SURVEY OF RESEARCH INTEGRITY MEASURES UTILIZED IN BIOMEDICAL RESEARCH LABORATORIES

LITERATURE REVIEW

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1. Overview of Report

The DHHS Office of Research Integrity (ORI) has contracted with the American Institutes for Research (AIR) to conduct a survey of federally funded biomedical researchers to ascertain the frequency of use of measures to promote the responsible conduct of research and to minimize the likelihood of scientific misconduct.

As an initial step in this process, AIR was requested to conduct a literature review to identify appropriate subject matter for inclusion within the survey. A prior literature survey available to ORI (Appendix A) indicated a limited number of relevant articles. We were instructed not to survey the lay-literature or news media regarding incidents of scientific misconduct. This report describes the search methods undertaken and the content areas in which information was obtained. Since the purpose of this review was to obtain information that would be pertinent and useful for developing the items for inclusion in the survey, an exhaustive report of the literature on scientific misconduct and research integrity measures is not provided here. Rather, a brief listing of specific content areas and domains where information has been found is presented, along with a bibliography of the results of the literature search.

2. Search Methods Utilized

The primary database utilized for review was MEDLINE. The PubMed user interface was used as the primary search engine (http://www.ncbinlm.nih.gov/entrez/query.fcgi). Several different databases within this service were used (e.g., BIOETHICSLINE, healthSTAR). The web site for the Food and Drug Administration (FDA) (http://vm.cfsan.fda.gov/~lrd/cfr58.html) was examined and provided the FDA manual for Good Laboratory Practices for Non-clinical Laboratory Studies. Additionally, searches were conducted using web engines that search for content within the public domain of the World-Wide-Web (e.g., http://www.Google.com; http://www.HotBot.com). These searches were particularly useful for locating information concerning institutional policies and training courses in the area of scientific integrity. Searches focused on terms such as plagiarism, data falsification, data

fabrication, good laboratory practices, good manufacturing practices, scientific misconduct, research integrity, research ethics, and training in research ethics.

Additional primary sources included the World Wide Web pages of the Association of American Medical Colleges (AAMC), http://www.aamc.org (and more specifically, http://www.aamc.org /research/dbr/compliance/curricula.htm), and a publication of AAMC (Korenman et al., 1994). We also examined the Educational Resources Information Center (ERIC) of the Department of Education, http://www.accesseric.org. Additional inquires were made of the National Institutes of Health (NIH), Office of the Director, and Office of the Deputy Director for Intramural Research. Additional review was conducted using the web sites for the AAMC journal *Academic Medicine*, for the *Journal of the American Medical Association,* and the journal *Science,* published by the American Association for the Advancement of Science.

3. Content Areas

The broad content areas for the survey were already established prior to the literature search based on Statement of Work (SOW) for the present study. Specifically, data fabrication, data falsification, and plagiarism were identified as the main domains of interest. These content areas were expanded upon by the formulation of additional related content areas discovered during the course of this literature review (Exhibit 1). What follows is a list of proposed content areas, each with citations that contain specific information related to the domain. Not all citations that are potentially relevant to a given domain are listed for that content area; rather, a list of sources that seem most relevant to a particular area is given. Since many articles span a number of domains, some articles are cited in more than one area. A bibliography of sources identified during the literature review is provided at the end of this report.

Proposed Content Areas for Survey
1. Data Fabrication
2. Data Falsification
3. Plagiarism
4. Data Management
5. Supervision/Mentoring
6. Good Laboratory Practices
7. Authorship
8. Peer Review
9. Conflicts of Interest and Commitment
10. Sharing of Information, Methods and Tools
11. Factors Contributing to Research Misconduct
12. Historical Cases of Misconduct
13. Courses/Training Material
14. Steps to Prevent Misconduct
15. Misinterpretation and Misrepresentation of Findings
16. Mechanisms Underlying Scientific Fraud and Misconduct

Exhibit 1. Survey of Content Areas

3.1 Data Fabrication

Fabricating or altering data for the purposes of developing experimental results and publications is an issue that was commonly mentioned through much of the literature. The articles referenced below discuss in detail some common themes and circumstances surrounding data fabrication, as well as scientists' and institutional representatives' attitudes towards this and other research misconduct issues.

(Berk, Korenman, & Wenger, 2000; Wenger, Korenman, Berk, & Berry, 1997)

3.2 Data Falsification

Closely related to data fabrication, data falsification also encompasses reporting or publishing only those experimental results that are favorable for one's hypotheses or position. It also includes "massaging" data, which may involve selection of data that will result in "favorable" results, using less than optimal analytical procedures in order to influence the significance of results, and providing misleading or incomplete explanations of experimental methodologies to obscure results, to make it difficult or impossible to replicate the study, or to make the study appear more sound (statistically significant or persuasive) than it actually was. This may involve creation of spurious "data" for part or all of a study; inappropriate exclusion of data or of experiments presumed or alleged to be "outliers"; arbitrary selection of data that are consistent with one's hypotheses while excluding data that are inconsistent; use of inappropriate procedures to reduce scatter or variance unless using an accepted method with the advice and consent of a reputable professional data analyst (usually but not necessarily a biostatistician); inappropriate use of statistical methods; failure to replicate 'data points' or experiments sufficiently to ensure reproducibility; or deliberate attempts to mislead.

(Berk et al., 2000; Chalmers, 1990; Stewart & Feder, 1987; Wenger et al., 1997)

3.3 Plagiarism

Copying the text and/or ideas of others without providing attribution was referenced in virtually all sources from the literature review. The practice can also include inappropriate, unacknowledged copying of raw data or derived values (e.g., figures, photographs, graphs, tables, and statistical calculations) from other researchers, engaging in duplicate publication of individual studies, and publishing fragments of a study in several different publications. Of growing concern is the copying of documents that have been disseminated via the Internet.

(Berk et al., 2000; Wenger et al., 1997)

3.4 Data Management

Much of the literature emphasizes procedures that could be put into place in order to help prevent misconduct in research. The management of raw data is one area where more controls may aid in prevention of misconduct. Some institutions have policies concerning data management, but it is not known how widespread these policies are, and how frequently and effectively they are being implemented. Guidelines for data management include: ownership of data (e.g., intellectual property), access to data, retention of data, and management of laboratory notebooks and computer data files.

(Freedland & Carney, 1992; Stewart & Feder, 1987)

3.5 Supervision and Mentoring

The quality and frequency of supervision and mentoring that trainees receive is one factor which may be related to the incidence of scientific misconduct in biomedical research laboratories. Some laboratories may lack formal policies relating to supervision. The level of detail of supervision may be an issue in many laboratories, where some mentors supervise all aspects of experimentation, whereas others may limit themselves to editing the manuscripts and reports of students and junior staff. The frequency of discussions or group meetings to discuss research results was cited as an issue, as was the ratio of mentors to trainees. Finally, some laboratories may require that students and postdoctoral researchers obtain formal training based on governmental and institutional requirements regarding scientific integrity and conduct. The American Association of Medical Colleges (AAMC) web site contains link to sites for training programs at seven academic medical centers (http://aamc.org/research/dbr/compliance/curricula.htm). These are displayed in Exhibit 2.

(Mathason, 1995; Wenger et al., 1997)

Institution	URL
Stanford University	http://www.stanford.edu/dept/DoR/rph/2-5.html
University of Michigan	http://www.responsibility.research.umich.edu/
University of California, San Diego	http://medicine.ucsd.edu/research/ethics/resources/
University of North Carolina	http://www.ais.unc.edu/responsible_conduct/rcrtoc.html
University of South Florida	http://www.fmhi.usf.edu/mhlp/ethics/ethics.html
AAAS Resources (Bibliography)	http://www.aaas.org/spp/video/resource.htm
Columbia University	http://cpmcnet.columbia.edu/research/rcr-crse.htm

Exhibit 2. Examples of Curricula for Teaching the Responsible Conduct of Research (Source: http://www.aamc.org/research/dbr/compliance/curricula.htm)

3.6 Good Laboratory Practices

The Food and Drug Administration's (FDA) *Good Laboratory Practices for Nonclinical Laboratory Studies* (CFR 21, Volume 1, and Part 58) was reviewed for regulations concerning laboratory practices. This manual indicates that testing facilities need to assure that there is a quality assurance (QA) unit in place, and that this QA unit is separate from and independent of the personnel engaged in the conduct of the research studies. The study director is identified as having overall responsibility for the technical conduct of the study. The regulations state that standard operating procedures should be put into place for many aspects of the facility, including data handling, storage, and retrieval.

Information concerning the "Good Laboratory Practices" (GLP) utilized in private industry was identified in the literature review. For one company, GLP primarily involves education and training, conducted through brief introductory tutorials (e.g., videotapes) and more extensive off-site courses lasting two days. The development and use of standard operating procedures (SOP) throughout the conduct of research is also encouraged, as is the use of a logbook checklist to ensure that all necessary information is accurately recorded in data logbooks as required by the FDA regulations.

The biotechnology and pharmaceutical industry and contract, clinical, and testing laboratories generally utilize the following techniques:

1. Bound laboratory notebooks with numbered pages are used, rather than loose-leaf notebooks, so that pages cannot be inserted or deleted without being detected.
2. All ancillary materials – e.g. printouts, graphs, figures, photographs, etc. - are pasted into the notebook or identified in a permanent unambiguous manner for archiving.
3. All notebooks are signed and witnessed on a daily basis. Notebooks are notarized periodically, especially if they include findings of special significance that may have future monetary significance (e.g., related to patents, trademarks, copyright, etc.).
4. Computerized data files are archived in a manner that a) prevent unauthorized alteration or deletion; b) document date, time, and mechanism of creation, the individual and processes entering or capturing the data, and the software or other mechanisms used for processing the data.

(Food and Drug Administration, 1999; Hopf & Karpiscak, 1994; Mathason, 1995)

3.7 Authorship

Several ethical issues exist with regard to authoring and publishing research results, including criteria for establishing the choice and order of authorship. There is a consensus that individuals should only be included as authors if they have made a meaningful contribution to the written product. The articles cited also point out that *all* authors should be held responsible for the contents of the article, and that journals should require authors to sign a written statement indicating, among other things, that the results

of the study were not significantly influenced by outside conflicts of interest. There is some discussion whether authors must be able to defend the contents of the entire article, or only the section(s) to which he or she has made a specific contribution. Additionally, procedures should be established to ensure that each author listed on an abstract has consented to being included as an author. Of particular concern within this area is the pressure on many researchers to publish. Authorship can affect status, prestige, reputation, self-esteem, promotion, tenure, security, job offers, ability to obtain grants, financial return, leadership positions, awards, and other rewards.

(Stewart & Feder, 1987)

3.8 Peer Review

Several of the ethical issues involved with peer review of scientific papers are closely aligned to plagiarism. For instance, a reviewer might appropriate the work or ideas from a paper or grant proposal that the researcher is reviewing. Having potential conflicts of interest can also affect the review process in that a researcher with outside interests may have bias either for or against a paper under review. Another type of misconduct might involve a researcher who purposely delays the review of a paper or study due to his or her own interests, e.g., to allow himself/herself, a friend, or a colleague to publish first.

(Korenman, Berk, Wenger, & Lew, 1998)

3.9 Conflicts of Interest and Commitment

Having potential, apparent, or real conflicts of interest can take many different forms, from industrial sponsorship of one's research to owning stock in a company whose products are potentially directly or indirectly affected by one's research practices and results. Most institutions and journals have policies that require researchers to disclose any financial relationships and time commitments to industries other than the institution where the work is conducted. In addition to the activities mentioned previously (e.g., delaying publication of results due to conflicts, and biased manuscript peer review), having conflicts of interest and commitments to industry can affect student research and

mentoring activities, for example students or fellows may be enlisted to engage in research activities directly relevant to the sponsoring industry. In addition, the sponsor of the research may impose certain restrictions on data handling and publication of results. For instance, publication may be delayed until the sponsor can obtain patents, and data may be owned by the sponsor and result in withholding of publications. A particularly difficult problem is the withholding of publication. Some industry-sponsored research may include a condition that publication can only occur following approval of the manuscript by the sponsor. This may result in the failure to publish results that are "negative" (e.g., not supporting a claim of improved therapeutic efficacy, failure to report findings of side-effects or deleterious effects, etc.). Some individuals and institutions refuse to accept support for research if accompanied by the requirement that publication is subject to review or veto by the sponsor.

(Berk et al., 2000; Wenger et al., 1997)

3.10 Sharing of Information, Methods and Tools

Several general issues of research integrity that do not readily fit into any of the previous categories were also found in the literature review. One such issue is the sharing of information among scientific colleagues. It is difficult to articulate general guidelines that will identify exactly what kind of information should be shared with whom, when, and under what conditions. There needs to be a balance between altruism, donating information "for the good of science," and the need to protect the intellectual or financial self-interest of the investigator, his/her colleagues, the laboratory director, and the institution. In addition to the possible sharing of ideas, data, and results, other issues may arise in conjunction with "tangibles" such as laboratory reagents, cells, antibodies, animals, tools and methodologies. Formal policies on such collegiality may not exist, but many researchers consider sharing of information to be a generally acceptable and ethical practice to further the conduct of scientific research. Releasing the results of research to the public (e.g., media) prior to professional review or publication was identified as an inadmissible practice by some but not all journals.
(Berk et al., 2000; Wenger et al., 1997)

3.11 Factors Contributing to Research Misconduct

Many factors have been cited as contributing to misconduct in scientific research. Competition is one of the factors of leading to ethical violations – competition for tenure, promotion, space, resources, prestige, recognition, and awards, among other things. In some cases there have been perceived pressures not to communicate certain important findings or work with scientific colleagues and other researchers out of fear of losing one's funding to others. Diffusion of responsibility among researchers may contribute to misconduct, particularly within larger laboratories. Of particular concern is the potential for conflict between the goals of the research institution and the ethics of research. For instance, in research institutions, systems that are designed to prevent, monitor, and investigate scientific misconduct consume resources and may appear to interfere with productivity, leading to a higher likelihood that these systems will not be utilized. Other potential factors include a fear of reprisal for reporting misconduct (particularly among junior scientists), inadequate education regarding research ethics and prevention of scientific misconduct, and personality characteristics of arrogance, egomania, and anti-social behavior.

(Biros, Fish, & Taggart, 1999; Freedland & Carney, 1992; Gustafson, 1995; Wenger et al., 1997)

3.12 Historical Cases of Misconduct

Several cases of individual scientists who have engaged in egregious misconduct are described in the literature review. These include the case of Dr. John Darsee, who engaged in extensive data fabrication, and Dr. Roger Poisson, who also falsified and fabricated data. Dr. Frances Collins reported the experience of discovering that a graduate student co-author had fabricated data for several studies. Broad and Wade discuss a number of celebrated cases in detail. Congressional hearings have been held on the subject.

(Broad & Wade., 1982; Parrish, 1999; Ryan, 1999; Stewart & Feder, 1987)

3.13 Courses/Training Material

Web sites of the Association of American Medical Colleges and several universities provide overviews of training courses and guidelines for education in research ethics for scientists and students. These sources provide excellent resources outlining the nature of research integrity and some of the most important current issues. The National Academy of Sciences has developed a manual that can be used by institutions as a guide for providing education on research integrity (*On Being a Scientist: Responsible Conduct in Research*). See Appendix B for policy statements and Appendix C for guidance on course content.

(Johns Hopkins University, 2000; Korenman & Shipp, 1994; National Academy of Sciences, 1995; University of California, San Diego, 1999; University of North Carolina, Chapel Hill, 1995; University of Minnesota, 1999)

3.14 Steps to Prevent Misconduct

Some steps can be taken within research institutions to help prevent misconduct. Although audits can be enforced through government agencies, internal audits may also help prevent scientific misconduct. For example, review of primary data is an important form of audit. Implementing industrial quality assurance concepts and "Good Laboratory Practices" is another step that may help reduce the likelihood of misconduct. This could often be as simple as the use of checklists and independent verification of results.

(Ryan, 1999)

3.15 Misinterpretation and Misrepresentation of Findings

Scientific evidence, even if properly collected, can be misrepresented. This is more likely to occur in areas of contention where there is a pecuniary interest in arguing a case, e.g., in lawsuits, advertising, and public health issues such as tobacco and disease. Bross addressed issues of data selection, inappropriate use of statistics, misleading or

obfuscating language, and systematic use of jargon and linguistics in order to mislead or persuade.

(Bross, 1991; Bross, 1994; Bross, 1975)

3.16 Mechanisms Underlying Scientific Fraud And Misconduct.

One of the factors underlying scientific misconduct may be a syndrome designated as Aberrant Self-Promotion, or "ASP." A considerable body of research exists and validated tests for this syndrome are available.

(Gustafson & Ritzer, 1995)

4. Discussion and Next Steps

The present literature review has provided considerable information concerning areas that are relevant to the survey. The sources identified are expected to be helpful for developing the survey items. Without exception, the materials that were reviewed indicated that scientific misconduct is a serious issue that needs to be addressed. In particular, several articles indicated that one current problem is the lack of reliable information concerning the prevalence of misconduct and of available measures to promote the responsible conduct of research. The survey that is administered to Laboratory Directors/ Principal Investigators will help to inform ORI about the current state of affairs regarding policies and practices in place to ensure research integrity. We recommend that information about current practices be solicited, as well as attitudes surrounding scientific misconduct, its perceived prevalence, and beliefs about the utility of education and/or other interventions in preventing misconduct. We believe that this information will contribute to future programs of ORI (e.g., to assist in the targeting of educational and preventive efforts using interventions that will be most meaningful and useful to the biomedical research community).

AIR will develop a set of draft survey items for the content areas outlined in this report. The items will request information on specific practices that institutes, laboratories, and

Principal Investigators undertake to ensure the responsible conduct of research, methods or practices used to detect misconduct, and attitudes related to scientific misconduct. These draft items will be presented to an Advisory Panel for review and comment. When the final set of items has been established, a computer-based survey will be developed for on-line administration of the survey to the sample of Principal Investigators.

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Appendices

Appendix A

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Appendix B

Examples of Policy Statements Regarding Responsible Conduct of Research

1. Johns Hopkins University
   Rules and Guidelines for Responsible Conduct of Research
   URL: http://infonet.welch.jhu.edu/policy/fac_pol_man/fac_pol1.html
   Date accessed: 11-09-00

2. Stanford University
   Scientific Misconduct: Policy on Allegations, Investigations and Reporting
   URL: http://www.stanford.edu/dept/DoR/rph/2-5.html
   Date accessed: 11-09-00

Appendix B-1

Rules and Guidelines for Responsible Conduct of Research

Johns Hopkins University
Rules and Guidelines for Responsible Conduct of Research
URL: http://infonet.welch.jhu.edu/policy/fac_pol_man/fac_pol1.html
Date accessed: 11-09-00Appendix B-1

URL: http://infonet.welch.jhu.edu/policy/fac_pol_man/fac_pol1.html

Faculty Policies

RULES & GUIDELINES FOR RESPONSIBLE CONDUCT OF RESEARCH

The distinction this School of Medicine has achieved as a center for research in the biomedical sciences is the result of dedication throughout the institution to the highest standards of professional conduct. In a time-honored system, the ethics of science are transmitted, along with practical and theoretical knowledge, to junior researchers by their senior colleagues. The atmosphere of truthfulness, accountability, and free exchange of ideas characteristic of this School has been considered sufficient to ensure responsible conduct of research. However, growth of the School and the greater complexity of regulations governing research make it increasingly likely that some researchers may not be fully aware of established norms. The purpose of this document is (1) to set forth principles and practices generally known and followed by researchers in the School of Medicine, (2) to ensure that all researchers in the School of Medicine are informed of institutional and governmental regulations that affect their work, and (3) to establish procedures designed to protect against fraudulent research, or unjustified charges thereof, with the least possible hindrance to scientific investigation.

This document is addressed to all faculty, postdoctoral fellows, students, and other research personnel in the School of Medicine. Everyone engaged in research in the School of Medicine should become familiar with its contents.

I. ORIENTATION AND GUIDANCE FOR FACULTY

General expectations for the academic conduct of faculty members and many specific requirements governing the conduct of research are set forth in the following documents:

- Policies and Guidelines Governing Appointments, Promotions, & Professional Activities of Faculty Members of The Johns Hopkins University School of Medicine

- The Sponsored Projects Handbook
- The Faculty Handbook of The Johns Hopkins University School of Medicine
- Guidelines of the Joint Committee on Clinical Investigation
- Use of Experimental Animals at the Johns Hopkins Medical Institutions and University
- Policy on Conflict of Commitment and Conflict of Interest
- Rules and Guidelines for Responsible Conduct of Research
- Procedures for Dealing with Issues of Professional Misconduct
- Grievance Procedure for Faculty, Fellows, and the Student Body

All faculty members should have copies of these documents and should be familiar with their contents.[1]

As teachers and researchers, faculty should be informed about ethical issues in research. Because these issues have rarely been part of their formal training, both current and new faculty should devote some effort and time to their study. They will thus be better able to inculcate in their trainees a clear understanding of the principles of academic integrity. Faculty also serves as role models and the manner in which they conduct their own research must be above reproach. Discussion of research ethics should be a regular part of department and division meetings.

A. RULE

1. The Office of the Registrar of the School of Medicine will distribute to each new faculty member the documents listed above and the booklet Honor in Science published by Sigma Xi. Faculty will be required to sign an acknowledgement of receipt of the above at the time they respond to their initial letter of appointment from the Dean.

II. SUPERVISION OF STUDENTS, POSTDOCTORAL FELLOWS, AND OTHER PERSONNEL

Preceptors are responsible for the careful supervision of their trainees and other research personnel. The complexity of scientific methods and the need for careful experimental design, caution in interpreting possibly ambiguous data, and advanced statistical analysis all require that the preceptor assume an active role of guidance and supervision. Preceptors should be prepared to give additional attention to a trainee or an employee who arrives in a research unit without substantial experience in laboratory science.

A. RULES

1. Responsibility for supervision of each student, fellow, or other (non-faculty) member of a research unit must be assigned to a specific faculty preceptor. For particular research projects, the responsible investigator should carry out supervision; overall supervision of each student or fellow must be assigned to a faculty advisor.
2. As a part of their orientation the Office of the Registrar of the School of Medicine must provide each new medical student and graduate student with a copy of this statement and also Procedures for Dealing with Issues of Professional Misconduct

and the booklet Honor in Science published by Sigma Xi. At the time of registration these documents must also be given to all postdoctoral fellows whose written acknowledgement of receipt of the documents will be kept on file in the Registrar's Office. Preceptors should familiarize trainees and other research personnel with relevant governmental and institutional requirements for conduct of studies involving healthy volunteers or patients, animals, radioactive or other hazardous substances, and recombinant DNA.

B. RECOMMENDATIONS

1. The ratio of trainees to faculty members should be small enough that close interaction is possible for scientific interchange as well as supervision of the research at all stages.
2. The degree of supervision by the preceptors should take into account the experience and skill of trainees. A preceptor should help the trainee develop not only good research practices and technical expertise, but also good research ethics.
3. The preceptor should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting, and storing data. The editing of manuscripts alone does not constitute adequate supervision by the preceptor.
4. Preceptors should have realistic expectations regarding the performance of trainees and other research personnel and should inform them of these expectations.
5. Collegial discussions among all preceptors and trainees constituting a research unit should be held regularly both to contribute to the scientific efforts of the members of the group and to provide informal peer review.
6. Preceptors should be alert to behavioral changes in trainees or other research personnel that may indicate inordinate personal or academic stresses or substance abuse. Stresses are particularly likely to occur at times of transition or as deadlines approach. Since the care with which research activities are conducted may be adversely affected by stress, a trainee or employee may need closer supervision at such times.

III. DATA GATHERING, STORAGE, RETENTION

The retention of accurately recorded results is of utmost importance for the progress of scientific research. Original laboratory data[2] must be retrievable not only to answer scientific questions but also to respond to questions that may arise about the propriety of research conduct. Errors may be mistakenly characterized as misconduct when the primary experimental results are unavailable. Moreover, a common denominator in most cases of alleged research fraud has been the absence of a complete set of verifiable data. The rules and recommendations in this section are designed to ensure that all research data are recorded appropriately and that access to them will be available when necessary. The University is aware that scientific investigation may be impeded if undue conditions are placed on the ability of departing investigators to retain custody of original data generated in the course of work performed here. Nevertheless, there are pragmatic reasons for preserving the University's ready access to original data. For example, access to original data may be necessary if the University is to render the most effective assistance in rebutting unjustified claims of fraud made against its researchers. Then, too,

the University is responsible for promoting the collective reputation for integrity of its researchers with public and private granting agencies. The inability to produce original data tends to place the integrity of research in question. Moreover, original data is always considered the best evidence for purposes of avoiding questions of admissibility in administrative or judicial proceedings.

A. RULES

1. Custody of all original data must be retained by the unit in which they are generated. When hospital records, which cannot be kept in the research unit, are used in research projects, summaries must be maintained by the investigator. An investigator who moves to another institution must submit to the department director a written request to remove original data from the University. This request must contain an itemized description of the data and must specify where the data will be located in the future. In granting such requests, the department director must remind the researcher that legally the data are the property of the University, that any inventions made here must be disclosed to the appropriate patent office of The Johns Hopkins University, and that original data must be made available for review if questions of scientific misconduct should arise. If the department director does not approve the removal of data, an appeal may be made to the Dean.
2. To date, no governmental regulations prescribe the length of time researchers must maintain original data. Until governmental regulations appear on this issue, the School will require that original data be retained for at least five years from the date of publication. Beyond that, where questions have been raised regarding the validity of the published data, investigators must preserve original data until such questions have been resolved to the satisfaction of the School and any involved government agencies. The chief of each research unit must decide whether to preserve original data for a given number of additional years or for the life of the unit.

B. RECOMMENDATIONS

1. Original experimental results should be kept in an orderly fashion in such a way that they are accessible and can be easily reviewed by peers. Records should identify when experiments were done and by whom.
2. Machine print-outs or other primary data (e.g. autoradiograms) should be affixed to or referenced from the laboratory notebook.

IV. AUTHORSHIP

Two critical safeguards in the publication of accurate scientific reports are the active participation of each coauthor in verifying any part of a manuscript that falls within his or her specialty area and the designation of one author who is responsible for obtaining coauthor verification. A gradual diffusion of responsibility for multi-authored or collaborative studies has led in recent years to the publication of papers for which no single author was prepared to take full responsibility.

A. RULES

1. One author from within the School of Medicine must be designated responsible for obtaining coauthor verification for any manuscript submitted for publication by a faculty member, fellow, or student as part of his or her activity at the School of Medicine. The designated author must give to the director of an appropriate department or division a copy of the title page of the manuscript, upon which a statement is added to the effect that everyone listed as an author has contributed to the paper significantly, has reviewed the manuscript, and stands behind the parts within his or her own area of expertise. Each listed author must sign this statement. These statements must be kept in the permanent files of the department or division.
2. Any faculty member, fellow, or student who submits an abstract must ensure that all named authors have consented to authorship prior to submission of the abstract. Each named author must be given a copy of the abstract.

B. RECOMMENDATIONS

1. Criteria for authorship of a manuscript should be determined and announced by each department or research unit. Authorship should be given generously, but only to those who have contributed significantly to the research, are prepared to stand behind their findings, and have reviewed the entire manuscript. The referral of patients included in a clinical study does not, in and of itself, constitute a significant contribution warranting co-authorship status. The practice of permitting "honorary authorship" is unacceptable and should be actively discouraged by primary investigators and heads of departments and research units.
2. All publications should credit research findings appropriately by citing relevant observations of others, as well as by recognizing the work and input of all contributors in their own environments.

V. PUBLICATION PRACTICES

Certain practices make it difficult for reviewer and reader to follow a complete experimental sequence. Among these are the premature publication of data without adequate tests of reproducibility or assessment of significance, the publication of fragments of a study, and the submission of multiple similar abstracts or manuscripts differing only slightly in content. In such circumstances, if any of the work is questioned, it is difficult to determine whether the research was done accurately, the methods were described properly, the statistical analyses were adequate, or appropriate conclusions were drawn. Investigators should review each proposed manuscript with these principles in mind.

A. RECOMMENDATIONS

1. The number of publications to be reviewed at times of faculty appointment or promotion should be limited in order to encourage and reward bibliographies containing substantive publications rather than those including a large number of insubstantial or fragmented reports.

2. Published papers should credit sponsors of the work and any acknowledgement requirements in grant and contract documents should be adhered to scrupulously since they are contractual obligations. Moreover, it is important that reviewers and readers be informed of the sponsorship of research projects in order that they may be alert to possible bias in the research arising from a sponsor's financial interest in the results.

VI. LABORATORY GUIDELINES

Because each research unit addresses different scientific problems with different methods, particular units may need to develop their own specific rules or guidelines regarding the prevention of academic misconduct. Such rules or guidelines should be provided to all new investigators when they start work in the unit.

VII. REPORTING ACADEMIC MISCONDUCT

The trust and good faith traditionally associated with The Johns Hopkins University School of Medicine will flourish only if every member of this community bears responsibility for upholding the highest standards of integrity. Should academic misconduct occur, early identification and intervention are in the best interests of everyone. Steps to be taken by anyone who suspects that another's research conduct has been improper are detailed in Procedures for Dealing with Issues of Professional Misconduct. The institution recognizes the risks to persons who report apparent scientific misconduct and has made every effort to protect them as well as those who might be accused in error.

A. RULE

1. It is a professional obligation of faculty, students, or fellows to inform superiors if they have reservations about the integrity of the work of another member of this academic community.

Acknowledgement: *"Guidelines for Investigators in Scientific Research,"* the report of the Committee on Professional Misconduct of Harvard Medical School, was very helpful in the preparation of this statement.

1. Copies are available from the Office of the Registrar of the School of Medicine.
2. While what constitutes "original" or "primary" data may differ from laboratory to laboratory depending on the technology used, in every instance an investigator is expected to maintain an accurate record of experimental data that is as close to the original form of the data as is practical. When the "original" data are so voluminous or are collected and/or modified in atypical ways (for example, in the case of data collected by computer), individual investigators should seek concurrence of their division or department head in deciding what aspect of their research will constitute primary data, bearing in mind the possible future need to support reported findings.

Appendix B-2

Scientific Misconduct: Policy on Allegations Investigations and Reporting

Stanford University

February 3, 1983, Revised February 15, 1995.
Research Policy Handbook Document 2.5, 8 pp.

Appendix C

Examples of Curricula for Teaching the Responsible Conduct of Research

C-1 University of North Carolina at Chapel Hill
Responsible Conduct of Research: University of North Carolina
URL: http://www.ais.unc.edu/responsible_conduct/rcrtoc.html

C-2 University of Minnesota
Education in the Responsible Conduct of Research
URL: http://www.research.umn.edu/ethics/curriculum.html
Date accessed: 11-09-00

C-3 University of California, San Diego
Resources for Research Teaching Ethics
URL: http://www.medicine.ucsd.edu/research/ethics/resources/
Date accessed: 11-09-00

Appendix C-1

Responsible Conduct of Research

University of North Carolina at Chapel Hill
Faculty Committee on Research.

URL: http://www.ais.unc.edu/responsible_conduct/rcrtoc.html

Appendix C-1

Responsible Conduct of Research

University of North Carolina at Chapel Hill

URL: http://www.ais.unc.edu/responsible_conduct/rcrtoc.html

From Responsible Conduct of Research

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Letter from Professor Linda L. Spremulli - Interim Vice-Chancellor for Graduate Studies and Research

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URL: http://www.ais.unc.edu/responsible_conduct/prologue.html

From Responsible Conduct of Research

PROLOGUE

The integrity of the research enterprise rests on the ethical and responsible conduct of investigations and reporting of results. Doing research in an ethical and responsible manner implies that those engaged in this activity are well informed about the standards of behavior accepted by the community of their peers. These include norms, rules and procedures, some of which are specific to a given discipline. This publication has been prepared to meet the following goals:

1. to inform new faculty, research personnel, postdoctoral research associates and students about policies and procedures at the University of North Carolina at Chapel Hill that govern the conduct of research; and

2. to contribute to the education of new students and research personnel on general standards of responsible conduct of research.

We are aware that considerable variations exist on the specific standards within different fields of study. Therefore, those directly involved in research training in different disciplines must be engaged in interpreting and translating the guidelines discussed in this brochure to their students. Research programs must foster the effective transfer of general and specific standards of responsible conduct of research to the new generation of investigators.

The preparation of this publication was made possible by the generous contributions of many colleagues and friends. The Faculty Committee on Research wishes to acknowledge and thank in particular Susan H. Ehringhaus, assistant to the chancellor and senior University counsel; Carolyn W. Elfland, associate vice chancellor for business; Richard L. Clark, scientific integrity officer in the School of Medicine; Margaret A. O'Connor, associate professor of English and American studies; Dwight A. Bellinger, associate professor of pathology; B. Susan Bauer, coordinator of the Committee on the Protection of the Rights of Human Subjects; Donald G. Willhoit, director, Health and Safety Office; Raymond Hackney, biological safety officer; Bob M. Wilson, radiation safety officer; Paul J. Ilecki, administrative assistant to the dean of the Graduate School. Also we would like to thank Robert P. Lowman, Associate Vice Chancellor for Research and Director, Office of Research Services, for creating two scenarios specifically for this brochure. We are also grateful to the Whitehead Institute for Biomedical Research and to Harvard Medical School and the President and Fellows of Harvard College for permission to use and adapt some of their fictional scenarios.

URL: http://www.ais.unc.edu/responsible_conduct/scenarios.html

From Responsible Conduct of Research

SCENARIOS

The Whitehead Institute for Biomedical Research (Cambridge, MA) and Harvard Medical School (Boston, MA) have developed a set of fictional scenarios to instigate and facilitate discussions on scientific integrity. With their permission, we have reproduced here representative scenarios focused on situations which individuals might face in their day-to-day research activities. Although some were written for scientists, all the scenarios can evoke important discussion topics in many different disciplines. Furthermore, Robert P. Lowman, Associate Vice Chancellor for Research and Director, Office of Research Services, created two scenarios intended to exemplify situations likely to be encountered by researchers in the social sciences. The scenarios, interspersed throughout the brochure, are offered as instruments for initiating discussions on standards of conduct and increasing awareness of potential situations in which individuals might be tempted to disregard these standards.

Scenario: At a Professional Meeting

(An English professor working on an important literary figure who died about 50 years ago is giving a paper on a panel devoted solely to the work of that author. The professor presents material he has uncovered since the publication of his well-received biography of a few years earlier. His research had been complicated by the literary figure's testamentary restrictions against direct quotation and publication of her letters, but those restrictions are not mentioned in the presentation today.)

Speaker: And she concludes her long letter to her publisher by saying, "never again will I deal with a company that permits such shoddy workmanship in its product." As you can tell in this and the many other passages I've quoted from this letter today, a sharp rebuke was a potent weapon in her hands. Any questions?

Listener: I've worked with her letters for years as have many others in this room, and I'd love to be able to quote from them as you have today. I have several questions, however. Have the restrictions been lifted? Has the individual library holding the letter you read from given permission for direct quotation? Won't remaining family members and her literary executors be disturbed by the quotations?

Speaker: Well, no. The restrictions are still in force as far as I know since an elderly niece insists that her aunt's wishes be followed. As to your other questions, I have respected the restrictions in all my written work, but in an informal setting such as this, I felt it was all right to quote directly.

Listener: But won't your decision here make it harder for all of us to get access to manuscript collections? Most require signing an agreement to abide by the restrictions in her will.

Speaker: Well then, for Heaven's sake, don't tell the libraries! (An uneasy chuckle ripples through the room.)

Consider:

- What is the responsibility of the researcher to abide by restrictions on the use of manuscript materials such as those mentioned above?
- Is the speaker's decision to quote from letters in oral presentations appropriate?
- Is the listener creating a tense situation over a triviality?

FEDERAL REGULATIONS

The research enterprise in the United States is supported by the federal and state governments, private foundations, and the commercial and industrial sectors of our society. The University of North Carolina at Chapel Hill received $244 million in research contracts and grants from the federal government and other sources in the 1994 fiscal year. This level of research funding places UNC-CH among the best-funded research institutions in the nation. This investment in faculty and student potential at UNC-CH reflects the quality of this University and the public trust in its stewardship. These include the responsible expenditure of funds, but above all the responsible conduct of the research supported by these funds.

The federal government, as the primary steward of public funds, has issued and implemented rules and regulations to guide recipient institutions in the proper management of research awards. Anyone who engages in research, whether funded through federal grants or not, must be aware of these regulations and follow them closely; to do otherwise is irresponsible (in many cases, unlawful) and might jeopardize safety, public trust and future support. Federal regulations, which might impact directly on your research and require your responsible implementation, have been issued in relation to the use of human subjects and vertebrate animals in research, use of radioactive and/or hazardous materials, recombinant DNA technology, misconduct in science, lobbying, conflict of interest, etc. This brochure addresses only some of these regulations.

Scenario: Tenure Track

Participants:

- Dick Matthews, Assistant Professor
- Peter Shelton, Chairman, Biology Department
- Sheila Barnes, Graduate Student
- Sandy Gladstone, Assistant Professor

(Dick Matthews and Peter Shelton are having lunch in the faculty dining room.)
Peter: I know the last six months have been hard on you, but the tenure committee has made its recommendation and the school council will vote next week. I think you can relax now.

Dick: I'm so glad it's almost over. You know, I've been writing all my life, but when I sat down to write the summary of my research accomplishments I went completely blank. I must have written twenty-five drafts.

Peter (laughing): That task affects everyone the same way. You have a terrific record, especially with that new article you have in press in Physiology Today. You took a problem that has plagued the field for 10 years and turned it around so that everyone can see the solution.

Dick: Thanks. It means a lot to me to hear you say that. I'm not sure where the idea came from myself. One day I was watching Rebecca, my six-year-old, draw and she insisted that I pick up a pencil, too. Earlier in the day, I'd been frustrated because experiments in the lab just weren't going the way I'd expected. I started doodling and suddenly I knew what the problem was. When I went back to the bench the answer was clear.

Peter: Well, wherever it came from, the timing couldn't have been better. I'm afraid I've got to go now; I have a student coming in at 1:00. I'll see you at the seminar at four.
(Peter picks up his tray and leaves; several minutes later, Sheila Barnes, a new graduate student in Dick's lab, sits down at the table.)

Dick: Hi, Sheila. How is your reading going?

Sheila: It's going well. I think I've got a pretty good idea where I want to start. I'm going to sit down this afternoon and try to draft a research plan. Then maybe we can talk about it tomorrow.

Dick: That's great. I'll be in my office by 9:30.

Sheila: Oh, by the way, I made you a copy of the titles list from my literature search. I thought you might be interested in the article I circled from the Canadian Journal of Biological Chemistry. I didn't think it would be of much use to me, but the title sounds like it might be vaguely related to the preprint you sent me before I left California. It's certainly an odd place for that topic to appear.

Dick: Thanks, Sheila. I'll take a look at it.

(Several hours later in Dick's office. He puts some papers down on his desk, walks to the window, and then walks back to his desk. He picks up the papers, throws them in the trash, and then retrieves them and walks out of the room.)

(Dick walks into the office of his close friend, Sandy Gladstone.)

Dick: Sandy, I have a big problem, do you have a few minutes to talk about it?

Sandy: Just a few, I promised Elaine I'd be home by 6:30. What is it?

Dick: Do you ever read the Canadian Journal of Biological Chemistry?

Sandy: No, I've heard it's a good journal, but I wouldn't expect it to have much relevance to my work. Why?

Dick: Well, Sheila Barnes was doing a literature search and she came up with this article by Janet Simmons. You remember Janet, we met her at the symposium two years ago in Toronto. Sandy, the article lays out the ideas in my new paper. I can't believe it. I don't remember discussing the topic in Toronto, but it's all here (waving the papers in his hand). I missed it because I never read the Canadian Journal and I know no one else in the department does either.

Sandy: What are you going to do?

Dick: I don't know what to do. I'm sure I developed the ideas independently, and if I withdraw my paper now it might jeopardize the tenure decision.

Sandy: I don't think you have to worry about your appointment. Your record is great even without the paper. Personally, I think you just have to acknowledge Janet's work. If you don't, there might be trouble later. You certainly don't need to withdraw the paper. Couldn't you just call Jim Bascom at Physiology Today and tell him you need to add a footnote? Look, I've really got to go home. I'll talk to you later.

Dick: I need some time to think. Sandy, you won't tell anyone about this will you?

Sandy: No, I won't even ask you about your decision.

(The next morning outside Dick's office:)

Sheila: Dick, thanks again for your comments on my research plan. They really helped. Oh, I almost forgot, did you find that article from the Canadian Journal?

Dick: No, I decided it probably didn't relate much to what we're doing.

Sheila: Oh good, the last thing I need now is something else to read.

Consider:

- What advice would you give to Dick Matthews, the tenure candidate?
- If Sandy Gladstone (Dick Matthews' friend) learned that Dick had decided to ignore the article in the Canadian journal, and he came and asked you whether he should take any action, what would you tell him?

UNIVERSITY POLICIES AND PROCEDURES

The University of North Carolina at Chapel Hill, as the organization responsible for the implementation of regulations issued by the federal and state governments, has formulated policies and procedures to be followed by the University community. Summarized below are those pertaining to research ethics, conflict of interest and conflict of commitment. As you embark on research activities at this University, you must be aware of these policies and procedures. You can obtain copies of these documents from the administrative offices of your department or school.

Policy and Procedures on Ethics in Research

Public trust in the integrity and ethical behavior of scholars must be maintained if research is to continue to play its proper role in the University of North Carolina at Chapel Hill and society. It is the policy of the University that research carried out by its faculty, research personnel and students be characterized by the highest standards of integrity and ethical behavior. Values essential in research conform to those that ideally govern behavior and activities in general society. Among these are honesty, performing your craft with skill and thoroughness, respect and fairness in dealing with others, and responsibilities to people and institutions. Skill and accuracy in collecting and reporting data in your work and, when necessary, prompt publication of errata are important aspects of the research enterprise. Fairness in assigning proper credit in publications for research contributions with regard to both authorship and the published results of others is essential. It is further the policy of the University to inform fully all affected parties if misconduct in research sponsored by, or under the administrative supervision of, the University has occurred. Misconduct in research violates the trust that society places in the scientist. It can not only erode trust, but also waste time and resources in misdirected efforts based on erroneous information.

Each member of the University community has a personal responsibility for implementing the University's "Policy and Procedures on Ethics in Research" in relation to any scholarly work with which he or she is associated and for helping his or her associates in continuing efforts to avoid any activity which might be considered in violation of the policy. Since education is the primary function of the University, educating graduate students, postdoctoral fellows and research associates in the values that govern research practices must be an important part of research training. Failure to

comply with the policy is considered to be a violation of the trust placed in each member of the research personnel and faculty of the University and shall be dealt with according to specified procedures.

For purposes of the policy, misconduct in research means:

1. fabrication, falsification, plagiarism, deception or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting or reporting research;
2. material failure to comply with federal requirements for protection of researchers, human subjects, or the public or for ensuring the welfare of laboratory animals; or
3. failure to meet other material legal requirements governing research.

Additional information regarding the "Policy and Procedures on Ethics in Research" and copies of this document may be obtained from your department chair, dean, vice chancellor and the University legal counsel. You are encouraged to review this policy and to discuss it within your program or department. If you have concerns pertaining to the implementation of this policy, or need further guidance in understanding it, you are encouraged to seek the advice of a trusted staff, faculty or administrator who is familiar with University policies and procedures.

Policy on Conflicts of Interest and Commitment

The number and complexity of relationships between universities and members of their faculties and research staffs on the one hand and private industry, the federal and state governments, and the nonprofit sector on the other hand have grown substantially in recent years. The purpose of the University's "Policy on Conflicts of Interest and Commitment" is to provide guidelines for those relationships that will help to assure the primacy of academic integrity.
Faculty and EPA non-faculty employees (exempt from the State Personnel Act) are encouraged to engage in appropriate outside relationships with commercial companies, the nonprofit sector, and the federal and state governments, if the activities are consistent with the objectives of the University. Such partnerships in support of the University's threefold mission of teaching, research and service are encouraged when they produce mutual benefits to participants and to society. Facilitating the transfer of technology to improve the health and productivity of society is an important goal of cooperative university-industry and faculty-industry relationships.

An essential part of the University's commitment to encourage the dissemination of its scholarly research activity and worthwhile technology transfer is protection of the University's integrity and its fundamental goals of education and open inquiry. To this end, faculty and EPA non-faculty employees are required by the "Policy on Conflicts of

Interest and Commitment" to avoid conflicts, and the appearance thereof, in relationships with outside organizations. The policy requires each faculty member and EPA non-faculty employee to disclose annually his or her financial relationships, time commitments and other relevant information associated with potential conflicts with University responsibilities.

Of particular concern is the impact on students and other trainees of activities that could potentially create conflicts of interest or commitment. Because of this concern, it is essential that all faculty and EPA non-faculty employees demonstrate at all times their commitment to the highest intellectual and ethical standards in all aspects of research, teaching and service, particularly where opportunities for conflict may exist. As a corollary, the training experiences of students are expected to incorporate the value of objectivity and the importance of public trust.

The term conflict of commitment relates to an individual's distribution of effort between his or her University appointment and outside activities. The latter may include professionally related and generally encouraged activities such as involvement with professional societies, participation on review panels and external professional activities for pay. These activities often promote professional development and enrich the individual's contributions to the institution, to the profession or discipline, and to the community.

The University's policy states that faculty and EPA non-faculty employees must devote their primary professional loyalty, time and energy to their teaching, research, service and, where applicable, patient care responsibilities at the University. Accordingly, outside activities and financial interests must be arranged so as not to interfere with the primacy of these commitments.

The term conflict of interest refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, a faculty member's or EPA non-faculty employee's professional judgment in exercising any University duty or responsibility or in conducting or reporting research. The bias that such conflicts may conceivably impart could adversely affect many University activities including decisions about personnel, equipment and supplies; advising of students; collection, analysis and interpretation of data; sharing of results; choice of protocol; and use of statistical methods.

The University's policy states that faculty and EPA non-faculty employees must avoid conflicts of interests that have the potential to affect adversely the University's interests, to compromise objectivity in carrying out University responsibilities or otherwise to compromise the performance of University responsibilities. Accordingly, outside activities and financial interests must avoid such conflicts. Furthermore, all conflicts, real or potential, must be fully disclosed to the University.

Additional information regarding the "Policy on Conflicts of Interest and Commitment" and copies of this document are available from your department chair, dean, and the University legal counsel.

Scenario: Late One Night

Participants:

- John Palant, Grad Student
- Sandra Dunn, Postdoc
- Barbara Steel, Professor

(After a group meeting on a Tuesday afternoon:)

Professor Steel: Sandra, you were unusually quiet at group meeting today. I thought you'd planned to discuss the results of your last fractionation. I wanted to go over the data with you this morning, but when I checked at your bench at 11:00 you hadn't come in. Is something wrong?

Sandra: No, nothing's wrong. I was reading the gels late last night and I overslept. I have a meeting now outside the building, but I'll knock on your door when I come in tomorrow.

Professor Steel: I'll be here, but try to catch me before lunch. I have appointments most of the afternoon.

(Three days later, in the hallway:)

Professor Steel: John, have you seen Sandra? She said she'd stop by on Wednesday to go over her data with me, but I haven't seen her since group meeting.

John: She hasn't been around much during the day, but I know she's been working at night. You know, it's strange. Monday she said she had an idea that might help me find the co-activator for my DNA-binding protein. I asked her about it at the meeting, but she said she'd been wrong and I should forget about it. I've been so frustrated the last few weeks that I haven't been coming back in after dinner.

Professor Steel: I know it's been hard, but I'm sure you're on the right track. You found the DNA-binding protein; you just need to find the coactivator to make the whole thing work. The changes we discussed at group meeting might do the trick. I've got a committee meeting now. Will you leave a note on Sandra's desk asking her to call me?
John: Sure. I'll let you know on Monday how things worked out.

(Monday morning in Professor Steel's office, a knock at the door:)

Professor Steel: Come in. Oh, Sandra, it's you, I've been trying to reach you for three days. Where've you been?

Sandra: Take a look at these. (She hands Professor Steel some papers.)

Professor Steel: What are they?

Sandra: I've drafted two papers. One describes the work we planned to talk about last week. I realized when I read the gels last Monday that I'd accidentally found the answer to John's problem. Suddenly, it was clear that we had an entirely new class of DNA binding proteins and their partner co-activators. I just needed one more experiment to confirm the results.

(Professor Steel quickly reads through the two papers.)

Professor Steel: This is terrific; I can't believe we didn't see this before. But Sandra, what about John? Why didn't you tell him you'd found the answer to his problem? I mean, this is his thesis project. You could have done the last experiment together. He should be included in the final paper, too.

Sandra: I don't think so. I've thought about it a lot. I put his name on the first paper because I started with his technique for isolating the DNA-binding activity, but the second paper on the coactivator and its implications for all regulation is mine. I want it to stand out in the journal with just two authors.

Professor Steel: I can't force you to put John's name on the paper, but I think you should consider it again. I like to think we all work together in this lab. Have you shown these papers to him yet?

Sandra: No. I thought I'd present them at group meeting tomorrow. What do you think?

Consider:

- If you were Professor Steel, would you insist that John Palant be included in the second paper?
- Should Sandra have done the experiment or should she have told John about her idea?

GUIDELINES

It is the intent of the University not only to inform you about rules and regulations, policies and procedures, but also to guide you in the implementation of these directives. Toward this end, guidelines have been prepared to help you in the proper conduct of your

activities on the Carolina campus. You should consult the "Guidelines for Sponsored Research at the University of North Carolina at Chapel Hill" (June 1, 1988), for information not covered in this brochure.

Guidelines for Research

(Adapted from the 1992 Graduate School Handbook)
It is important for the University as well as for the individual scholar and investigator not just to know how to deal with fraud in research when it has occurred but to be prepared to prevent such fraud from occurring in the first place. You should comport yourself in such a way that even the suspicion of fraud is unlikely to arise and, if it does arise unjustly, you have the records in hand to prove that the allegation was unwarranted. Therefore, the Faculty Committee on Research devised the present guidelines, relating to data gathering, storage and retention; publication practices and authorship; and supervision of research personnel. Many are based on similar guidelines already extant at other institutions or in UNC-CH's School of Medicine. Although they do not have the force of law or regulation, they are strongly commended to your attention as desirable and prudent practices.

The most important ingredients in avoiding fraud are the integrity and high ethical standards of the research project leader. If a researcher cuts corners and is more concerned with next week's publication or next month's research grant renewal than with a life-long reputation and the integrity of the research, these guidelines are not likely to be of much help. They have been designed to assist those who are determined to maintain high standards in their research careers.

In making the following recommendations, the Faculty Committee on Research recognizes that there are wide variations from one field to another. Nevertheless, the committee strongly urges adherence to these guidelines, if necessary with appropriate modifications to accommodate solidly established practices within a field.

General University Policies

Anyone engaged in research must abide by University, divisional, and departmental policies and procedures concerning research.

Data Gathering, Storage and Retention

A common denominator in most cases of alleged scientific misconduct has been the absence of a complete set of verifiable data. The retention of accurately recorded and retrievable results is of utmost importance for the progress of scientific inquiry. A scientist must have access to his or her original results to respond to questions including, but not limited to, those that may arise without any implication of impropriety. Moreover, errors may be mistaken for misconduct when the primary experimental results are unavailable.

Recommendations:

1. Original research results should be promptly recorded, and should be kept in as organized and accessible a fashion as possible.

2. The research project leader should retain the raw research data pertinent to publication for a reasonable period of time (normally five years) after publication. In no instance should primary data be destroyed while questions may be raised which are answerable only by reference to such data.

3. Documentation of required committee approvals from the human subjects in research committee (Institutional Review Board [IRB]) and the animal use in research committee (Institutional Animal Care and Use Committee [IACUC]) should be retained in the research project leader's files for a period of five years.

Publication Practices: Authorship

A gradual diffusion of responsibility for multi-authored or collaborative studies has led in recent years to the publication of papers for which no single author was prepared to take full responsibility. Two critical safeguards in the publication of accurate scientific reports are the active participation of each coauthor in verifying that part of a manuscript that falls within his or her specialty area and the designation of one author who is responsible for the validity of the entire manuscript.

Recommendations:

1. An author submitting a paper should never include the name of a coauthor without that person's consent. Each coauthor should be furnished with a copy of the manuscript before it is submitted. Coauthorship should be offered to (and limited to) anyone who has clearly made a significant contribution to the work.

2. Anyone accepting coauthorship of a paper should realize that this action implies a responsibility as well as a privilege. If a potential coauthor has serious reservations concerning a publication, the individual should decline coauthorship.

3. The senior author or authors of a paper, individually or in concert, should be prepared to identify the contributions of each coauthor.

4. Simultaneous submission of essentially identical manuscripts to different journals is improper.

5. As a general principle, research should be published in the scientific literature before reports of such research are released to the public press.

Supervision of Research Personnel

Careful supervision of all research personnel by their research project leaders is in the best interest of the trainee, the institution and the scientific community. The complexity of scientific methods, the necessity for caution in interpreting possibly ambiguous data and the need for advanced statistical analysis all require the research project leader's active role in the guidance of research personnel.

Recommendations:

1. All research personnel, such as technicians, graduate students and postdoctoral trainees, should be specifically supervised by a designated research project leader.

2. The ratio of research personnel to project leaders should be small enough that close interaction is possible for scientific interchange as well as oversight of the research at all stages.

3. The project leader should supervise the design of experiments and the process of acquiring, recording, examining, interpreting and sorting data. (A project leader who limits his or her role to the editing of manuscripts does not provide adequate supervision.)

4. Collegial discussions among project leaders and research personnel constituting a research unit should be held regularly, both to contribute to the scientific efforts of the members of the group and to provide informal peer review of research results.

5. The project leader or supervisor should provide each investigator (whether student, postdoctoral fellow or other research personnel) with applicable governmental and institutional requirements for conduct of studies involving healthy volunteers or patients, animals, radioactive or other substances, and recombinant DNA.

Date: April 28, 1989
(Received by the Faculty Council)

Scenario: Home Runs

Participants:

- Jim Farber, Postdoc
- Daniel Stern, Assistant Professor
- Dick Winston, Professor
- Anna Wong, Graduate Student
- Paolo Donato, Graduate Student

(Between the fifth and sixth innings at a faculty-student softball game, postdoc Jim Farber stops to talk for a minute with Daniel Stern. Stern is an assistant professor; he and Farber had the same adviser in graduate school.)

Jim: Hi Dan, I haven't seen you at beer hour lately. What have you been up to besides hitting home runs?

Dan: Things have been very busy in the lab, and I've received 10 papers to review in the past five weeks.

Jim: I don't know how you manage it all; anything exciting in the papers?

Dan: Well, as a matter of fact, Peter Van Norman's group in Sweden has discovered that the pbj gene has a third exon. It's top secret. I wouldn't tell you, but I know you've stopped working on the gene last year.

Jim: Actually, we're working on a related gene, pbh; we suspect that the product of pbh might form heterodimers with the pbj protein. Oh look, you're up at bat and I better move into the outfield.

(One day later: Jim Farber is reporting his conversation with Dan Stern to his lab director Dick Winston and others in his research group.)

Dick: Jim, are you sure that Dan said pbj has a third exon? That would explain why we had so much trouble cloning it. It might also explain the problems we've been having with pbh.

Jim: I'm sure that's what he said. In fact, last night I came back to the lab after the game and reanalyzed our data on pbh. It all fits. I don't know why we didn't see it. We just need two experiments to confirm the results, and then we can write a paper that describes pbh explores the relationship between the pbh and pbj products.

Paolo: Wait a minute, Jim. You can't use information you got from Dan. He had no business telling you in the first place. You remember how secretive Van Norman's group was at the meeting in Madrid last month. You really should call them and tell them we've heard about their results.

Jim: I disagree. I didn't go looking for this information. Their paper most likely will be published before ours anyway.

Paolo: I can't believe you really feel that way. This information probably saved us two months work on pbh and it will help us confirm our theories about the relationship between pbj and pbh. We've got to call Van Norman's group.

Anna: I think you're being overly dramatic, Paolo. If we give them full credit for their contributions in our article, that should be enough. After all, if we call Van Norman's group now we'll probably get Dan in trouble. I'm sure he didn't realize the intensity of the competition between Van Norman's group and ours, and Van Norman will get the credit for cloning pbj. What do you think, Dick?

Consider:

- Is Jim Farber at fault in the first conversation (for asking Dan Stern if he's noticed anything interesting in the papers)?
- Should Jim Farber have used the information received from Dan Stern to reanalyze his own data?
- How would you answer if you were Dick Winston?

Guidelines for the Use of Human Subjects in Research

The code of ethical conduct mandates that the rights of human beings used as subjects in research be protected: risks must be minimized, written informed consent obtained, and confidentiality or anonymity maintained. To assure that these rights are upheld, federal legislation requires that institutions receiving federal funding for research comply with regulations from the Department of Health and Human Services (DHHS) for the protection of human research subjects. These regulations require that all behavioral or biomedical research involving human subjects conducted at or sponsored by the institution (and not exempt from the requirement) be reviewed by an Institutional Review Board (IRB) prior to the involvement of those subjects. The University maintains five IRBs for these purposes: one in the Division of Academic Affairs and one each in the Schools of Medicine, Dentistry, Nursing and Public Health. In general, research will be reviewed by the IRB associated with the researcher's home department or school; however, research involving patients at the UNC-CH hospitals must be reviewed by the IRB of the School of Medicine.

Each IRB has its own procedures; researchers are encouraged to contact the relevant IRB to obtain the necessary guidelines, forms and schedule of meeting dates. In general, each IRB will require an explication of the rationale and design of the study; subject characteristics and selection procedures; potential risks and benefits; procedures for

minimizing risk; procedures and forms for obtaining informed consent; and procedures for the appropriate handling and reporting of data to maintain confidentiality or anonymity. The investigator (and the faculty advisor, if student research is proposed) must sign an assurance statement agreeing to abide by the rules and regulations of the University. Protocol changes must be approved and annual IRB review of the project is required.

The IRB will review the application to ensure that risks to subjects are minimized (through the use of sound research design, no exposure to unnecessary risk, and where possible, the use of procedures already being performed); risks are reasonable in relation to the benefits; selection of subjects is equitable; informed consent is sought and documented; and, where appropriate, provisions are made for monitoring data collection to assure subject safety, protection of privacy and maintenance of confidentiality.

Certain research involving human subjects may be exempt from IRB review or receive an expedited review, if the research entails no more than "minimal risk" and meets other categorical requirements. Research involving certain vulnerable populations (e.g., prisoners, minors, fetuses, pregnant women) cannot be exempted from or receive expedited review. In general, the determination of exemption or expedited status is not made by the individual investigator but by the appropriate IRB.

Investigators are referred to "The University of North Carolina at Chapel Hill Assurance for Compliance with the DHHS Regulations for Protection of Human Subjects" and to the manuals of the respective IRBs for additional information and guidance. The staffs of the IRBs and the University's Office of Research Services are also available to provide consultation.

Guidelines for the Use of Vertebrate Animals in Research

The laws and regulations that govern the use of animals for research have recently changed to reflect society's increased concerns for the humane care of animals in research. Every investigator is obligated to understand these regulations, as well as generally accepted ethical principles, and to incorporate them into their research efforts. Although there are many federal, state and local regulations governing the use of animals, there are two main sets of regulations with which the investigator should be familiar. These are the "Animal Welfare Act" (AWA) enforced by the United States Department of Agriculture (USDA) and the Public Health Service (PHS) "Policy on Humane Care and Use of Laboratory Animals" administered by the Office for Protection from Research Risks (OPRR). Many of the USDA regulations are similar to those of the PHS policy. Both of these policies require each research institution to establish an Institutional Animal Care and Use Committee (IACUC) with defined responsibilities. These include the review of all proposed activities related to the care and use of animals, semi-annual review of the institution's program for animal care and semi-annual review of all animal facilities and animal research areas. Federal policy directs the IACUC to evaluate research proposals by investigators to ensure that the number of experimental animals is

appropriate; non-animal alternatives are used if possible; any pain or distress is minimized; use of animals has been justified; activities do not unnecessarily duplicate previous efforts; personnel are appropriately qualified; and animal activities are in accord with the USDA regulations and PHS policy.

Many of the standards in the USDA regulations and PHS policy are very precise, especially those concerning the care and housing of animals. The standards include requirements for temperature, humidity, lighting, cage space, cage cleaning, room air exchanges, equipment and, for some species, programs that enrich the animals' living environment.

As with most aspects of scientific research, the honesty and integrity of the individual researcher is required to comply with these standards.

Questions about the use of vertebrate animals in research should be directed to the chair of the Institutional Animal Care and Use Committee, the Office of Research Services or the University legal counsel.

Scenario: The Case of the Pressured Postdoc

Ben, in his final year as a postdoc, works in a well-known lab on a project recognized to be on the cutting edge of his field. There is enormous pressure to get papers out as expeditiously as possible as the competition is always pressing. Ben is under more stress than usual because he is also job hunting and was told he needs to bolster his C.V. The deadline for submission of abstracts to his society's annual scientific meeting is in two days and Ben is convinced that presenting a paper at that meeting would give him visibility that would enhance his job search.

The problem is that the data are not quite in place. He needs four or five more experiments which should take two months to complete. Fortunately, the trends in the data seem clear and he is certain that he can extrapolate accurately enough to fit in a few data points which will permit him to draw general conclusions for the abstract.

Another encouraging circumstance is that his mentor and lab chief, Dr. Santos, just gave Ben a copy of a colleague's manuscript that he is reviewing for a journal. He feels Ben's work would benefit by his reading the paper. Several of the proposed experiments and implications for future research described in the manuscript are exciting, new to Ben and fit well with Ben's work. Some ideas from the manuscript seem logical and would certainly add substance to Ben's abstract. Ben's conscience is assuaged that he is not plagiarizing since the manuscript has not even been accepted for publication and, in fact, his abstract will be in print first. Besides, he is careful to paraphrase, including no text from the manuscript.
His friend John, a trainee from another lab, comes in to help Ben write up the abstract. In looking at the data, John notes that two values are outliers, undoubtedly the result of

some "noise" in the system. John advises Ben to drop these values in order to trim and smooth the curve. Ben is surprised by this advice, but John assures him that "everybody does it" and that including these points will only confuse the reader. John cites the example of a physicist who, in a famous paper, apparently dropped many observations. Despite cooking the data by claiming that the published data included all observations, he nonetheless won the Nobel prize and went on to a highly successful career. Because of the submission deadline, Ben realizes that he cannot repeat his experiments to see if he can replicate his results.

Dr. Santos, Ben's lab chief, is a very successful researcher who is on the lecture circuit. Before leaving town, he tells Ben to go ahead and send in the abstract, and leave him a copy that he can read when he returns next week. Ben has always appreciated the freedom that his chief provides. He never has to fear that his chief is constantly looking over his shoulder like some chiefs do. John's chief does that and has even told John what results he is expected to get. Ben's chief rarely even asks to review Ben's lab books which is really a relief since they are in such disarray. Often during an experiment things get so hectic that Ben has to postpone entering the data till the next day. And occasionally data and even his notebooks get misplaced. The only request that his chief makes is that his name be included on all of Ben's manuscripts. Ben is happy to oblige knowing that by keeping his chief happy, a good letter of recommendation will be forthcoming. He expects his chief to be pleased to find on his return that Ben has been industrious, sending off the abstract not only for the meeting but also in the form of a short paper for their field's journal.

Consider:
This case raises a number of issues with which investigators must grapple. Some of the issues that you may wish to discuss include (but are not limited to):

- the consequences of the pressure to publish
- whether or not one can justify sharing privileged information
- the definition and manifestations of plagiarism
- the nature, potential justifications and implications of fabrication, trimming and cooking data
- expectations related to the collection, retention and reporting of data
- the differences, if any, in reporting data that will be submitted as an abstract or as a journal article
- the role and obligations of the mentor, including the optimal level of supervision and his/her place within the list of authors
- the distinction between honest mistakes and deliberate unethical behavior which may focus on the role of intent in misconduct.

Guidelines for the Use of Hazardous Materials in Research

An important component of research today is knowing how to handle hazardous substances to minimize risks to the experimenter, the campus community and to the environment. The principal investigator (PI) is responsible for the education and training necessary to handle hazardous materials safely. The PI must ensure that the laboratory adheres to University guidelines. The University, in turn, is responsible for adhering to state and federal regulations.

Ultimately the laboratory's PI is responsible for educating and training laboratory personnel to handle hazardous materials safely; however, research personnel must take the initiative to inform themselves about the risk inherent in using the materials planned in the protocol. This can be a daunting task, especially if pioneering research is breaking new ground in the laboratory. Nevertheless, researchers must stay informed about the risks involved in the procedures performed, because all research personnel are responsible for their own conduct.

Obtaining Information

1. If research is likely to involve chemical compounds whose properties are unfamiliar, researchers should consult a copy of the Merck Index. This superb index has entries that are brief and to the point.

2. Each laboratory must have a "Material Safety Data Sheet" (MSDS) on file for every hazardous substance. Researchers should consult these sheets when using a particular compound for the first time. Research personnel also should be certain to keep the file up-to-date by requesting the latest MSDS from the vendor when placing an order. Copies of MSDSs also may be obtained from the Health and Safety Office.

3. The PI must have a copy of the University's "Laboratory Safety Manual" and a "Laboratory Safety Plan" on file and must hold a meeting with members of the laboratory to discuss these documents' contents. The plan lists the hazardous materials that are used, how and where they are stored, and how they are handled and disposed.

4. Before beginning work in a new laboratory, personnel should take the time to find out the location of the nearest fire alarm, fire extinguisher, safety shower, eye wash station and spill kit. This is especially important for students who rotate among several laboratories during their first year of graduate study.

5. Procedures for the use of radioactive materials are quite specific, due to state and federal regulations. The PI must have a copy of the University's "Radiation Protection Manual" on file. The laboratory will be inspected at least twice a year (at random times) to ensure compliance. The PI must review the responsibilities that each member of the laboratory has concerning the ordering, receipt, storage,

use and disposal of radioactive substances. Research personnel must comply with these regulations.

6. Procedures for the use of biohazardous agents are governed by state and federal regulations. The PI of every laboratory where such agents are found must have a copy of the University's "Biological Safety Manual" on file. Research personnel must comply with these regulations.

7. Procedures for the use of blood and other potentially infectious bodily fluids are also governed by state and federal regulations. Employees who are potentially exposed to blood and other bodily fluids must receive special training and be offered vaccine free of charge. PIs whose research involve such agents must have on file a copy of the University's "Exposure Control Plan". Research personnel must comply with these regulations.

8. Disposal of laboratory waste, including chemical, biological and radioactive waste is controlled by state and federal regulations. The PI must train research personnel in the safe disposal of these wastes. These wastes are normally not discarded along with ordinary trash or through the sewer system. Questions regarding disposal of labora-tory wastes should be directed to the Health and Safety Office.

9. UNC-CH requires attendance at orientation training courses on the use of hazardous materials in the laboratory, including use of hazardous chemicals and radioactive materials, and on the handling of human blood and other potentially infectious materials. These courses are legally mandated by state and federal regulations and documentation of attendance at these training courses must be kept on file in the laboratory.

10. Questions about how to handle hazardous substances to minimize risks should be directed to the Health and Safety Office.

Inspections

Currently, laboratories are inspected on a random schedule to monitor their safe use of hazardous materials and radioactive substances. Laboratories with good safety records are monitored less frequently. Copies of safety records must be kept on file by the PI. Project members may ask to see copies of the last inspections to ensure their understanding of the safety procedures and to become aware of any problems that the laboratory has had in the past. While it might appear that a particular citation involved a trivial matter that did not itself constitute a serious hazard, a laboratory researcher's careful adherence to safety policies also reflects the level of integrity in science necessary for pioneering research. A particular regulation that seems unnecessary should not be ignored. Instead, project members should find out why the regulation is enforced; then, if not satisfied with the explanation, they should work with the Health and Safety Office to change the regulation.

Summary of Documents on File in Your Laboratory

1. Laboratory Safety Plan
   The PI must prepare this plan and discussed it each year with all members of the laboratory. (For a more complete description, please see page 33.)

2. Laboratory Safety Manual
   This manual is prepared by UNC-CH. It contains emergency phone numbers, summaries of safety practices, lists of regulated carcinogens, hazardous substances, and suggested storage and disposal procedures. It also contains the "Lab Worker Registration Form" that each laboratory member and the PI must fill out and return to the Health and Safety Office.

   If applicable, the following documents must be kept on file in the laboratory:

3. Material Safety Data Sheets
   (For a more complete description, please see page 28.)

4. Radiation Protection Manual
   This manual is prepared by UNC-CH. It contains the "Radiation Worker Registration Form" that each laboratory member and the PI must fill out and return to the Health and Safety Office (Appendix B) and the "Certification of Current Inventory" (Appendix C) that must be filled out each time the laboratory orders radioactive materials. This document also explains the "Inventory Record and Radioactive Waste Disposal" forms, principles of radiation protection, survey requirements, personnel monitoring and emergency procedures.

5. Biological Safety Manual
   This manual is prepared by UNC-CH and describes safe handling procedures for pathogens. It includes procedures and forms for registering recombinant DNA experiments with the Institutional Biosafety Committee.

6. Exposure Control Plan
   This plan is prepared by UNC-CH. It contains procedures for the safe handling of blood and other bodily fluids as well as personnel training requirements and vaccination options.

Scenario: Conflict of Interest

Three faculty members in the same academic department have formed an outside consulting firm, and each consults with the firm one day per week. Each of the three

faculty members is an active member of the graduate faculty at the university, and each is serving as advisor or major professor to several graduate students.

As the consulting business grows, the professors decide to hire additional staff at their company. They have a special need for technically trained staff members, and so they decide to hire some of their own graduate students on a part-time basis. The rationale for hiring their graduate students is several-fold. First, they are known entities. Second, they are well trained in the specific areas of expertise that are the focus of the company. Third, there is insufficient graduate student support in the department, and this outside employment can help ease the fellowship shortage. Fourth, with real world technical employment experience, the faculty members reason that their students will be more employable after completing their degrees.

All is fine until the company has a major project due for a client at the same time one of the graduate students~who is key to completion of the project~has a major seminar presentation scheduled in a course taught by a faculty member who is not a principal in the company. One of the partners in the company places pressure on the graduate student to put in longer hours at the company, even though the graduate student believes she needs the time to prepare for her seminar presentation.

Consider:

- Should faculty members avoid all instances of dual relationship with their students (e.g., major professor and employer), or are some forms of dual relationship acceptable? If some dual relationships are acceptable and other unacceptable, how can you tell the difference?
- Some writers suggest that the power differential between faculty member and student gives the student in this situation little practical recourse for redress of grievances. How should the student proceed in this case to protect her own interests?

Guidelines for Laboratory Safety Plan

"Laboratory Safety Plans" for individual laboratories are required by the Occupational Safety and Health Administration (OSHA) regulation, "Occupational Exposures to Hazardous Chemicals in the Laboratories," commonly referred to as the OSHA Laboratory Standard. This standard requires a written plan that sets forth procedures, equipment, personal protective equipment and work practices capable of protecting employees from health hazards presented by the chemicals used in the laboratory. At UNC-CH this plan consists of the "Laboratory Safety Manual", which covers general safety procedures for University laboratories, and a "Laboratory Safety Plan" prepared by the Principal Investigator to address the specific hazards and precautions in a specific laboratory. The "Laboratory Safety Plan" identifies the hazards in the laboratory, describes specific handling procedures and precautions for special hazards, and outlines emergency safety procedures in the event of a fire or chemical spill. The "Laboratory Safety Manual" and "Laboratory Safety Plan" must be available to all employees in the laboratory; the contents of these documents must be discussed with each employee.

Instructions for the preparation of "Laboratory Safety Plans" are found in Chapter II of the "Laboratory Safety Manual."

Scenario: Appropriation of Data and Authorship

A doctoral student completed and successfully defended his dissertation and received his Ph.D. The then-former graduate student accepted non-academic employment in a position where publication was not expected. About a year later, a member of the dissertation committee~not the major professor, but an individual who had played an instrumental role as a consultant on the substance and methodology of the dissertation~submitted an article to a refereed journal using the data of the dissertation as the basis of the article. The article was accepted for publication and was in press.

The article had been submitted with the faculty member as the first author and the former graduate student as the second author. No other authors were listed. The manuscript did not mention that the data were collected as part of the dissertation of the second author.

The submitted manuscript came to the attention of a senior member of the department, who was part of a committee considering the first author for promotion from associate professor to professor. The manuscript "in press" was part of the documentation provided by the faculty member under consideration for promotion. The senior faculty member thought the order of authorship unusual and was concerned that the manuscript did not mention its dependence on the dissertation. Because the senior faculty member knew the former graduate student well, he called the former student and learned that the former student did not know the manuscript had been submitted, had not cooperated in the preparation of the manuscript, had never seen a copy of it, and believed he should have been senior author on any paper derived from the dissertation.

Consider:

- What should the senior faculty member do?
- Are there circumstances that would justify the action of the faculty member who prepared and submitted the manuscript for publication?
- Should the author of a dissertation always be first author on any derivative publication?
- Would the answers to the questions above be different if the faculty member who wrote the article was the student's major professor?

Guidelines for Researchers Using Recombinant DNA

The policy of this University states that all PIs are responsible for complying with the "NIH Guidelines for Research Involving Recombinant DNA Molecules," regardless of their research projects' funding sources. At UNC-CH the majority of work with recombinant DNA can be grouped into the following three categories:

1. Some recombinant DNA work is exempt from the Guidelines (Section IIID of the Guidelines). This group includes (but is not limited to) experiments that: a) use as host-vector systems E. coli K-12, Saccharomyces cerevisiae, Saccharomyces uvarum, or Bacillus subtilis and their plasmids; b) use recombinant DNA molecules containing less than 1/2 of any eukaryotic genome that are propagated and maintained in cells in tissue culture; and c) do not meet any of the conditions listed in section 2 below. These experiments should be reported on Appendix A of the "Internal Processing Form" from the Office of Research Services when applying for a grant.

2. Prior approval by the Institutional Biosafety Committee (IBC) is required for recombinant DNA work that involves: a) the release of genetically engineered organisms to the environment; b) human, animal or plant pathogens; c) genes for toxins or other potentially dangerous products; d) cultures of more than 10 liters; e) infection of plants or animals with microorganisms altered by genetic engineering; f) whole-organism transformation of vertebrates, invertebrates or plants; or g) human subjects. For these experiments the form "Registration of Recombinant DNA Experiments" should be completed and sent to the Health and Safety Office. An additional form should be completed for gene transfer experiments involving whole animals or plants. These forms can be obtained from the Health and Safety Office.

3. Some recombinant DNA work not included in either of the above categories falls under the guidelines and must be reported to the IBC, although prior IBC approval is not required. Examples include: a) experiments in which all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes; b) experiments involving recombinant DNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (with some restrictions); and c) many, but not all experiments involving whole plants. These experiments are to be reported on the form "Registration of Recombinant DNA Experiments."

For experiments that do not fall clearly into one of these groups, consult the Guidelines found in Chapter 11 of the "Biological Safety Manual" and the IBC. All experiments involving recombinant DNA must be carried out at a minimum of biosafety level 1 (see the "Biological Safety Manual"). To verify whether experiments are exempt, to obtain copies of the "NIH Guidelines" or to obtain copies of the registration forms for IBC approval, contact the Health and Safety Office.

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Appendix C-2

Resources for Teaching Research Ethics

Research Ethics Program -University of California, San Diego

URL: http://medicine.ucsd.edu/research/ethics/resources/

Appendix C-2

Resources for Teaching Research

Research Ethics Program -University of California, San Diego

URL: http://medicine.ucsd.edu/research/ethics/resources/
Date last modified = June 1, 1999

[Note: This document contains many links to other html documents on the word wide web. The reader should regard this, in effect, as a table of contents, and should consult the URL given above using a Web browser. In that manner, the reader can readily access the links to other materials.]

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Authorship and Publication (Journal of the American Medical Association)

Authorship Task Force (Council of Biology Editors)

Uniform Requirements for Manuscripts (International Committee of Medical Journal Editors)

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Scientific Integrity (Virginia Commonwealth University)

"Ethics and survival skills in academia" (under development) (University of California, San Diego)

Syllabi in Ethics (University of San Diego)

Survival Skills Web Sites

Survival Skills and Ethics Program (University of Pittsburgh)

Preparing Future Faculty

Reshaping the Graduate Education of Scientists and Engineers (National Academy of Sciences)

Ethics Web Sites

On Being a Scientist: Responsible Conduct in Research (National Academy of Sciences)

Ethics Update (University of San Diego)

On-line Science Ethics Resources (Virginia Polytechnic Institute and State University)

Funding Announcements

Research on Ethical Issues in Human Studies (NIH)

Mentored Scientist Development Award in Research Ethics (NIH)

Short-Term Courses in Research Ethics (NIH)

Ethics Centers and Programs

Association for Practical and Professional Ethics (Indiana University)

Center for Bioethics (University of Minnesota)

Center for Computing and Social Responsibility (De Montfort University)

Center for the Study of Ethics in the Professions (Illinois Institute of Technology)

Ethics Center for Engineering and Science (Case Western Reserve University)

Institute for the Study of Applied and Professional Ethics (Dartmouth)

Poynter Center (Indiana University)

Program in Ethics in Science and Medicine (University of Texas Southwestern Medical Center at Dallas)

Guidelines on Integrity of Research

FEDERAL

Integrity of Research Policy (National Science Foundation)

Integrity of Research Policy (Public Health Service)

INSTITUTIONAL

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Integrity of Research Policy (UCSD)

Guidelines for Conduct of Research (NIH, Intramural)

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Appendix C-3

University of Minnesota

Education in the Responsible Conduct of Research

URL: http://www.research.umn.edu/ethics/curriculum.html
Date accessed: 11-09-00

Appendix C-3

Education in the Responsible Conduct of Research

A Curriculum and Guide for Course Development
University of Minnesota

URL: http://www.research.umn.edu/ethics/curriculum.html

[Note: This document contains many links to other html documents on the word wide web. The reader should regard this, in effect, as a table of contents, and should consult the URL given above using a Web browser. In that manner, the reader can readily access the links to other materials.]

Last year in accordance with the Education in the Responsible Conduct of Sponsored Research and Grants Management Policy, a faculty committee was appointed by Christine Maziar, Vice President for Research and Dean of the Graduate School. Working through the l998- l999 academic year the committee developed a curriculum and guide for a course. This curriculum will serve as the foundation for the development and delivery of educational programs in responsible conduct and the management of sponsored projects for faculty.

The curriculum identifies 10 important topics relevant to the responsible conduct of research and offers learning objectives, University policies, content outlines, case studies, and references for each topic.

Although not a final product, this Curriculum is made available to emphasize the importance of the educational program and to facilitate consistency in discussion of these important ethical issues through both the graduate programs and the faculty and staff development programs. Please refer comments and suggestions to Rschtrng@tc.umn.edu

Minor modifications were made to the presentation of the material to facilitate navigation on this website, 1/14/99.

Prologue

Marty Dworkin, 9/15/99

The past few decades have seen a remarkable intensity of the social and commercial consequences of research and scholarship, as well as an attendant increase in administrative complexity. The significant increase in public funding of research has led to increased scrutiny of the ways these funds are used, and to increased demands for accountability on the part of the investigators. It is therefore necessary to raise the level of awareness of these issues by all those involved in the research effort.

The matter is further complicated because, as academics, our scholarship is intertwined with our responsibilities as graduate mentors and teachers. The University has mandated that we respond to this matter explicitly and effectively. The strategy that has evolved has been to formulate a syllabus for a course in "The Responsible Conduct of Research" that will be required of all faculty, students and staff.

We have divided the subject matter into 10 categories; thus, they may be clustered to suit the peculiar requirements of students, faculty or staff, or for each disciplinary group. The topics are as follows:

History and Values Relating to Research and Scholarship
Social Responsibility; Scientific Fraud; Reporting Misconduct
Authorship
Plagiarism; Peer Review
Research Data Management
Funding; Fiscal Management
Intellectual Property; Conflict of Interest
Environmental Health and Safety
Animal Subjects
Human Subjects

NOTE: for purposes of this web site, the ten topics were reorganized as shown on the navigation bar on the left.

These sections are presented in more or less detail, depending on the nature of the subject. Common features are:

Statement of Learning Objectives
Relevant University policies
Outline of content with text
Case Studies
References

The modules are intended as teaching guides and source material to be used selectively or to be expanded, depending on the particular circumstances of their use. The content will be available as a resource book/syllabus to faculty responsible for educational programs in the responsible conduct of science. The curriculum will also be placed on the web to promote its visibility. The University of Minnesota is a research university; nevertheless,

we must be constantly aware of the relationship between our research and scholarship, on the one hand, and our responsibilities as teachers on the other. When considering any aspect of the proper conduct of research, the implications of our responsibilities as teachers, mentors, advisors and protectors of our students must be included.

In an even broader sense, as members of the university community we are obliged to maintain the highest standards of behavior with regard to such issues as respect and encouragement for diversity, interactions with our colleagues and the avoidance of any form of harassment of our students or subordinates.