Data Retention Policies
The preparation, sharing and retention of appropriate records are essential components of any research endeavor at the University. The University, its faculty and its trainees have a common interest and a shared responsibility to assure that research is appropriately recorded, shared and retained. Original records may be required to protect the University’s intellectual property rights, to answer ongoing questions regarding management of a research program, to address possible questions that may arise regarding the propriety of research conduct and to comply with the data sharing requirements of many sponsors. Most importantly, it is essential that original research records be mutually available to all the collaborators on a research project.

Definition of Research Records

Research records include, by way of example but not limitation, material contained in research notes, laboratory notebooks and in other media such as computer disks and instrument printouts. Significant research materials or products generated by any research are also part of the record and should be retained and available.

Sharing of Research Records

Research records must always be available to collaborators (co-investigators, supervisors and their trainees). In collaborative projects, all investigators should know the status of all contributing research records and have access to them consistent with confidentiality restrictions. Investigators also should be aware if their research records are subject to specific data sharing requirements of a sponsor.

Retention of Research Records

Faculty, or the responsible investigators, have the obligation to ensure that, for all aspects of their research program, sufficient records are kept to document the experimental methods and accuracy of data collection as well as the methods and accuracy of data interpretation. This policy does not create an obligation to retain the research records of an unfunded project unless it results in publication or involves the use of animals or human subjects. Research records should be archived for a minimum of five years after final reporting or publication of a project (or longer if required by an external sponsor, law, rule or regulation). The archived records should be the originals. In addition, the records should be kept for as long as may be required to protect any patents resulting from the work. If any questions regarding the research are raised during the required retention period, the records should be kept until such questions are fully resolved. In the event an investigator leaves the University for any reason, the original research records must be retained at the University and the investigator’s department and collaborators notified as to their location.

Ownership of Research Records

The primary owner of research records is the University. The University has the right of access to the supporting records for all research carried out through the University with the understanding that information or data that would violate the confidentiality of sources or subjects involved in the research should not be disclosed. In addition, extramural sponsors providing support for research at Duke University may have the right to review any data and records resulting from that extramural support.
Policy 7.9
Guidelines for Responsible Conduct of Scholarship and Research

Responsible Official: VP for Research Administration
Administering Division/Department: Research Compliance
Effective Date: April 30, 2007
Last Revision: April 30, 2007

Overview

These guidelines describe a standard of practice for the conduct of scholarship and research at Emory University. The University complies with all applicable laws and regulations (see Appendix). The guidelines are intended as a statement of desirable practices. They are based on three important principles:

I. The University is obligated to protect and foster the academic freedom and intellectual integrity of all members of the University community in their pursuit of knowledge;

II. The University is accountable to outside funding sources that support the research and scholarship of its faculty; and

III. Every scholar has ultimate responsibility for the accuracy and validity of his/her own work and that of junior co-investigators, fellows, and students. Each scholar shared this responsibility with colleagues with whom she/he establishes collaborative relationships.

Applicability

This document applies to research in all areas of intellectual inquiry. A separate section addresses issues specific to scientific research. These guidelines are intended to heighten awareness of potential ethical problems and to instruct individuals regarding appropriate procedures for resolving and documenting ethics-related matters. The focus is on the individual scholar; the purpose is to emphasize that his/her responsibility includes a duty to maintain high scholarly and ethical standards, and a commitment to instill those standards in co-investigators, students and trainees.

Scientific inquiry, scholarly contributions, creativity, and academic accomplishment can take many forms and may vary among disciplines. The issues addressed by these guidelines are essential to all scholarly activity within the University community. Scholarly responsibility, quality of scholarly activity, security of scholarly contributions and their sources, responsible authorship, and provision for training in ethics of each discipline are issues inherent to all areas. The implications of these guidelines apply as fully to the scholar who co-authors a history textbook as to the laboratory scientist who reports a biological discovery, or the clinician who publishes a case report.

The guidelines address the following concerns:

- the scholar's authority and responsibility for research activities;
- the establishment of the quality of research;
- authorship of publications, including multiple publications and requisites for authorship;
- the supervision of students and other trainees;
- the education of trainees in research ethics and integrity;
- access to and retention of scientific research protocols and data; and
- the social responsibility of the scholar.
C. Access to and Retention of Scientific Research Protocols and Data

1. Both the research director and the University have responsibilities and, hence, rights concerning access to, use of, and maintenance of original research data. (“Ownership of Research Data”. Estelle A. Fishbein, Academic Medicine, 66:129, 1992 and “Workshop Summary”. L.J. Rhoades, Data Management in Biomedical Research: Report of a Workshop, USPHS, pp. 2-9, 1990.) Consistent with the precepts of academic freedom and intellectual integrity, the investigator/scholar has the primary authority to make judgments involving the use and dissemination of the data.

2. Each faculty member/preceptor is ultimately responsible for the maintenance and proper retention of research records. These records should include sufficient detail to permit examination for the purposes of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing their authenticity, and confirming the validity of the conclusions.

3. Each preceptor should maintain a laboratory manual that describes all major procedures. Correspondence with institutional review committees and records of the use of controlled substances and radioactive materials should be maintained as part of the research record in accordance with governmental, regulatory, and University policies.

4. A standardized system of data organization should be adopted and should be communicated to all members of a research group and to the appropriate administrative person. The appropriate administrative person should be determined by the sub-unit.

5. Where feasible, all original primary data are to be retained by the faculty member or by his or her designee. Accepted practices for retaining data vary among disciplines and depends on the perishability nature and logistics of retaining each type of data. Each investigator should treat data properly to ensure authenticity, reproducibility and validity and to meet the requirements of relevant grants and other agreements concerning the retention of data. Primary data should be reserved for a reasonable duration to ensure that any questions raised by the researcher, colleagues, or readers of any published results can be answered. It is recommended that, where feasible, data be retained for seven years; in circumstances where there are no federal or other requirements such as those referred to in the Appendix, sub-units of the University may wish to establish uniform standards and procedures for retention and destruction of data. Data should not be destroyed without proper notification of and approval by an appropriate administrative person. In unusual cases (e.g., data used for a patent application filed by the University), it may be necessary for original data to be kept at the University. Potentially patentable data should be signed and dated by the preceptor at the time they are entered into notebooks or maintained by other methods of retention in the event the results are questioned.

6. In the event the scholar leaves the University, an Agreement of Disposition of Research Data may be negotiated by the scholar and the department chair or dean to allow the scholar’s data, notebooks, and other data retention materials (other than clinical research records) to be transferred to the new institution. Consistent with the same precepts, and to fulfill its obligations to funding sources and others, the University will ensure in such agreements access to the transferred data for purposes of review. In unusual cases (e.g., data used for a patent application filed by the University) it may be necessary for original data to be kept at the University. In such cases an individual written agreement shall be signed which preserves the scholar’s right to access and copy (where practical) such data. In cases of multi-institutional studies, the institution of the primary study director is ultimately responsible for guaranteeing appropriate access to, use of, and retention of original data.

7.9.03 References

*“Policies and Procedures for Investigation of Misconduct in Research”, Emory University, 2 March 1989.*


*“Authorship and Other Credits”, N. Fotion and C. C. Conrad, Annals of Internal Medicine, 100:592, 1984.*


# APPENDIX V

Time Minimums for Research Data Archival

<table>
<thead>
<tr>
<th>Research Data</th>
<th>Laws, Policies and Regulations</th>
<th>Time Periods</th>
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<tr>
<td>Proposals not funded</td>
<td>Not defined, but may contain proprietary information</td>
<td>Not defined</td>
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</tbody>
</table>
| Expired Grants and Contracts | - Office of Management and Budget (OMB) Circular A-110*  
- Grants Policy of Funding Agency | OMB - Three years after completion of the entire research project  
Federal - follows OMB  
Private – Varies--see specific policy |
| Clinical Trials  
(All relevant records) | Food and Drug Administration (FDA)  
Notice: “Good Clinical Practices: Consolidated Guidelines” | At least two years after the last approval of a marketing application or at least two years after formal discontinuation of clinical development of the investigational product or longer if required by contract, but in no instance less than three years after the completion of the Clinical Trial |
| - Patent files  
- Data in support of patent | U.S. Patent Law | 17 years from the date of the patent application |
| Research Data which supported enactment of a federal, state or local law | Not defined | Indefinite |

* = OMB Circular A110 Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations”

NOTE: If a sponsored agreement exists, see specific archival requirements contained therein.
RESEARCH DATA: OWNERSHIP, RETENTION AND ACCESS

Policy Statement
Individual researchers and the University have rights and responsibilities with respect to research data. This Policy describes the basis of data ownership and the standards for the collection and retention of data, in addition to requirements for data access. This Policy also provides guidance with respect to transfer of research data in the event a researcher leaves Northwestern University.

Reason for Policy/Purpose
This Policy assures that research data are appropriately recorded and archived, and available for review under appropriate circumstances.

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Who Approved This Policy
Vice President for Research

Who Needs to Know This Policy
Faculty, students, other trainees, staff, and all other members of Northwestern University’s research community.

Website Address for this Policy
http://www.research.northwestern.edu/policies/documents/research_data.pdf

Contacts
If you have any questions about this policy, you may contact:

1. Executive Director, Office for Sponsored Research – (312) 503-7955, osr-chicago@northwestern.edu (Chicago) or (847) 491-3003, osr-evanston@northwestern.edu (Evanston)

2. Director, Office for Research Integrity – (312) 503-0054 or nu-ori@northwestern.edu

Definitions
For the purpose of this Policy, “research data” means all information in whatever form (e.g., both physical and electronic) collected and/or generated in the course of a sponsored research project conducted at the University, under the auspices of the University or with University resources. This includes original and derivatives of research data, including recordings of such data. Examples of research data include, but are not limited to:
- Records necessary for the reconstruction and evaluation of the results of research;
- Data contained in laboratory notebooks;
- Data collected using instrumentation or systems and stored in an electronic format;
- Case report forms and source documentation for human subject research studies.

Pursuant to Northwestern’s Policy on Retention of University Records, “Records” include “recorded information of any kind and in any form including writings, drawings, graphs, charts, images, prints, photographs, microfilms, audio and video recordings, data and data compilations, and electronic media, including e-mail.”

This Policy does not address ownership of intellectual property, which is governed by Northwestern’s Patent and Invention Policy and Copyright Policy.

Policy/Procedures
1.0 Ownership and Responsibilities

As a federally funded research institution, the University, in order to meet the requirements of research sponsors, asserts ownership over the research data for projects conducted at the
University, under the auspices of the University or with University resources. Although the University as owner of the research data must meet the requirements of sponsors, good management practice and practical considerations necessitate that the University and researchers act in partnership to fulfill these obligations.

As custodians of research data, Principal Investigators (PIs) and other researchers are stewards of research data. At the same time, no matter how such responsibilities are delegated, the flow of accountability runs from the PI being responsible to the institution for the stewardship of research data, just as the institution is ultimately responsible to the research sponsor.

Research data are to be accessible to members of the University community, external collaborators and others as appropriate (e.g., for patent applications or journal submissions). Where necessary to assure needed and appropriate access (e.g., for research misconduct investigations), the University may take custody of research data in a manner specified by the Vice President for Research.

Northwestern’s responsibilities with respect to research data include, but are not limited to:

1. complying with the terms of sponsored project agreements;
2. ensuring the appropriate use of project resources, e.g., animals, human subjects, recombinant DNA, biological agents, radioactive materials, etc.;
3. protecting the rights of researchers, including, but not limited to, their rights to access to data from research in which they participated;
4. securing intellectual property rights;
5. facilitating the investigation of charges, such as research misconduct or conflict of interest;
6. maintaining confidentiality of research data, where appropriate; and
7. complying with applicable state and federal laws and regulations.

The PI’s responsibilities with respect to research data include, but are not limited to:

1. ensuring proper management and retention of research data in accordance with this Policy;
2. establishing and maintaining appropriate procedures for the protection of research data and other essential records, particularly for long-term research projects;
3. ensuring compliance with program requirements;
4. maintaining confidentiality of research data, where appropriate; and
5. complying with applicable state and federal laws and regulations.

2.0 Data Retention

Research data must be retained for a minimum of three years after the financial report for the project period has been submitted. In addition, any of the following circumstances may justify longer periods of retention:

1. research data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
2. if litigation or other dispute resolution, claim, financial management review or audit related to the research project is started before the expiration of the three year period, or commenced after the three year period but the relevant data and records have not been destroyed, the research data and other project records must be retained until all
litigation/dispute resolution, claims, financial management review or audit findings involving the records have been resolved and final action taken;

3. if any charges regarding the research arise, such as allegations of research misconduct, research data must be retained consistent with the Northwestern University Policy on Retention of University Records, or as otherwise instructed by Northwestern’s Office for Research Integrity or Office of General Counsel;

4. if a student is involved, research data must be retained at least until the student’s degree is awarded (or the student otherwise leaves Northwestern University) and any resulting papers are published;

5. when research is funded by an award to or contract with Northwestern that includes specific provision(s) regarding ownership, retention of and access to technical data, the provision(s) of that agreement will supersede this Policy;

6. research data from human subject research studies must be maintained consistent with the Human Subjects Protection Program Policy Manual and the Policy on Retention of University Records;

7. if other regulations, federal oversight, sponsor policies or guidelines, journal publication guidelines or other University policies require longer retention, all applicable sources must be reviewed and the research data must be kept for the longest period of time applicable.

Beyond the period of retention specified here, the destruction of research data is at the discretion of the PI. Destruction of research data must follow applicable federal regulations, Northwestern policies on record retention and data disposal, sponsor requirements and other applicable guidelines.

Research data will normally be retained in the unit where they are produced. Please refer to the Policy on Retention of University Records for additional guidance on responsibilities related to the retention of research data and records.

3.0 Transfer in the Event a Researcher Leaves Northwestern

When individuals other than the PI involved in research projects at Northwestern leave the University, they may take copies of research data for projects on which they have worked, subject to relevant confidentiality restrictions. Original data, however, must be retained at Northwestern by the PI.

If the PI leaves Northwestern, and a project is to be moved to another institution, ownership of the original data may be transferred from Northwestern to the PI’s new institution upon request from the PI subject to: (a) the prior written approval of the Vice President for Research; (b) written agreement from the PI’s new institution that guarantees (1) its acceptance of ongoing custodial responsibilities for the data and (2) Northwestern having access to the original data, should such access become necessary for any reason; and (c) relevant confidentiality restrictions, where appropriate.

Forms / Instructions
N/A
## Policy: Laboratory Notebook and Recordkeeping

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<th>Date:</th>
<th>06/23/04</th>
<th>Policy ID:</th>
<th>RES-002</th>
<th>Status:</th>
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### Policy Type:
University

### Contact Office:
Vice President for Research (Office of the)

### Oversight Executive:
Executive Vice President and Provost

### Applies To:
University-wide.

### Table of Contents:
- Policy Statement
- Recording and Storage of Laboratory Data

### Reason for Policy:
This policy describes the University’s position of the importance of recordkeeping in research to ensure that complete data is maintained in an accessible format to support verification of research processes undertaken and of the data obtained as an outcome of such processes.

### Policy Summary:

#### Definition of Terms in Statement:
- **Laboratory Notebook**: The logbook of all processes and procedures performed in the course of research which shall be kept in such a manner as to enable an investigator to reproduce the steps taken.
- **Data**: The results of research procedures.

#### Policy Statement:
The investigators and all research fellows, assistants, technicians and students involved in research activities, shall maintain complete and verifiable records of the procedures they have followed in pursuing all research, and the subsequent data they have thereby obtained.

**Recording and Storage of Laboratory Data:**
The retention of accurately recorded and retrievable results is of the utmost importance in the conduct of research, and it is the responsibility of each investigator to maintain such records in a secure location.

Data and notebooks resulting from sponsored research are the property of the University of Virginia. It is the responsibility of the principal investigator to retain all raw data in laboratory notebooks (or other appropriate format) for at least five years after completion of the research project (i.e., publication of a paper describing the work, or termination of the supporting research grant, whichever comes first) unless required to be retained longer by contract, law, regulation, or by some reasonable continuing need to refer to them.

If the principal investigator leaves the University of Virginia, he or she may transfer such data to another institution, provided that the Vice President for Research and Graduate Studies is informed of this transfer and approves of it. This shall be subject to the proviso that the University is given written assurance that the data will be retained for the required five-year minimum retention period.

The notebook or logbook shall be kept in a secure location where it cannot be removed by an unauthorized person.

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Policy on Data Stewardship, Access, and Retention

Adopted By: Research Policy Advisory Committee
Adoption Date: December 16, 2010
Approved By: Vice Chancellor for Research
Approval Date: February 21, 2011

1.0 Purpose: Establishes University policy to assure that research data are appropriately maintained, archived for a reasonable period of time, and available for review and use under the appropriate circumstances.

2.0 Scope: This policy shall apply to all University of Wisconsin-Madison faculty, academic staff, visiting scholars, postdoctoral fellows or other trainees, research technicians, and graduate or undergraduate students and any other persons at UW-Madison involved in the design, conduct or reporting of research at or under the auspices of UW-Madison involved in the design, conduct or reporting of research at or under the auspices of UW-Madison, and it shall apply to all research projects on which those individuals work, regardless of the source of funding for the project.

3.0 Definitions:

Data means recorded factual material, regardless of the form or media on which it may be recorded, that is commonly accepted in the research community as necessary to validate research findings. For example, data may include writings, films, sound recordings, pictorial reproductions, drawings, designs, or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, statistical records, and other research data.

This definition pertains to both primary and secondary data. Primary data means data generated by research conducted at the University, under the auspices of the University, or with University resources. Secondary data means data owned and or generated by another party, data collected from administrative records, or data designated for public use, but used in whole or in part for research conducted at the University, under the auspices of the University, or with University resources.

This definition of data excludes research results based on data such as preliminary analyses, drafts of research papers, published papers, plans for future research, peer reviews, or communications with colleagues.

This definition does not supersede any campus policy pertaining to intellectual property.

Principal investigator (PI), for purposes of this policy, means a researcher with primary responsibility for a research project, a definition that applies whether or not the research is sponsored by an external funding source. A PI's responsibility includes both leadership of the scientific/technical aspects and compliance with administrative aspects of the research.
Others on campus, including certain academic staff titles, visiting scholars, postdoctoral fellows or other trainees, and graduate or undergraduate students, who would initiate a research project and are not themselves eligible to be a PI, must identify a faculty member, academic staff person with permanent PI status, or other authorized person to serve as principal investigator.

**Other research contributors** mean any persons other than the PI who have made a substantial contribution to the conception and design of research, acquisition of data, or analysis and interpretation of data. Contributors may include faculty collaborators, academic staff, visiting scholars, postdoctoral fellows or other trainees, research technicians, and graduate or undergraduate students. In general, persons performing narrow technical or clerical tasks would not qualify as contributors.

4.0 **Policy:** UW-Madison must retain research *Data* in sufficient detail and for an adequate period of time to enable appropriate responses to questions about accuracy, authenticity, primacy and compliance with laws and regulations governing the conduct of the research. It is the responsibility of the **Principal Investigator** to determine what needs to be retained under this policy.

4.1 **Scope:** The University's requirements for stewardship of the research record for projects conducted at the University, under the auspices of the University, or with University resources are based on regulation (OMB Circular A-110, Sec. 53), UW System policy, and sound management principles. UW-Madison's responsibilities in this regard include, but are not limited to:

1. Complying with the terms of sponsored project agreements;
2. Ensuring the appropriate use of animals, human subjects, recombinant DNA, disease-causing agents, radioactive materials, and the like;
3. Protecting the rights of students, postdoctoral scholars, and staff, including, but not limited to, their rights to access *Data* from research in which they have participated;
4. Facilitating the investigation of charges, such as scientific misconduct or conflict of interest; and
5. Support university personnel in securing and protecting intellectual property rights.

Where research is subject to an agreement with UW-Madison that includes specific provision(s) regarding retention of and access to *Data* and other records of research conducted under the auspices of the University of Wisconsin-Madison, the provision(s) of that agreement will supersede this policy. However, University of Wisconsin System Financial & Administrative Policies on Extramural Support Administration (G2) Section V.B.(9) "Data" provides that "No agreement shall be entered into with any extramural sponsor which allows for the transfer of the ownership of data."

In the case where an outside party has provided a University of Wisconsin-Madison investigator with secondary Data for the purposes of research, requirements to retain research Data in sufficient detail and for an adequate period of time will apply to that portion of secondary Data used in the research.

4.2 Stewardship and Retention: Principal Investigators should adopt an orderly system of Data organization, access, and retention and should communicate the chosen system to all members of a research group and to the appropriate administrative personnel, where applicable. Particularly for long-term research projects, PIs should establish and maintain procedures for the protection of essential records in the event of a natural disaster or other emergency.

Research Data must be archived for a minimum of seven years after the final project close-out, with original Data retained wherever possible. Principles of good stewardship would justify longer periods of retention in the following cases:

1. Data must be kept for as long as may be necessary to protect any intellectual property resulting from the work;
2. If any charges regarding the research arise, such as allegations of scientific misconduct or conflict of interest, Data must be retained until such charges are fully resolved; and;
3. If a postdoctoral scholar or other trainee, graduate student, or undergraduate student is a Research Contributor, Data must be retained at least until the degree is awarded, training is completed, or it is clear that the individual has abandoned the work.

Beyond the period of retention specified here, the disposal of the research record is at the discretion of the PI and his or her department or work unit (e.g., laboratory). As a practical matter, Data may be translated to more efficient storage media as long as the essential nature of the Data is not lost. For example, lab notebooks may be scanned, audio recordings transcribed, questionnaires coded and digitized, and the like.

Records will normally be retained in the unit where they are produced. Research records must be retained on the UW-Madison campus, or in facilities under the auspices of University of Wisconsin-Madison, unless specific permission to do otherwise is granted by the Vice Chancellor for Research.

4.3 Access: As part of the stewardship of research Data, the Principal Investigator shall create explicit understandings with Other Research Contributors regarding access to and use of Data. These understandings ought to reflect access appropriate to one's role and contribution to the conception and design of research, acquisition of Data, or analysis, and interpretation of Data.
It will also be the responsibility of the Principal Investigator to follow the requirements of any sponsored agreements with regard to access to Data.

Where necessary to assure needed and appropriate access, the Principal Investigator, upon request of the university, must provide the university with research Data. Under extraordinary circumstances, such as research misconduct, the university will take all necessary steps to ensure integrity of the Data in a manner specified by the UW Policy for Misconduct in Scholarly Research (FP&P II-314).

None of these provisions is intended to supersede the Principal Investigator's right to keep Data proprietary until the results of the research have been published and the aims of the research have been fulfilled.

4.4 Transfer in the Event a Researcher Leaves UW-Madison: When individuals involved in research projects at UW-Madison leave the University or move to a different research group or position at UW-Madison, they may, with PI approval, take copies of research Data that they have generated or to which they have made a substantial contribution for projects on which they have worked. Original Data, however, must be retained at UW-Madison by the Principal Investigator.

If a Principal Investigator leaves UW-Madison, and a project is to be moved to another institution, the Data may be transferred with the approval of the Vice Chancellor for Research, and with written agreement from the PI's new institution that guarantees: 1) its acceptance of custodial responsibilities for the Data, and 2) UW-Madison access to the Data, should that become necessary.

5.0 Roles and Responsibilities: The Principal Investigator is responsible for the stewardship and retention of research Data as well as for determinations concerning access to and appropriate use of Data.

Other Research Contributors are responsible to cooperate with the PI in carrying out the requirements of this policy.

The dean(s) of the school(s)/college(s) in which the PI is appointed may hear appeals concerning issues of access to Data and determine who shall have access.

The Vice Chancellor for Research may hear appeals to a dean's determination concerning access to Data and make a final determination. The Vice Chancellor for Research may determine, consistent with campus policy, who is eligible to serve as a Principal Investigator.

6.0 Related Documents/Resources:
University of Wisconsin-Madison Research Data Services
http://researchdata.wisc.edu/

University of Wisconsin-Madison Intellectual Property Policy and Procedures
(www.grad.wisc.edu/research/ip/policies.html)