIH's *Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources* complements the data sharing requirements described above.[18]

Similarly, NIH issued a policy statement in May 2004 on the sharing of unique model organisms to ensure that the research resources developed with NIH funding are made readily available in a timely fashion to the research community. Investigators are expected to include in the application/proposal a description of a specific plan for sharing and distributing unique model organism research resources. Unlike the NIH Data Sharing Policy, the submission of this plan is not subject to a cost threshold of $500,000 or more per year in direct costs.[19]

Finally, as of January 25, 2008, researchers receiving NIH funding to conduct genome-wide association studies (GWAS) are expected to submit descriptive information

[17] This is defined as "Recorded factual material commonly accepted in the scientific community as necessary to document and support research findings." http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#fin

[18] The *Principles and Guidelines appeared in a Federal Register Notice* published on Thursday, December 23, 1999 (64FR72090)

[19] The Model Organism policy appeared in the May 7, 2004 NIH Guide as Notice # NOT-OD-04-042

about the study to a publicly accessible NIH GWAS centralized repository. Additionally, researchers are encouraged to submit curated and coded phenotype, exposure, genotype, and pedigree data to the repository that will be made available, following de-identification and coding, for research purposes, via request to an NIH Data Access Committee.

B. NATIONAL SCIENCE FOUNDATION

As of January 18, 2011, NSF requires that all proposals include a "Data Management Plan" that details how the proposal will conform to the NSF Data Sharing Policy. This policy, as described in the Award & Administration Guide (Chapter VI.D.4), notes that "Investigators are expected to share with other researchers, at no more than incremental cost and within a reasonable time, the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF grants. Grantees are expected to encourage and facilitate such sharing." Criteria for compliance with the Data Management Plan mandate may be determined by specific guidance by Directorates, Offices, Divisions, Programs, or other NSF units, but in general is established in the Grant Proposal Guide (Chapter II.C.2.j). The Guide suggests that a compliant Plan may include the following information:

1. Types of data and other materials to be produced in the course of the project;
2. Data and metadata format and content standards;
3. Policies for access and sharing;
4. Policies for re-use, re-distribution, and the production of derivatives; and
5. Plans for archiving and for preservation of access.

IV. WHEN AN INVESTIGATOR LEAVES THE INSTITUTION, WHAT HAPPENS TO THE DATA?

There are a variety of circumstances under which active and productive researchers may leave an institution. Generally, researchers will believe it is appropriate for them to take all of their research records with them. Yet, institutions are obligated to assure access to and the retention of data, and possibly to defend the value of associated intellectual property. If the departure is the result of failing tenure, or of perceived or real disputes with the institution, investigators are unlikely to take a positive view toward institutional claims to data. The challenges associated with departure of principal investigators represent another clear and, perhaps, the most compelling justification for institutions to consider the establishment and communication of policy describing rights and obligations of all parties in the management and retention of research data, materials and other records.

Institution Check:

Institutional policy should describe how research data and materials will be managed when an investigator departs to ensure the institution is able to meet the institutions obligations in support of the institutions obligations (as grantee) under sponsored agreements and intellectual property agreements including patents and data sharing agreements and in support of FDA-regulated products.

Institutional policy should address or describe any grievance procedures that can be used by investigator over ownership and retention questions.

Institutional policy should address its obligations when an investigator retires or ceases to be an active investigator. Policy needs to address the disposition of lifetime collections, unrelated to a sponsored agreement or other continuing obligations.

V. OTHER OBLIGATIONS AND RESTRICTIONS ON DATA RETENTION, ACCESS, AND REPORTING

Beyond the 3-year data access and retention requirements found in OMB Circular A-110/2CFR 215 Section 53 and required by good research practice, federal regulations place additional obligations on institutions to protect and limit access to research data and information in certain specific fields. Such restricted areas include the use of sensitive and classified information, select agents and toxins, export-controlled technologies and information governed by state statutes. In addition, information and data developed under sponsored research or collaborative agreements with commercial partners, or used to support patent applications covering resulting technologies, may require access limitations and longer intervals of safeguarding. In addition, clinical or preclinical research may have additional restrictions e.g., Good Laboratory and Good Clinical Practices and privacy regulations. Finally, some agencies have study registration and public reporting requirements.

Before conducting research in the above-noted areas, institutions should establish standards to protect the integrity, confidentiality, and availability of research data. At a minimum, policies and procedures should be developed to limit physical or electronic access to data, protect research information from accidental or intentional release to unauthorized persons, and prevent the alteration, destruction or loss of research data. Such policies and procedures must also comply with local requirements, such as state open record and medical record confidentiality laws. The following regulations and/or areas of research provide special data access, retention and reporting provisions.

A. HIPAA – HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

For institutions engaged in clinical research, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects the confidentiality of health information of research subjects, including a requirement that an express authorization, or waiver of such authorization, be obtained prior to the use of a subject's individually-identifiable health information for research purposes (Privacy Rule). Researchers should be aware of the Privacy Rule because it establishes the conditions under which covered entities like hospitals and health care facilities can use or disclose private health information (PHI) for many purposes, including for research. Although not all researchers will have to comply with the Privacy Rule, the manner in which the Rule protects PHI could affect certain aspects of research. HIPAA also provides specific security requirements for health data access and storage, as well as information retention regulations.[20] In general, covered entities that release PHI for research to non-covered entities should restrict the non-covered entity's use of PHI to that authorized by the research subjects in contracts or business associate agreements. Additionally, the covered entities must maintain a record of that release for six years to provide for participant access to his or her PHI use records.

The Health Information Technology for Economic and Clinical Health Act of 2009 [21] establishes privacy requirements for electronic health records (EHR) used by health care clinicians and staff. The Act directs the HHS Secretary to promulgate new regulations to

Institution Check:

Institutional agreements with Business Associates (under HIPAA) and consulting agreements should incorporate PHI use restrictions applicable to the covered entity.

Proposed changes to HIPAA under the provisions of Health Information Technology for Economic and Clinical Health Act of 2009 will affect how data is collected and stored. Institutions should consider how the changes affect them as covered entities and the role of their IRBs and Privacy Boards.

Investigator Check:

Pre-clinical studies must by conducted under the FDA GLP Guidelines in order for the data to be used to support clinical trials.

[20] The HHS Office of Civil Rights with NIH provides guidance on HIPAA and research. See http://privacyruleandresearch.nih.gov/default.asp.

[21] HITECH is Title XIII of Division A (concerns health information technology) and Title IV of Division B (concerns Medicare and Medicaid provisions) of the American Recovery and Reinvestment Act of 2009 (ARRA, PL 111-5)

govern the disclosure of EHR. As a part of this statutorily required revision of the Privacy Rule, HHS is considering in August 2011 excluding from accounting under HIPAA disclosures made for research purposes. As these changes to the Privacy Rule are finalized, the management of research data falling under HIPAA will change significantly.

B. FDA DATA AND RECORD REGULATIONS

The Food and Drug Administration (FDA) regulations at 21CFR58.1 "prescribes good laboratory practices for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products."

Good clinical practices (GCPs), including human subject protection (HSP) are accepted international requirements for the conduct of research involving human subjects. Many countries have adopted GCP principles as laws and/or regulations. The FDA's regulations for the conduct of clinical trials address both GCP and HSP. Institutions and investigators must be acquainted with the additional data recording and record retention requirements that are contained within the FDA regulations.

FDA regulations at 21 CFR Part 11 apply to electronic records created, maintained and transmitted pursuant to FDA investigational new drug and device applications. Although intended primarily for pharmaceutical and medical device industry sponsors, research institutions are now increasingly subject to the regulations, as a result of pass-through requirements in sponsored research agreements, as well as institutions themselves holding investigational new drug and device applications.

For projects that involve FDA regulated articles, records must be kept based on whether the individual is only the investigator on a project or whether he/she is the sponsor as described above. If only the PI, records must be kept for a period of 2 years following a marketing application approval for the drug; or if a marketing application is not filed or FDA approved, 2 years after the investigation is discontinued and the FDA is notified.

The 2003 FDA document "Computerized Systems Used in Clinical Trials" provides guidance, in part, for compliance with electronic data requirements.

In view of the HIPAA privacy regulations and FDA electronic record requirements, institutions engaged in clinical trials with FDA-regulated drugs or medical devices, which involve the use of individually-identifiable subject healthcare information, should, at a minimum, develop and employ standard operating procedures for the following:

- Data collection and handling;
- The use of medical records and individually-identifiable personal health information by investigators, students, and visitors;
- Computer system integrity;
- Data back-up, recovery and contingency plans; and
- Data retention - for a six-year period.

Institution Check:

Institutions should review all agreements and regulations concerning sensitive information restrictions.

C. SELECT AGENTS AND DUAL USE

Institutions using, possessing, or transferring biological agents or toxins that are deemed a threat to public health under the Public Law 107-188, the Public Health Security and Bioterrorism Preparedness Response Act of 2002, must comply with the regulatory requirements for the use and transfer of select agents, including the security policy requirements. The institution must have registered with the federal government and those individuals who have access to the regulated agents and toxins must

pass a Federal "security risk assessment" before using the agents/toxins. Some investigators may not be given access to the regulated agents and toxins. The research institution must have a plan describing and implementing inventory controls; the training for individuals with access to the select agents; an emergency response plan; and physical and cyber security mechanisms. In addition, the institution must establish a robust record system that monitors the types and quantities of select agents on the site and who has accessed the agents. The records must be maintained for three years. [22]

The National Science Advisory Board for Biosecurity (NSABB) review of "dual-use research" has extended to consider oversight of research involving select agents and toxins as well as synthetic biology. Dual-use research is defined as biological research with legitimate scientific purpose that may be misused to pose a biologic threat to public health and/or national security. In a May 2009 report on Enhancing Personnel Reliability for Individuals with Access to Select Agents, the NSABB acknowledged the heightened concerns surrounding the potential misuse of dangerous pathogens but recognized the challenge of dealing with the risk of the "insider threat" to high-containment biological facilities without undermining life sciences research. The work of the NSABB will continue to serve as a foundation for discussion and deserves the research community's attention. As a part of this review, the NSABB recommended a review of the select agent and toxins list to consider removing some agents from the list and to tier or rank the list by risk.

Investigator and Institution Check:

The use of select agents and toxins should be monitored carefully to ensure that anyone with access to the agents and toxins has been checked by the Federal government.

Institution Check:

Institutions should consider the manner in which the dual use and select agent research is conducted. Some institutions have initiated requirements that ensure two investigators are present whenever this research is conducted. Other reliability measures can be considered

[22] The regulations governing the use of select agents are managed by the Centers for Disease Control (CDC) of the Department of Health and Human Services and the Animal and Plant Health Inspection Service (APHIS) of the US Department of Agriculture. The CDC's Select Agent Program information and regulations can be found at: http://www.cdc.gov/od/sap/ Information and regulations managed by APHIS is available at: http://www.aphis.usda.gov/programs/ag_selectagent/.

The need for a tiered approach is echoed in the report issued by the Federal Experts Security Advisory Panel in November 2010 (as revised and issued, June 2011). Convened by the President under Executive Order 13546, the Panel makes specific recommendations on agents/toxins that pose the highest risk and those that should be removed from the list of select agents and toxins. The Panel recommends that personnel reliability be linked to the risk level of an agent and addresses controls in the facilities and operations as well.

The regulations governing the use and management of select agents and toxins will remain a dynamic process and investigators and institutions engaged in research using select agents and toxins must be alert to any and all changes in regulations and policy.

D. EXPORT-CONTROLLED TECHNOLOGIES

Federal laws restricting exports of goods and technology have been in existence in one form or another since the 1940s.[23] The export control laws and regulations have several purposes: to restrict exports of goods and

[23] Currently regulations governing exports of information and technology are implemented by the U.S. Department of Commerce through its Export Administration Regulations (EAR—trade protection), the U.S. Department of State through its International Traffic in Arms Regulations (ITAR—national security), and the U.S. Department of Treasury through its Office of Foreign Assets Control (OFAC—trade embargoes). Commerce's Bureau of Industry and Security (BIS) provides information on the EAR at: http://www.bis.doc.gov/ ; the OFAC site provides information on embargos, http://www.treas.gov/offices/enforcement/ofac/ and, information on the ITAR is accessible on State Department's site at: http://www.pmdtc.org/itar_index.htm COGR has prepared a brochure, *Export Controls and Universities: Information and Case Studies* (February 2004), providing greater detail and description of the regulations and offering advice on how to manage the regulations with regard to research. The brochure is available on COGR's web site at: http://www.cogr.edu/Pubs_ExportControls.cfm

technology that could contribute to the military potential of other countries; to prevent proliferation of weapons of mass destruction; to advance U.S. foreign policy goals; and to protect the U.S. economy and promote trade goals. Investigators and administrators need to be aware that these laws may apply to research, whether sponsored or not. While it is important to understand the extent to which the regulations do not affect normal institutional activities, investigators are urged to review their activities with the appropriate institutional officer to determine whether their work falls within the exemptions and exclusions normally afforded academic research or will require an export license. The regulations are complex; the lists of controlled technologies and information are long; and compliance can be difficult. The discussion below offers only a brief and very general outline of the regulations – investigators must seek expert institutional advice.

The Export Administration Regulations (EAR) and International Traffic in Arms Regulations (ITAR) apply to the transfer of certain restricted physical items, the provision of related defense services and the disclosure of controlled technical information to persons and entities ***outside*** the United States ("exports"). The controls apply also to the disclosure of controlled information and the provision of defense services to foreign nationals ***inside*** the United States ("deemed exports"). In some instances, these regulations will require that the institution obtain a special license before an export or deemed export occurs.

Both the EAR and ITAR exclude from controls – including the licensing requirements – disclosures to foreign nationals inside the United States in classes or associated teaching laboratories. Additional exclusions are also provided for "publicly available" or "public domain" information disclosed at conferences or presented in journal publications. The "fundamental research" exclusion from export controls applies to basic and applied

research in science and engineering where the information that results from the research is "ordinarily published and shared broadly in the scientific community." The research must be carried out openly and without restrictions on publication or access to or dissemination of the research results.

The fundamental research exclusion applies only to disclosure to foreigners in the U.S. of otherwise controlled information or technical data. The publicly available/public domain exclusion applies in the US and abroad, provided that certain methods of publication that are recognized by the ITAR must occur in the US. None of these exclusions apply to actual shipment outside US borders of things (physical items including, for example, specified scientific equipment), defense services (e.g., training foreign nationals inside or outside the United States) or non-public dissemination of information to restricted foreign nationals, e.g., emails, meetings, etc. Even where the work falls clearly within the fundamental research exclusion, export controls may still arise from interactions with third parties, such as vendors or manufacturers that provide export-controlled information or items to a research institution for use to carry out the research.

To the extent that the disclosure of information falls within the "safe harbor" of the fundamental research, publicly available/public domain, or that another regulatory exclusion or licensing exemption applies, researchers need not be concerned about export control issues. But, in all cases, a researcher should consult with an institutional expert to help make that determination.

In order to ensure that the institution's work stays within the "safe harbor" of fundamental research or publicly available/public domain exclusions, investigators and research administrators will want to review any agreements, including subcontracts, carefully. The review should focus on restrictions on the ability to publish and

restrictions on the personnel that may be used on the project or those who may have access to the research.

E. CLASSIFIED RESEARCH

The sharing of research data developed under a classified, e.g., secret or top secret, agreement is strictly limited. Institutions that engage in classified research must have a Facility Security Clearance (FCL), an administrative determination that a facility is eligible to access classified information and perform classified research. To receive a FCL, the institution must design and implement systems that satisfy the requirements for the absolute control of access to and retention of classified research data. All equipment used in the research process, and all communications must be secured. All visitors to a secured site must have a security clearance appropriate to the security level of the facility. To have access to classified data, each investigator must receive an individual security clearance.

Relatively few research institutions are cleared to conduct classified research. However, an investigator from another institution, with appropriate clearance, may conduct research at a secure facility. If the research involves classified information, the work itself and its results will be classified and access to and use of the information will be limited and may be in conflict with institutional policies. Investigators should contact their research administration office to determine if the facility is cleared before considering the development of a potentially classified research program.

F. PATENT APPLICATIONS

Although the U.S. Patent and Trademark Office rules found in Chapter 37 of the Code of Federal Regulations do not prescribe a specific period for retention, best practice requires that research data used to support a patent application should be archived for the entire 20

Institution and Investigator: Check:

The conduct of classified research should be carefully considered because of the implications such research has on academic freedom. Additionally, data and material management will require a significant investment in time and resources.

Institution and Investigator: Check:

Investigators should be aware of the institution's policies for disclosure of intellectual property, in general, and as related to sponsored agreements. Protection of intellectual property rights may limit the sharing of data through publications, data sharing agreements or plans, and other restrictions on sharing research materials.

year patent term plus any extensions. Retention of data and other research documentation is critically important to support the date of invention and claims within the application, as well as to defend the patent. In view of this expansive time interval, a growing number of institutions now require archiving of original research data and materials used to support patents and patent applications, including original laboratory notebooks, with their offices for technology licensing, with copies of the data provided to the inventor(s).

G. STATE PUBLIC RECORDS STATUTES

All states place a primary obligation upon their public offices and agencies, including public academic institutions, to provide citizens with reasonable access to agency records. In most states, this access requirement is provided for by a public records act or "sunshine law" which also may specify what types of information may be exempt or protected from public disclosure. As an example, the State of Ohio exempts medical records, intellectual property records, and any records whose release is prohibited by state or federal law from the State's public record act.[24] Like Ohio, many states provide an exemption from public disclosure for these confidential or sensitive records. In addition, most states have specific statutory requirements for the reporting of certain public health issues or information, such as contagious diseases.

State-supported institutions should have a clear understanding of how their public records acts are interpreted and enforced by their state attorney generals' offices

[24] See, for example, State of Ohio Revised Code Revised Code (ORC),Section 149.43: http://ohio.gov/government.stm (A) (1) "Public record" means records kept by any public office, including, but not limited to, state, county, city, village, township, and school district units, and records pertaining to the delivery of educational services by an alternative school in Ohio..." Public record" does not mean any of the following: (a) Medical records; ... (m) Intellectual property records; ... (v) Records the release of which is prohibited by state or federal law.

and courts. Data access and retention policies should be developed with the view that many, if not most, "standard" transactions, such as sponsored research agreements, may need to be disclosed pursuant to a public records request. Access and retention policies for human subject and animal care and use data, as well as data and security plans for select agent research are especially challenging. Institutions engaged in collaborative research programs with state-supported schools must also be aware of such obligations.

H. INDUSTRY SPONSORED RESEARCH

Collaboration with industry enhances a research institution's understanding of the challenges facing industry by exposing investigators to industrial concerns and industrial approaches to research. Conversely, collaboration with research institutions helps industrial scientists to stay current in the latest developments in broad areas of basic science of strategic interest to the company.

Two very different cultures interact in the collaboration between research institutions and industry. Research institutions' culture is shaped by the core missions of education, research and service based on the free exchange of ideas and providing the public with access to an impartial source of information. In contrast, the focus of industry is on meeting customer needs in a way that maximizes profit to stockholders. Thus, industry research and development agendas tend to be driven by profit objectives and protection of competitive positions through limiting disclosures of information and publication of research results.

Research agreements with industry sponsors require careful negotiations to avoid placing unreasonable or unpredictable restrictions on the access to and dissemination of research results. Universities prefer open research efforts with unrestricted publication of research results. In contrast, industry sponsors often desire

limited or no publication of research results to protect the company's proprietary position.

A commonly negotiated compromise regarding publication provides the industry sponsor the opportunity to review and comment on a proposed article in advance of publication. This permits the sponsor to identify proprietary information the article will disclose, and/or to delay publication for a specified period, e.g., 60 days, in order to file patent applications before publication to avoid loss of U.S. or foreign patent rights. It is essential for preserving the fundamental research and publicly available/public domain exclusion from export controls that the right to comment is only that, and it is not a right to approve the research results before they are published. It is also critical to the preservation of the fundamental research exclusion and concerns over "private business use" that this comment period be limited.

Institutions that accept some form of a confidentiality provision in their research agreements should ensure that investigators understand the restrictions and limitations that these impose. Violations of such provisions may accrue potential liability to the institution and to individual investigators for breach of contract, or possibly to individual investigators under insider trading laws.

Compromise positions regarding intellectual property have been reached to satisfy the requirements of both parties. In general, universities retain title in intellectual property resulting from industry-sponsored research, with certain rights in it granted by license to the industry sponsor. The scope of the license may range from a nonexclusive, royalty-free right to use results for internal purposes to an exclusive royalty-bearing license for commercial applications.

No one "solution" fits all circumstances, so terms are negotiated on a case-by-case basis. Institutional ownership of the research data under industry agreements should

Institution and Investigator Check:

Investigators must understand any restrictions or limitations on the publication of research results under an industry sponsored agreement. Pre-publication reviews for proprietary information may impact the publication. The ability of students to complete their degree requirements and dissertations should be protected. This may require delay of progress reports to commercial sponsors.

Institution Check:

Institutions should consider a variety of options in industry agreements to ensure the ability to publish results of the research. Options include short delays for review by sponsor to identify proprietary information; unrestricted publication of methods rather than results; etc.

parallel the institutional publication and intellectual property rights.

Recently, pharmaceutical sponsors have been attempting to greatly limit the release of data produced in clinical trials. Many agreements mandate that raw data NOT be shared openly. Investigators may be allowed to publish overall study results without approval by the sponsor, but this is rare. Generally, sponsors strive to control the release of the data. This approach has raised serious concerns about the dissemination of information on unsuccessful trials or trials with negative results.

Institution Check:

Institutions should review all agreements and regulations concerning sensitive information restrictions.

I. OTHER FEDERAL DATA REQUIREMENTS

Sensitive Data: While encouragement of data sharing and dissemination of results by the federal government and other sponsors is the norm, there has been an increased trend to limit the sharing of data produced under federal funding in those areas that are deemed "sensitive." Controlling such sensitive data requires special accommodations.

Projects requiring a small amount of data storage should consider the use of external hard drives in order to keep the data off of computer networks. The external hard drives should incorporate encryption at least 256mb or higher and should be locked when not in use.

Institutions may want to consider higher capacity alternatives to support larger data storage needs. Designating a specific server as a controlled server would be a possible alternative. There are several considerations for setting up such a server such as:

- Hardware and software support for the server must be provided by U.S. citizens only
- The existence of the server should not be visible to anyone on the network

- Physical and remote access to the server is controlled and monitored at all times
- Externally contracted support includes the appropriate restrictions and is monitored at all times.

If sensitive data needs to be shared, the originator should use appropriate encryption software with the same configuration as the receiver.

When sensitive data is to be removed, a simple "delete" action is not adequate. The hard drive must be destroyed or the data should be electronically shred.

As with any other matter related to sensitive information, training the individuals responsible for maintaining the electronic storage medium is critical for their understanding and ability to handle the data consistent with all requirements.

Lastly, as a consideration for public universities, each should check their respective State laws for public access requirements prior to any electronic retention of sensitive or classified records. State law may not have contemplated electronic storage of these types of restricted data and may subject the data to open records laws.

The **Confidential Information Protection and Statistical Efficiency Act,** (CIPSEA)[25] establishes uniform confidentiality protections for information collected for statistical purposes by US statistical agencies, Bureau of Labor Statistics, Bureau of Economic Analysis and the US Census Bureau. This statute prohibits disclosure or release, for non-statistical purposes, of information collected under an agency pledge of confidentiality. Investigators who want to access CIPSEA-protected information will be asked to ensure the data maintains the

[25] CIPSEA, Title V of the E-Government Act of 2002 (Pub.L. 107-347, 116 Stat. 2899, 44 U.S.C. § 101)

same protections afforded it by the federal agency and to allow for agency review of any research publication, presentation, etc., to ensure that confidential information is not being disclosed.

The **Federal Information Security Management Act of 2002** (FISMA)[26] requires each federal agency to develop, document, and implement an agency-wide program to provide information security for the information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor, or other source including institutional investigators and staff.

The National Institute of Standards and Technology (NIST) has been charged with developing security standards for the federal agencies and its Special Publication 800-53, Revision 3 (August 2009) set the catalog of management, operational, and technical security controls for both national security systems and non-national security systems.

Because FISMA applies to both information and the information systems used by the agency, contractors, and other organizations that possess or use federal information or which operate, use, or have access to federal information systems (whether automated or manual on behalf of a federal agency, FISMA has broader applicability than prior security law. For the purposes of FISMA, federal laboratories and research facilities are agency components and their security requirements are identical to those of the managing federal agency in all respects. Security requirements will be included in the terms of the contract or other similar agreement. If an

[26] FISMA, 44 U.S.C. § 3541, et al. OMB Guidance to Agencies, M-10-15, April 21, 2010, FY 2010 *Reporting Instructions for the Federal Information Security Management Act and Agency Privacy Management.* This Guidance includes a FAQ section that describes, for agencies, how to incorporate and monitor contractor and grantee compliance with FISMA.

investigator is accessing, contributing to or managing for an agency a federal data system, the institution's electronic systems will be expected to maintain these FISMA standards for security.

J. PUBLIC STUDY REPORTING

Public Access: Federal agencies also expect that investigators will promptly prepare and submit for publication significant findings from work conducted under agency grants. For instance, as of April 7, 2008, all peer-reviewed articles that arise, in whole or in part, from direct costs funded by NIH, or from NIH staff, that are accepted for publication, must be submitted to the National Library of Medicine's PubMed Central, to be made publicly available no later than 12 months after the official date of publication.[27] This policy revised a similar February 2005 NIH policy which made such submissions voluntary.

ClinicalTrials.gov: The Food and Drug Administration Amendments Act of 2007 (FDAAA) Title VIII, expands the National Library of Medicine (NLM) clinical trials registry and results database known as ClinicalTrials.gov. It imposes new requirements that apply to certain trials supported by the National Institutes of Health (NIH). Trials subject to FDAAA are called "applicable clinical trials" (ACT). Any ACT supported in whole or in part by an NIH grant (including cooperative agreements) must be in full compliance with FDAAA. The trial's "responsible party" is responsible for two basic elements of compliance: the registration of the ACTs in ClinicalTrials.gov, and the reporting of summary results information (including adverse events). NIH requires all NIH grantees, regardless of whether or not they are the "responsible party" under FDAAA to certify in the grant application and progress report that the responsible party has made

Investigator Check:

Obligations to meet the publication or public access requirements of NIH and other agencies fall on the investigator and extend to co-investigators as well. Most institutions have created resources to assist investigators in meeting these obligations and agreeing to journal copyright policies.

[27] http://publicaccess.nih.gov/policy.htm

all required submissions to ClinicalTrials.gov for ACTs funded in whole or in part by the NIH.

The **National Science Foundation (NSF) has added a Public Outcomes Report** to its requirements for reporting on grants supported by the agency. Designed to meet the statutory requirement in the America COMPETES Act,[28] investigators are required to post, within 90 days following the end of the grant, the project outcomes report designed for the general public to the website Research.gov. This report is to be a brief, generally two to three paragraphs, summary of the nature and outcomes or findings of the project that address the intellectual merit and broader impacts of the work.

[28] America COMPETES Act of 2007 (PL 110-69); NSF PAPP AAG II.E.3

VI. WHEN RELATIONSHIPS (COLLABORATIONS AND MENTORING) FAIL: DISPUTES OVER DATA

While there is a regulatory and legal framework surrounding the ownership, access and retention of research data, disputes over research data still occur. These may occur when research collaborations between investigators are severed or strained, when post-doctoral fellows or graduate students have differing expectations from their mentor over attribution of results, or when investigators practice poor human resource management.

In some cases, disputes can be settled by acknowledgement and reference to federal or sponsor regulations or by institutional policies that provide a framework for dispute resolution. But more often than not, there may not be an avenue for definitive and clear resolution and disputes need to be handled and resolved on a case by case basis. Institutional policies should provide a clear process for resolving such cases.

NSF Public Outcomes:

Institutions will want to remind investigator(s) of this additional responsibility and consider alerting investigator(s) to the need to protect some types of information from public disclosure until appropriate, e.g., inventions, or to hold information as confidential, as in the case of individually identifiable human subjects' information.

VII. RESPONDING TO ALLEGATIONS OF RESEARCH MISCONDUCT

Federal agencies have been directed to develop policies based on the Federal Policy for Research Misconduct developed by the Office of Science and Technology Policy in December 2000. Most of the federal agencies supporting research have agency policies developed under the Federal Policy.

Generally, these policies require grantees to establish policies and procedures to ensure the integrity of research. A central element of these requirements is the establishment by the grantee of formal procedures under which the grantee will evaluate and investigate allegations of research misconduct and, under certain circumstances, report the results of these reviews to the sponsoring agency.

Central to the review and evaluation of all allegations of research misconduct due to falsification or fabrication of data is the objective, critical analysis of the original records of data from the research project. The ability of a grantee institution to accomplish this analysis depends on the maintenance and availability of high quality, accurate data by all investigators. This data will be reviewed and, likely, sequestered during the course of a research misconduct inquiry and investigation.

One of the most compelling justifications for institutions to formulate standards for data recording and retention by its investigators is the obligation to ensure the integrity of the institution's research enterprise. The unavailability of clear, accurate and detailed records of research data for at least the required three-year period after the end of a project period could serve as grounds for a finding of research misconduct and the imposition of sanctions from a federal agency sponsor.

Institution Check:

One of the most critical components of responding to an allegation of research misconduct is the sequestration of data. The institution should have clear mechanisms for sequestering data in a manner that allows appropriate research activities to proceed while the allegation is addressed.

Investigator Check:

The ability to produce research data and materials to support the conclusions presented in a publication, etc., is the key to providing a defense against an allegation of research misconduct. Investigators must ensure that the recording of research material and presentation of research data is accurate and complete. Investigators should review laboratory procedures with everyone participating in a project to ensure the consistent recording and retention of data and materials.

Each agency's policies may be different and institutions and investigators want to review the policies. The Public Health Service /Office of Research Integrity (ORI) policy assumes, under a burden of proof concept, that the absence of research data reflects misconduct (the respondent's affirmative defense is gone). In general, the standard of proof in cases of research misconduct involving federal funds is the preponderance of the evidence. For PHS/ORI allegations, the institution or the Office of Research Integrity (ORI) bears the burden of proof for making a finding of research misconduct. The destruction, absence of, or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct when the institution or ORI establishes by a preponderance of the evidence that: the respondent intentionally, knowingly, or recklessly had research records and destroyed them; had the opportunity to maintain the records but did not do so; or maintained the records and failed to produce them in a timely manner. The institution or ORI must find that the respondent's conduct constitutes a significant departure from accepted practices of the relevant research community. To date the ORI has not made research misconduct findings based solely on the absence of evidence. If ORI were to do so, the absence of research records would serve as evidence of misconduct and the tier of fact would determine the weight of that evidence. (Also see the regulation's preamble at 70 Fed. Reg. 28370, 28371 (May 17, 2005)).

APPENDIX A

DEFINITION OF RESEARCH DATA AND RESEARCH MATERIALS

POLICY CONSIDERATIONS

As COGR approached the revisions of its *Access to, Sharing and Retention of Research Data: Rights and Responsibilities (*2011), we observed that the meaning of "data" as used in Federal regulations and policies has become increasingly ambiguous. There does not exist a common definition among Federal agencies, and the definitions used by agencies do not always reflect the meaning applied within the research community, which itself does not have a uniform definition. The intention of the material in *Access to, Sharing and Retention of Research Data: Rights and Responsibilities* (2011) is to outline for use by the research community various Federal regulations and policies, as written. Nonetheless, we believe it is useful to begin a discussion of the meaning of "research data" as a part of this effort. Engaging in a similar discussion of the meaning of research data on individual campuses will provide some clarity on what documents and materials institutional policies and procedures address, and how to assist the community in managing those documents and materials to achieve compliance with Federal regulations and policies.

DEFINITION AND OWNERSHIP OF "RESEARCH DATA"

Both the rights and responsibilities surrounding ownership, access to and retention of data, as well as the definition of research data, vary based upon sponsorship of the project, nature of the funding instrument implementing the award, and general context of the situation. Frequently, the term "research data" is confused with what are, by definition, research materials. Thus, the very definition of research data poses problems in attempting to delineate, in the context of ownership/access/retention, the overall responsibilities of the research institution and its researchers. For the purposes of a specific research agreement, the investigator and institution should review the agency's particular definition and expectations. If the institution is developing its own general policy, the use of a broader definition will offer a more comprehensive and useful tool. The distinction between research data and research materials will affect how institutions resolve questions of access, retention and ownership.

Generally, research data consists of information that provides a quantitative and/or qualitative description or characterization. Consistent with this definition, the Office of Management and Budget's (OMB) Circular A-110, *Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other*

Non-Profit Organizations, defines research data "as the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues."

The OMB definition refers to "recorded factual material." How the information is recorded has no bearing on whether it is research data for the purposes of management or not. The National Institutes of Health makes this point clear in its definition of "data" as "recorded information, regardless of the form or medium on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data."

Research materials are those materials from which data can be extracted. Materials are tangible or physical objects, e.g., writings like a database, cells, molecules, designs, plans, forms, flow charts, planets, plants, and/or animals. Thus, in making the distinction between research *data* and research *materials*, it's important to distinguish between the entities containing the data and the data *themselves*. For example, a lab notebook, a recording, or an insect are not data but contain data or represent entities about which data (description or characterization) can be created.

All Federal agency policies and regulations do not employ a similar distinction between **data** and **materials**. As a consequence, institutions will need to review the policies for each agreement or agency to ensure compliance. For example, the NIH definition of research data includes materials such as data files, which are recorded but in most cases will not provide a quantitative or qualitative description or characterization in and of itself. The Federal Acquisition Regulations (FARs) that provide general terms and conditions for Federal contracts includes computer software and software documentation in its definition of "data;" the Defense contract regulations (DFARS) reference "technical data" which includes computer software documentation but not the software programs or source codes. The Environmental Protection Agency (EPA) goes further by carving out "raw data" to include "laboratory worksheets, memoranda, notes or exact copies thereof, that are the result(s) of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study" (40 CFR Part 742)

Thus, it is important for institutions and investigators to be knowledgeable about the definition of the term "research data" in the context of specific federal regulations, and to provide a clear definition of the term when referring to research data in institutional policy.

The OMB definition of research data applies across Federal agencies and, thus, may provide the most useful general framework for discussing the access to and retention of research data. In this definition, preliminary or "raw" data or research materials without analysis are not included for the purposes of access by the general public.

However, institutions need to decide how to address ownership, access and retention associated with research materials. These materials are necessary for other critical purposes such as validating research findings, supporting patent applications, use as evidence in investigations of research misconduct, or if the research data are used by a Federal agency for public policy or regulatory purposes. There are Federal agency policies and regulations that address the sharing of research resources and materials.

CASE SENARIOS

DATA RETENTION SCENARIO 1

Dr. Patricia H. Dee's electronic data archive is supported by the Department of Chemistry at Sunshine Institute. Preliminary data is stored on a computer in Dr. P. H. Dee's office, as well as in lab notebooks. Sunshine Institute suffers a power outage and because the department did not routinely back up the archive, some of her preliminary data is lost. Dr. Dee routinely backed up data on her personal computer, and no preliminary data that was stored on this machine was lost.

ISSUES & MANAGEMENT - DATA RETENTION SCENARIO 1

The institutional delegation of responsibility to store data has become increasingly complex in an electronic environment. Some institutions have developed digital data retention policies on an institutional level, although these policies may be limited to select types of data, and may ignore research data. Other institutions have not yet tackled any institutional standards on digital/electronic retention, yet individual departments may promulgate guidance and expectations for digital storage, and for the responsibilities associated with shared computer drives. Yet other institutions have implemented digital libraries, specifically intended for housing research data, but may not have outlined expectations for retention periods. Whether at a global institutional level, or an individual departmental/unit level, outlining the expectations and responsibilities of data storage and retention is important. And whether or not these expectations have been formalized into "policy", the absolute critical need to work with information technology (IT) staff in outlining electronic requirements and capabilities is evident.

In this particular case, it does not appear that Dr. Dee's research will be adversely affected by the power outage, as Dr. Dee's preliminary data was also stored on a personal drive unaffected by the incident. However, if research data had been lost, and if this loss would have resulted in negative consequences to the ongoing research, the institution may have been required to report this incident to Dr. Dee's research sponsors.

The question of institutional responsibility to safeguard research data is interesting and not clear cut. Federal agencies have not, in cases of natural disaster or unanticipated and serious technical failures, penalized grantee institutions for inadequate safeguards. However, federal agencies expect, as often stated in the "environment and resources" sections of approved grant proposals that the institution has the

ability to conduct the science and ensure that the research outcomes are protected to a reasonable degree. Thus, it is in the grantee institution's best interests to ensure that the standards imposed in its electronic storage requirements reflect the effective practices of other research institutions.

DATA RETENTION SCENARIO 2

Professor Phillipe Callay is a world renowned paleontologist who has been funded by the National Science Foundation (NSF) and other federal agencies for decades. His research has resulted in thousands of valuable research samples recording various measurements of the earth's age and evolution. Due to university budgetary constraints and loss of funded faculty, the Department of Earth and Environmental Science is going through a downsizing that has resulted in loss of departmental space. Dr. Callay's samples have been stored in department space and these samples now have to be moved to off-site storage. Dr. Callay appeals to the university to pay for these charges as he has no unrestricted money available to pay for storage.

ISSUES & MANAGEMENT - DATA RETENTION SCENARIO 2

Ongoing storage of physical and tangible research samples of active faculty is a concern of all research institutions as space is at a premium (not to mention the storage of research collections that are bequested in good faith to institutions!). Best practices dictate that each research department establish standardized guidance for the storage of tangible (and in this case, permanent) objects. Research data that takes the form of cell lines, cultures, and biological materials invoke other strategies of shared repositories and the shared responsibility of the cost of storage.

As noted under federal policy, the baseline requirement to store data is three (3) years from the termination of the grant as evidenced by the submission of the final financial report. However, in reality, faculty will normally keep research data, in whatever form, in perpetuity. Professor Callay's geological samples may ultimately prove to be a valuable resource for future paleontologists, as well as provide a resource for Callay's ongoing work.

One could argue that the Department of Earth and Environmental Science has housed these samples in research space on-site until this point in time, thus providing the necessary infrastructure for Dr. Callay's research, and indeed may have accrued Facilities and Administration (F&A), or indirect, reimbursement from the calculation of the use of this space if it also housed active research projects. In the absence of a formal institutional policy, and in the absence of a definite statement by the Department that ongoing storage is NOT an institutional responsibility, the likely

conclusion would be that the Department should continue to support Dr. Callay's research and continue to pay for storage regardless of location.

DATA ACCESS SCENARIO 1

Dr. Justgot A. Kay is a promising new researcher who is studying the role of certain proteins in stroke. Dr. Kay recently received a National Institutes of Health (NIH) Research Career Development Award (RCDA) to jumpstart her research career and hopes that this award will lead to the foundation of her future work. However, she has only recently started on the experiments. Dr. Kay has heard from NIH that a researcher at another institution has requested a copy of her entire grant application under the Freedom of Information Act (FOIA). Dr. Kay feels that release of this information could jeopardize her entire research career.

ISSUES & MANAGEMENT - DATA ACCESS SCENARIO 1

This scenario is one that both new and established researchers find threatening. It is commonly accepted that all investigators have a right to privacy or privilege of their new research ideas and direction. Funded research proposals that encompass such new research plans may very well contain sufficient data to enable others to replicate or at least advance in the same directions. Shared knowledge is ultimately good in order to further scientific objectives. But for the untenured or unfunded investigator, the significance of losing the edge on preliminary research ideas, and thus for research support on future publications is enormous. Applicants are permitted to mark specific pages of the proposal that contain proprietary or confidential information. This type of disclaimer will identify for the peer reviewers and agency officials what material should not be disclosed. If an applicant fails to mark the proposal when submitted, protecting the information is still possible.

FOIA regulations, in exemption 4, provide for the withholding of certain information, including potential intellectual property. Therefore, Dr. Kay should consider identifying to the funding sponsor's FOIA office that part of the RCDA proposal that may contain intellectual property that could become the subject of a patent application. She should argue that withholding this information from disclosure is important to future commercialization efforts based on such confidential information, and important as well as to Dr. Kay's career as an independent investigator. Accordingly, the identified information may be exempt from disclosure under FOIA, Sections 552 (b)(3) and (b)(4) of USC Title 5.

Investigators should note that the research administration and technology transfer staff can be very helpful in formulating responses to FOIA requests, and that these offices should be contacted prior to sending a written appeal to the federal agency.

DATA ACCESS SCENARIO 2

Dr. I. M. Knew is also a promising young researcher working with Dr. Sogood, an established nationally-renowned researcher in environmental health who has assisted in the development of public policy. Recently, Dr. Knew has undertaken research of airborne particulates that could lead to certain environmentally-caused lung diseases. The Environmental Protection Agency (EPA) has funded her work under a grant to Dr. Sogood with the intent of assessing whether stricter regulations should be enacted to guard against these diseases. Dr. Knew has learned that Dr. Sogood's funded proposal is being requested under the Freedom of Information Act. Dr. Knew believes that release of this information could jeopardize her entire research career.

ISSUES & MANAGEMENT - DATA ACCESS SCENARIO 2

This scenario is very similar to the proceeding scenario, but with one substantive difference. Those investigators working in areas that are closely aligned with the formulation of public policy or regulation are now subject to the additional requirements of the Shelby Amendment, or A-110, Section _(d)(1), as stated on page 9. Thus, research data retained by the grantee institution, not just provided to the federal government, may be subject to the disclosure requirements of FOIA.

However, it is important to note that the requirements for data disclosure under the Shelby Amendment only apply to "published research findings under an award that were used by the Federal Government in developing an agency action that has the force and effect of law". In this particular scenario, Dr. Sogood's and Dr. Knew's research proposal conceivably does NOT fall under these conditions, as 1) the research findings have not been published and 2) it would be unknown at this early point whether these finding would have contributed to federal policy or regulation. Therefore, Dr. Sogood and Knew could appeal to the EPA's FOIA office to restrict certain portions of the research proposal as noted in the previous example.

DATA SHARING SCENARIO

Dr. Duncan Saco, Professor of Neurology at Fairport Health Sciences Center, has an extremely successful research program. The research is primarily funded by NIH, however some of his support is generated by a Center for Excellence that has been funded by private foundations and corporate sponsors. Dr. Saco indicated in one of the funded applications that he would provide access to final research data via shared files from a computer data archive. Dr. Katie, a colleague and competitor at San Antonio College is conducting parallel research and is preparing a new funding application to NIH. Dr. Katie requests that Dr. Saco give him access to preliminary data

from currently conducted studies in support of his application. Dr. Saco, not wanting to lose his competitive edge, refuses the request. Dr. Katie contacts the Vice President for Research at Fairport Health Sciences Center.

ISSUES & MANAGEMENT - DATA SHARING SCENARIO

Requests for the sharing of research data among research faculty may invoke some of the same issues as the request for copies of funded applications under FOIA. Agencies such as NSF and NIH have made their expectations for the sharing of research results including data well known, however some flexibility is vested to the creator of the data in terms of the timing of the release. Some private foundations have recently moved beyond the federally mandated timelines on sharing, and have prescribed in the grant's terms and conditions, the need to share prepublication or preliminary data with other organizations that are funded by the private foundation.

In this scenario, Dr. Saco's refusal to grant Dr. Katie access to his preliminary data may be reasonable. Under NIH policies, sharing of research data should occur no later that at the time of acceptance for publication of the main findings of the final data set. It appears that the information that Dr. Katie is seeking is for currently conducted studies, and the release of data by Dr. Saco may be premature. Given that this research is also funded by corporate sponsors, there may be other considerations in the terms and conditions of those funding agreements that may restrict early release of research data, at least without the review of the corporate sponsors. It does not appear that either Dr. Saco or Fairport Health Sciences Center is obligated to provide access at this time, although in the interests of scientific collegiality, the Vice President for Research should justify the decision to deny access, and perhaps provide a timeframe for the ability to share the requested information with Dr. Katie.

One thing to keep in mind is that there is no definitive reason not to provide the research data earlier than at the time of final research results. Institutions and investigators may choose to share research data at an earlier point, sometimes accompanied by a non-disclosure agreement to limit the use of such data to a specific purpose. Early release of data is at the discretion of the investigator, but he/she should seek counsel from the institution's technology transfer office in order to protect any potential intellectual property that may result from this data. [29]

[29] The CREATE Act provides a tool for dealing with this issue to enable collaboration between researchers at different institutions. COGR has developed information to assist research institutions in implementing the CREATE Act provisions. http://www.cogr.edu/Pubs_intellectual.cfm

RESTRICTED RETENTION AND ACCESS SCENARIO 1

Dr. Connie F. Dental is a biostatistician in the School of Mathematical Sciences at Enormous State University (ESU) and a co-investigator on a clinical trial of an investigational new drug for treating workplace fatigue sponsored by Speedy Pharmaceutical, Inc. The sponsored programs office readily executes Speedy's standard clinical trial agreement, which, buried among the terms, includes the representation that ESU complies with all applicable FDA regulations, including those at 21 CFR Part 11.

Dr. Dental receives the clinical data of subjects enrolled in the trial from the principal investigator, Professor Fran Nology in the Department of Neurology, and performs the necessary statistical analysis before submitting the data electronically to Speedy. While accessing the lab computer for another project, Professor Dental's graduate research assistant, Justin Once, finds the trial data and research subject individually-identifiable protected health information (PHI). The PHI includes a detailed description of one subject's therapeutic failure and subsequent lapse into an untimely deep sleep while tallying provisional and absentee ballots at her place of employment, the board of elections in a populous swing-state. Justin posts the story on his web log along with some of the subject's PHI, which quickly gains the attention of both red and blue political theorists. Shortly thereafter, the now wide-awake subject contacts the Office for Civil Rights at the U.S. Department of Health & Human Services.

ISSUES & MANAGEMENT - RESTRICTED RETENTION & ACCESS SCENARIO 1

Access

ESU's obligations and responsibilities for protecting the subject's individually-identifiable protected health information (PHI) should be contained in the university's HIPAA research authorization form and the research informed consent document, which were signed by the subject prior to her participation in the research. Institutions often combine these two documents. Whether combined or presented separately, the HIPAA research authorization form should list, with specificity, who has access to the subject's personally-identifiable health information during and after the trial.

The responsibilities and obligations disclosed in the research authorization and consent document(s) should also mirror the access and disclosure obligations contained in the clinical trial agreement between ESU and the sponsor, including if the data will be accessed by 3rd parties, in this case, the sponsor. The clinical trial agreement should also contain any sponsor or institution-specific retention requirements for the PHI and trial data.

The unauthorized release of PHI exposes ESU to significant liabilities. HIPAA includes both civil and criminal penalties for covered entities that misuse personal health information. For civil violations of the standards, the government may impose monetary penalties up to $100 per violation, up to $25,000 per year, for each requirement or prohibition violated. Criminal penalties apply for certain actions such as knowingly obtaining protected health information in violation of the law. The graduate student's actions may result in criminal penalties ranging from $50,000 and one year in prison for certain offenses, up to $250,000 and 10 years in prison if the offenses are committed with the intent to sell, transfer or use protected health information for commercial advantage, personal gain or malicious harm.

If the sponsor is using the PHI and data to support an application for an investigational new drug, then the FDA requires that ESU retain the records for two (2) years after the study is discontinued, or for two (2) years following approval of the sponsor's marketing application for the drug. In addition, NIH and FDA regulations require that the subject informed consent form be retained for at least three (3) years after the completion of the research. The HIPAA Privacy Rule also provides subjects with access rights to their own PHI and requires that institutions holding the PHI maintain the information and a record of all disclosures for six years following the use or disclosure of PHI in a study.

RESTRICTED RETENTION AND ACCESS SCENARIO 2

Still-active Emeritus Professor Lax Adazikal in the Department of Automotive Engineering at Oversize Institute of Technology (OIT) has had a long-standing personal consulting relationship with Ugoe Automotive, Inc., as well as a number of research projects sponsored by the company. Ugoe has filed a number of patent applications on inventions created by Dr. Adazikal as a consultant and has licensed inventions resulting from the sponsored research agreements with OIT. Ugoe and OIT are finalizing a license agreement for the Dr. Adazikil's inventions, including an exciting new technology that is expected to be used by most automobile manufacturers.

Ugoe and OIT receive notice from the U.S. Patent and Trademark Office of a patent interference action filed by Ugoe's main competitor, Valhalla Motor Works. The main issue is priority of invention.[30] Dr. Adazikal is asked to produce the original lab notebooks, along with technical drawings made by his final graduate student, Lone Goen, who graduated and left OIT nearly five (5) years ago. Most unexpectedly, Dr. Adazikal cannot locate the notebooks or most of the original research records in his office and laboratory.

[30] As of March 16, 2013 the first inventor to file a patent application will have priority. See http://www.uspto.gov/aia_implementation/index.jsp

The sponsored research agreements with Ugoe require that OIT keep all information pertaining to the agreement confidential for an indefinite period, but are otherwise silent on the retention of data. Although the OIT Office of Research is in the process of developing a data retention policy, no formal policy exists at this time. To compound matters, the OIT local newspaper, the Tattler Tribune, learns of the patent dispute. The Tattler makes a public records request for the patent applications, Professor Adazikal's lab notebooks, his consulting agreement with Ugoe, the sponsored research agreements and the draft Ugoe license agreements.

ISSUES & MANAGEMENT -
RESTRICTED RETENTION & ACCESS SCENARIO 2

The open-ended confidentiality and non-existent data retention terms agreed-to by OIT are still fairly common in industry-drafted agreements. Institutions should request reasonable time limits, for example, for three to five years. Time limits on confidentiality can be further refined by limiting the scope of the confidentiality obligations to include only information provided by the sponsor and not information generated by the institution. As noted in the discussion, the retention of data used to support institutional patents requires a longer term. Institutions should consider developing a formal process, often managed by their technology licensing offices, which assures that lab notebooks and data used to support patent applications are, at a minimum, archived through the course of the patent prosecution process and, if a patent is awarded, for the term of the patent.

Public record requests for research information, such as the one made by the Tattler Tribune for Professor Adazikal's lab books, the sponsored research agreement and the proposed technology license agreement, depend primarily on the applicable state open record law and any statutory exclusions from disclosure. The State of Nirvana's (home to OIT) open records law provides exclusions from disclosure for "intellectual property records". This provision would likely protect Professor Adazikal's lab books from disclosure. Similarly, an exception in Nirvana's open record law for "trade secrets" may allow OIT to withhold its sponsored research and license agreements, or portions of those agreements, with Ugoe Automotive. OIT may be able to redact sections of the agreements that contain any scientific or technical information or any proprietary business information, such as royalty rates and commercialization milestones.

Investigators and administrative staff are advised to contact their institution's legal counsel for advice on responding to public records requests and interpreting disclosure requirements and exceptions contained in applicable public records laws.

RESTRICTED RETENTION AND ACCESS SCENARIO 3

Dr. Deana Phlagelat is a researcher in the Department of Biological Sciences at Super State University (SSU) and an expert in the encapsulation of biological materials. Dr. Phlagelat was recruited to SSU six years ago along with another investigator, Dr. Ted Puffer, a toxicologist with special expertise in paralytic marine toxins. Since that time, Drs. Phlagelat and Puffer have established a successful and well-funded, multi-disciplinary research group and have jointly invented a number of diagnostic test kits for marine toxins and envenomations.

Drs. Phlagelat and Puffer received a grant last year from the NIH for developing a diagnostic test kit for saxitoxin, a potent shellfish toxin, and have conducted this new line of scientific investigation at SSU's new Biosafety Level 3 laboratory facility. The group has already developed a new method for isolating and producing the attenuated toxin necessary for the diagnostic test that relies primarily on a previous technology developed in their lab. This technology was licensed four years earlier by the SSU Office for Technology Transfer to Eh, Inc., a European drug and diagnostic device manufacturer.

Drs. Phlagelat and Puffer plan to present their new method at the World Conference on Marine Envenomation, meeting outside the US, with their former graduate student and co-inventor of the Eh-licensed technology, Dr. A.L.M. Rasheed. Dr. Rasheed is a junior faculty member at the University of Colombo in a foreign country. During an informal discussion regarding their grant and the upcoming non-US meeting, Drs. Phlagelat and Puffer's program officer at the NIH offers to contact a colleague at the Centers for Disease Control (CDC) to ensure that the presentation should not be a problem. Shortly thereafter, SSU receives requests from the CDC Select Agent Program Office (SAP) as well as the Bureau of Industry and Security (BIS) at the U.S. Department of Commerce. The SAP requests documentation of investigator and employee access to the Saxitoxin. The BIS is interested in Dr. Rasheed's access to the lab and SSU's license agreement with Eh. The agency is particularly interested in visits by foreign scientists from the main company office to SSU five years ago prior to the license, to view and discuss the technology.

ISSUES & MANAGEMENT - RESTRICTED RETENTION & ACCESS SCENARIO 3

Compliance with the latest select agent and export administration regulations and guidance will likely prove particularly challenging, especially for institutions, such as SSU, which are conducting collaborative research with foreign institutions and investigators, or commercializing their technology with foreign partners. Because of the

length of the relationship between the researchers and the long-standing relationship with the foreign-owned company, Eh, Inc., including the prior licensing agreements, it is unclear if the research and its results fall under current select agent and export control regulations. The select agent and export control regulations, in particular, are very complex. It will be important for the investigators to seek expert institutional advice in preparing a response to the requests from the CDC and BIS.

As noted in the discussion, the select agent regulations apply to saxitoxin. At the initiation of the research (post-2002), SSU was required to ensure that only individuals approved for access to saxitoxin under the select agent regulations had access to and worked with the saxitoxin. SSU is required to keep complete documentation of those individuals, including Dr. Rasheed while a graduate student, who accessed the saxitoxin at SSU for a period of three years. SSU should be prepared to make its security plan available for careful review by the CDC Select Agent Program Office, including its inventory and control procedures, as well the SSU access records for the saxitoxin, during this time.

The on-going communication about the toxin – the technology to make the attenuated toxin – may be controlled information, as defined by the US Department of Commerce's Bureau of Industry and Security (BIS) in the Export Administration Regulations (EAR). The applicability of the "deemed export" regulations should be reviewed by an expert to make this determination. If so determined, the communication of this controlled information – this "deemed export" – to Dr. Rasheed or the Eh Inc. scientists in their labs in at SSU may require a license under EAR before the communication occurs. In the absence of an EAR regulatory exclusion, an export of controlled items is "deemed" to take place when it is released to a foreign national – even within the SSU lab in the United States.

However, under the long-standing interpretation of the EAR, the "fundamental research" exclusion might apply to these communications if they are made as a part of the research project on the campus in the US. Any information arising during or resulting from the research at SSU would be covered by the fundamental research exclusion. However, transfer of the toxin itself to a foreign country, even as a part of the research project, is an export to which the exclusion does not apply and for which a license is required.

The BIS might also be interested in Drs. Phlagelat and Puffer's collaboration with Dr. Rasheed at the University of Colombo because the fundamental research exclusion does not apply to the research if it takes place in a foreign country. However, the planned presentation of the technology at the World Conference in a foreign country may be exempt under the EAR regulations for publicly available/public domain if the conference, itself, meets the criteria established for presentations at open meetings.

Before sharing any additional information with Dr. Rasheed, or supplying any materials to the Society for Marine Envenomations in preparation for the Conference, Drs. Phlagelat and Puffer and SSU should consult with institutional experts to determine the applicability of the regulations.

Researchers and institutions are encouraged to review additional information on the export administration regulations in the COGR brochure: Export Controls and Universities.

DISPUTE SCENARIO 1

Dr. A and Dr. B are colleagues at Superior University; both anesthesiologists and research faculty. Dr. B is a junior faculty member; Dr. A is senior tenured faculty member and was the chair of Dr. B's doctoral committee. Years ago, Dr. A had an R01 grant on which Dr. B was heavily involved, e.g., she was "the" clinician who had practical experience in the area; her dissertation dovetailed with this project; she received release time to collect data for grant. Dr. B was interested in pursuing this line of inquiry further once on the faculty, but Dr. A had a writing block. At least three articles have been published in recent years using the R01 data; all of them with Dr. A as first author and Dr. B as second author; all of them as a result of Dr. B taking the lead in doing the writing. Dr. B has gone on to build in this area, and has recently gotten a five-year NIH grant to do further work in this area.

Dr. B's NIH grant makes use of algorithmic formulae that came from the older project, but those formulae have never been published in literature. Once new data are available, it will be difficult to get that data published if formulae are not in literature. Dr. A wrote one draft focusing on this material, but it was not in publishable form. It has been "in revision" for 7-8 years. Dr. B has offered to take the lead in getting this manuscript published, with Dr. A as first author, since she was PI of original project. Dr. A has said NO because she intends to do it. Dr. A is a perfectionist and it is likely that the article will never get written. Dr. B needs a solution.

ISSUES & MANAGEMENT - DISPUTE SCENARIO 1

As noted, there are no easy solutions for most cases that involve disputes over ownership, access and retention of research data. Some institutions may have formalized policies with respect to settlement of authorship disputes, and these mechanisms may be helpful in resolving disputes with respect to research data, whether this is in the form of mediation overseen by a senior academic leader or a committee.

In this case, Dr. B. has not disputed the ownership of Dr. A's preliminary data; Dr. B. indeed may already have access to this data and has offered to write the final manuscript utilizing preliminary results. The source of dispute is Dr. A's procrastination that is hampering Dr. B's ability to further and to publish her own research results.

There are several alternatives to handling this particular case. One solution would be that Dr. B could appeal to the Chair of Anesthesiology. As a junior faculty member, the publication of Dr. A's data is critical to Dr. B's research productivity and tenure. Ultimately, the Chair should be very instrumental in convincing Dr. A to either complete the manuscript (perhaps by offering some clinical release time) or to allow Dr. B to write the publication, allowing Dr. A to provide input prior to submission for publication. Skillful mediation and a convincing argument from the Chair may be the most amenable solution and maintain the collegiality of the researchers.

If a more reasoned approach does not work, the situation could be raised to a higher level, such as to the VP for Research. It is in the University's (and the taxpayer's) best interest that this work be published. Indeed, the University may consider that Dr. A's procrastination is beyond the level of acceptability. The University does, as a matter of legal principle, own the research data that was generated under the NIH R01 grant. While fairly unprecedented, the University's VP could inform Dr. A to provide all the background data to Dr. B if the publication was not completed within a reasonable time frame, in order for Dr. B to complete the manuscript.

DISPUTE SCENARIO 2

Professor Washington and Professor Lincoln are both employed at Grant University. Professor Washington is the PI of a large center grant; his primary appointment is in the Department of Pediatrics. Dr. Lincoln's primary appointment is in the Department of Mechanical Engineering and serves as a project PI on Dr. Washington's grant. Unfortunately, they have a disagreement over the research direction and potential success of Professor Lincoln's subproject and Dr. Washington threatens to call the funding agency to request a change in scope (i.e., elimination of Dr. Lincoln's subproject) in the interest of furthering the overall project. In addition, Dr. Washington requests that Dr. Lincoln provide him with the preliminary and secondary data from the subproject to date to verify his assumption. Dr. Lincoln refuses and threatens to call the funding agency himself to allege that Dr. Washington has mismanaged the grant.

**ISSUES & MANAGEMENT -
DISPUTE SCENARIO 2**

Unfortunately, what began as a potentially successfully cross-disciplinary multi-investigator project has now transformed into dispute surrounding research direction. Such disputes involving research data are even more difficult when the investigators come from different departments and across schools or colleges. As such, more parties need to come to the table to resolve issues, and when the project is funded by federal agency, there is more opportunity to bring a dispute outside the institution and create havoc.

The authority of the Principal Investigator to request data generated in a subproject presents an interesting question. While the PI does have the responsibility for the overall scientific conduct of the project, requiring preliminary data absent an allegation of misconduct is highly unusual. The PI does have responsibility to report a change in scope to the funding agency, and to ensure the success of the research. However, it should also be recognized that there are no guarantees to the viability of proposed research goals, and that funding agencies should accommodate for change in direction if these are in the best interest of the science. In this situation, the request for the data does not appear to be reasonable.

In this particular case, there again needs to be some intervention at a senior academic leadership level. The funding agency should be informed at the appropriate time with respect to a change in scope, but not before internal disputes are dealt with. As with the preceding example, one possible solution would be that the Chairs of Pediatrics and Mechanical Engineering could intervene and mediate the appropriate solution. Any allegations of mismanagement should be resolved, and the success and viability of Dr. Lincoln's subproject should be explored. Absent an amicable solution, it may not be possible to sustain a long-term collaboration between Dr. Washington and Dr. Lincoln, however, a short-term agreement should be reached with respect to the ongoing grant. The issues surrounding the research data are only secondary to the bigger problem of a failing collaboration.

MISCONDUCT SCENARIO 1

Prof. Green is a senior investigator whose research is supported by grants from the NIH. Prof. Green's research is highly dependent on data gathered through interviews of human participants which are conducted by graduate students and postdoctoral fellows in her laboratory. Prof. Green is a respected leader in her field and spends much time away from the laboratory speaking at conferences and seminars, and reviewing grants. Many of Prof. Green's departmental colleagues are concerned with her time away from campus and fear that the post-doctoral fellows and graduate

students are not receiving enough attention. One day, one of these concerned colleagues, who has just finished reading a series of recent papers from Prof. Green's laboratory, comes to the department head with an allegation that data in three papers authored by a graduate student may have been falsified. The graduate student had just defended his thesis and left the department to take a postdoctoral position elsewhere. When an inquiry committee appointed to review the allegation asks to see the student's notebooks, they learn that most of the data books are either missing or incomplete. When asked, the student indicates that all his data books were left on the lab bench exactly where he had been instructed by Prof. Green to leave them. Prof. Green remembers the conversation but can't recall recovering the books and transferring them to a safe location. In short, it appears that the books are lost.

ISSUES & MANAGEMENT – MISCONDUCT SCENARIO 1

Absent a university policy outlining responsibilities for maintaining the research records, most practicing scientists would assume they are responsible for data management and retention for research conducted in their laboratory or under their direction. Since Prof. Green directed the students to place the notebooks in a specific location for retrieval, Prof. Green seems to have assumed responsibility, as well.

The absence of an institutional policy doesn't relieve an investigator from maintaining appropriate and adequate records sufficient to validate the research results. As the mentor for her graduate students and post-doctoral fellows, Prof. Green assumes the responsibility to teach them the professional standards in her discipline. These standards for conduct include maintaining complete and accurate records and an absolute prohibition against the falsification of data and results. Unfortunately, the lost and incomplete notebooks will make it difficult to conduct the inquiry into the allegation of falsification of data – an allegation of research misconduct.

As an NIH-funded project, the inquiry and, if necessary, investigation will be conducted under the Public Health Service (PHS) Policy on Research Misconduct. This policy assumes that "the absence of or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct." These facts are likely sufficient to have the inquiry committee determine there is a reasonable basis for the allegation to fall within the definition and recommend a full investigation. During the investigation, Prof. Green may bring documentation forward to prove honest error and the university must consider any evidence presented by Prof. Green and prove by a preponderance of the evidence that the misconduct (the falsification of data) occurred. The absence of the notebooks will weigh against Prof. Green in this determination.

If the inquiry committee makes a recommendation for an investigation, the university must report the results of the inquiry to PHS Office of Research Integrity.

MISCONDUCT SCENARIO 2

Dr. Smith is a co-investigator on an NIH-funded Specialized Center of Clinically Oriented Research (SSCOR) grant and has taken full responsibility for conducting the research in his section even though he is not listed as the section PI. He is responsible for all research related procedures for the study, including submitting progress reports and renewal applications to both the NIH and to the institution's IRB. He submits at least one progress report to the NIH providing details of completed research procedures on a large number of human subjects and conclusions drawn from those procedures. He fails to submit a continuing review application to the IRB within the approval period, causing IRB approval to lapse. He must submit a new application to be approved by the IRB in order to continue the research.

During the course of the research project, he accepts a new position at another institution and must transfer research duties to another investigator for the duration of the project. Transitions such as this occur regularly at this institution and typically require several meetings between the outgoing and incoming investigators to exchange information and to review protocols, consent forms, measurement tools, data collection approaches, as well as any primary data obtained before the transition. Dr. Smith is unable, at that time, to produce the materials needed for the transition. Subsequently, Dr. Smith claims that the primary data was stored on two laptops, neither one of which was backed up and both having been lost in two unrelated but serious accidents. In the absence of the primary data, he is asked to provide corroborating evidence/information on the procedures performed on the subjects discussed in the NIH progress report. He provides information on only a handful of subjects thus calling into question the accuracy of the information in the progress report.

ISSUES & MANAGEMENT - MISCONDUCT SCENARIO 2

As described in the assessment of Data Retention Scenario 1 above, the delegation of responsibility to store data has become increasingly complex. Institutional policies addressing institutional data may or may not cover research data. For a collaborative grant, the management of data and expectations and responsibilities for data storage and retention should be outlined as a part of the shared responsibilities. In this case, the loss of research data through accidents involving personal computers is a significant loss to the project and could have been avoided by ensuring that data collected and analyzed on personal computers was systematically backed up on a central computer or in a digital library.

The failure to respond completely and accurately to the request for corroborating evidence to support the progress report submitted to NIH raises questions on the integrity of the progress report. Because of the absence of evidence to support the scientific progress report the institution should initiate a research misconduct inquiry. The Department of Health & Human Services' Public Health Service (PHS) regulations will need to be followed because of the NIH sponsorship. Under the PHS regulations, "the absence of or respondent's failure to provide research records adequately documenting the questioned research is evidence of research misconduct." To reach a finding of research misconduct, the institution must determine that, under the standard of the preponderance of the evidence, that Dr. Smith "had the opportunity to maintain the records but did not do so."

Because the missing data is private health information, the institution has additional obligations in managing the inquiry and investigation and to report the loss of data. The Health Insurance Portability and Accountability Act (HIPAA) requires the securing of private health information (PHI) and failure to meet the HIPAA Security Rule standards may require a reporting of a breach of security to the Federal government. HIPAA Privacy Rules may or may not be applicable if some PHI must be disclosed during the course of the inquiry and investigation.

The institution should determine whether it is appropriate to notify the HHS Office of Research Integrity at the initiation of the inquiry if the loss of the research data and the allegation of research misconduct may have a negative impact on the health and safety of the public, affect the integrity of the on-going PHS/NIH supported research and research process. Because the research is on-going, the institution should consider notifying the appropriate NIH institute or center as the strength of the overall research project may be placed in jeopardy because of the data loss.

Finally, the institution should examine its obligations to the human subjects in the research and report the lapse in IRB approval to the HHS Office for Human Research Protections.