

GUIDELINES FOR THE RESPONSIBLE CONDUCT OF RESEARCH

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THE GUIDELINES

The purpose of this set of guidelines is to provide a positively oriented set of practical suggestions for maintaining integrity in research. Not only does the ethical conduct of science satisfy a scientific moral code; it also leads to better scientific results because the adherence to ethical research practices leads to more attention to the details of scientific research, including qualitative analysis and quantitative and statistical techniques, and to more thoughtful collaboration among investigators. Also, the credibility of science with the general public depends on the maintenance of the highest ethical standards in research.

Observance of these guidelines will help an investigator avoid departures from accepted ethical research practice and prevent those most serious deviations that constitute research misconduct. **Research misconduct** is defined as fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion, or disputes over authorship or credit. Misconduct as defined above is viewed as a serious professional deviation that is subject to sanctions imposed both by the University, by many professional associations, and, in the case of research proposed to or funded by a federal agency, by that agency.

These guidelines can be used as a common repository of generally accepted practice for experienced researchers and as an orientation to those beginning research careers. Although some of these principles apply to all fields of research, much of what follows deals with scientific research, including those areas of the social and behavioral sciences that involve collection and interpretation of data. These materials can be adapted or specified in a more particular form appropriate for each scholarly discipline or academic unit. In fact, many academic units have developed excellent handbooks on research ethics and integrity. When in doubt about the accepted ethical standards in a particular case, a researcher should discuss the matter on a confidential basis with an academic supervisor, another respected colleague, or the University Research Integrity Officer.

This guidance document is not a policy but is an accompaniment to existing University-wide policies and procedures governing research, a partial list of which is found in the Appendix. Ethical concerns in research are the subject of the Responsible Conduct of Research Course, a self-administered education, testing, and certification program, accessible through the University of Pittsburgh CITI training website at: <http://www.citi.pitt.edu/citi/>.

MATTERS OF ETHICAL CONCERN IN RESEARCH

1. Plagiarism

Authors who present the words, data, or ideas of others with the implication that they are their own, without attribution in a form appropriate for the medium of presentation, are committing theft of intellectual property and may be guilty of plagiarism and thus of research misconduct. This statement applies to reviews and to methodological and background/historical sections of research papers as well as to original research results or interpretations. If there is a word-for-word copying beyond a short phrase of six or seven words of someone else's text, that section should be enclosed in quotation marks or indented and referenced, at the location in the manuscript of the copied material, to the original source. The same rules apply to grant applications and proposals, to clinical research protocols, and to student papers submitted for academic credit. Not only does plagiarism violate the standard code of conduct governing all researchers, but in many cases it could constitute an infraction of the law by infringing on a copyright held by the original author or publisher. An author should cite the work of others even if he or she had been a coauthor or editor of the work to be cited or had been an adviser or student of the author of such work.

The work of others should be cited or credited, whether published or unpublished and whether it had been written work, an oral presentation, or material on a Web site. Each journal or publisher may specify the particular form of appropriate citation. One need not provide citations, however, in the case of well-established concepts that may be found in common textbooks or in the case of phrases which describe a commonly used methodology. Special rules have been developed for citing electronic information.¹

Members of a research group who contribute to work that is later incorporated into a proposal or protocol are entitled to be consulted and informed as to what their role will be if the proposal is funded or the protocol approved. A charge of plagiarism in the proposal or protocol on grounds that such members are not later included as part of the team that conducts the approved or funded research, however, can usually not be sustained. Such researchers who are excluded from subsequent research are entitled, however, to be considered for coauthorship in publications if their contributions merit it.

2. Misuse of Privileged Information

¹ Gibaldi, J., *MLA Handbook for Writers of Research Papers*, 4th ed. NY: MLA, 1995 and Li, X. and N. Crane, *Electronic Style: A Guide to Citing Electronic Information*, Westport, Meckler, 1993

One particularly serious form of plagiarism is the misuse of privileged information taken from a grant application or manuscript received from a funding agency or journal editor for peer review. In such a case, the plagiarism is a serious matter of theft of intellectual property because it not only deprives the original author of appropriate credit by citation but could also preempt priority of first publication or use of the original idea to which the source author is entitled. Also, one who breaches confidentiality by showing a privileged unpublished document to an unauthorized person can be held to a shared responsibility for any subsequent plagiarism of the document committed by that unauthorized person.

3. Data

a. Integrity of Data

Fabrication and falsification of research results are serious forms of misconduct. It is a primary responsibility of a researcher to avoid either a false statement or an omission that distorts the research record. A researcher must not report anticipated research results that had not yet been observed at the time of submission of the report. In order to preserve accurate documentation of observed facts with which later reports or conclusions can be compared, every researcher has an obligation to maintain a clear and complete record of data acquired. As stated in the University's *Guidelines on Research Data Management*, "records should include sufficient detail to permit examination for the purpose of replicating the research, responding to questions that may result from unintentional error or misinterpretation, establishing authenticity of the records, and confirming the validity of the conclusions." The intentional destruction of research records or the failure to maintain and produce research records supporting a questioned research publication or report may be considered to be circumstantial evidence of research misconduct.

Meticulous record-keeping is a sound scientific practice which provides an accurate contemporaneous account of observations that become a permanent reference for the researcher, who otherwise might not remember several weeks, months, or years later exactly what had been observed or what methods had been used. An accurate record also serves others who may want to replicate the observation or to apply a method to other situations. In addition, it is an aid in allowing the eventual sharing of information with others and as documentation that might disprove any subsequent allegation of fabrication or falsification of data.

In many fields of laboratory research, it is standard practice to record data in ink in an indexed permanently bound laboratory notebook with consecutively numbered pages. Research methods, including statistical treatments, should be either described in the notebook or referenced by citation to some other primary or secondary source. Information on materials used, along with their sources, should be recorded. Entries should not be erased or whited out. If mistakes are to be corrected, a thin line should be drawn through the erroneous

entry so as not to obscure it and an initialed dated correction written separately, along with an explanatory note, near the original entry or in the margin. All entries or at least all pages of a notebook should be dated and initialed. Such records may also be important at a later date in establishing scientific priorities or intellectual property claims.

All data should be recorded contemporaneously with the production or observation of the data. If some data are obtained as printouts from instruments or computers, these printouts should be appropriately labeled and pasted into the notebook or, if pasting is not possible, stored securely and referenced in the notebook as to storage location. If unique critical materials, such as cell lines, archeological artifacts, or synthetic chemical intermediates, are prepared or discovered, they should be preserved and appropriately labeled, and explicit instructions should be written in the notebook as to where they are stored. Extensive data sets may be stored either as hard copy or on disks. In such cases, carefully documented definitions for codes should be included, together with rules for applying them to the experimental, clinical, or field data and notes.

The use of computers in research laboratories is a necessity, and managing the data generated and stored is becoming a challenge to the investigator. As more and more data are generated electronically, current documentation methods involve both the hand-written laboratory notebooks discussed above as well as electronic files pertaining to experiments. Establishing processes to organize, store, and protect such electronic data is becoming crucial. One way to manage the generated electronic data is to use electronic lab notebooks. Such notebooks allow the direct entry of laboratory observations, results from data analysis, and the seamless transfer of electronic data and images from a variety of laboratory instruments in a centralized fashion. In addition, background information on reference materials or protocol details can be entered from electronic sources. One advantage of using such a notebook is the ability to secure the data electronically so as to prevent subsequent data manipulations. In addition such systems will also provide the ability to add electronic signatures for further validation. Electronic notebooks can be developed in house or can be purchased from a commercial vendor. In establishing a process to protect the data and ensure that the data are formatted so that they could not be modified, one suggestion would be to write the data to a CD-ROM (CD-R) where they could not be modified or overwritten.

Research in social sciences and in some clinical biomedical fields poses specific problems with respect to the availability of primary data for use by other researchers or by reviewers of allegations of possible scientific misconduct. The protection of human subjects requires that data be used, stored, and disclosed in a way that ensures the privacy of individual research subjects. Furthermore, while for purposes of analysis these data are frequently coded and entered into computer files with only code numbers identifying the individual subjects, there is often an interest of the researcher in reviewing the coding procedures in order to identify either random or systematic mis-entry of data into files. To satisfy these

guidelines fully, the primary data—clinical or laboratory records, questionnaires, tapes of interviews, and field notes—should be available for review. See also **3.c.** below. (In some research areas, anthropology for example, field notes are viewed as the product of the researcher rather than as data, and are thus customarily not made available to others.) Where possible, questionnaires should be stored without identifiers, using only code numbers to link them to computerized files. Records, including transcripts of taped interviews, can be redacted to remove names and other key identifiers. The rules and procedures for carrying out such redactions should be available to anyone who reviews the data. Access to health information identified with a particular subject is restricted, as discussed in **11**.

b. Use and Misuse of Data

Researchers should acquaint themselves with the relevant quantitative methods available for processing data, including graphical and tabular methods of presentation, error analysis, and tests for reliability.

Research integrity requires not only that reported conclusions are based on accurately recorded data or observations but that all relevant observations are reported. It is considered a breach of research integrity to fail to report data that contradict or merely fail to support the reported conclusions, including the purposeful withholding of information about confounding factors. If some data should be disregarded for a stated reason, confirmed by an approved statistical test for neglecting outliers, the reason should be stated in the published accounts. A large background of negative results must be reported. Any intentional or reckless disregard for the truth in reporting observations may be considered to be an act of research misconduct.

Special care must be taken in the use of photo-images not to misrepresent the underlying data. When using imaging-processing software, like Adobe Photoshop, for example, in preparing a blot for viewing it is improper to add or delete a band, to differentially adjust the intensity of one or more bands, to label an image from one experiment as representing a different experiment, to splice lanes without using a line indicating the deletion, or to juxtapose pieces from different gels onto a single image.

Modifying an approved protocol in the midst of a clinical or epidemiological study or changing the character of an approved study (e.g., from an exploratory to a confirmatory study) without prior approval is improper and could be viewed as research misconduct.

Expenditure of government grant funds for fabricated or falsified research is not only a violation of research ethics but also a federal crime, and those responsible may be subject to prosecution for fraud with the possibility of a demand for restitution of funds to the government, a fine, and/or imprisonment.

c. Ownership of and Access to Data

Research data obtained in studies performed at the University of Pittsburgh and/or by employees of the University are not the property of the researcher who generated or observed them or even of the principal investigator of the research group. They belong to the University of Pittsburgh, which can be held accountable for the integrity of the data even if the researchers have left the University. Another reason for the University's claim to ownership of research data is that the University, not the individual researcher, is the grantee of sponsored research awards. Reasonable access to data, however, should normally not be denied to any member of the research group in which the data were collected. If there is any possibility that a copyright or patent application might emerge from the group project, a written agreement within the group should specify the rights, if any, of each member of the group to the intellectual property. A researcher who has made a finding which may be patentable should file an Invention Disclosure with the Office of Technology Management.

A principal investigator who leaves the University is entitled to make a copy of data to take to another institution so as to be able to continue the research or, in some cases, to take the original data, with a written agreement to make them available to the University on request within a stated time period. A formal Agreement on Disposition of research Data should be negotiated in such cases through the Office of Research. Each student, postdoctoral fellow, or other investigator in a group project should come to an understanding with the research director or principal investigator, preferably in writing, about which parts of the project he or she might continue to explore after leaving the research group. Such an understanding should specify the extent to which a copy of research data may be taken. Co-investigators at another institution are entitled to access the data which they helped to obtain.

For unique materials prepared in the course of the research, such as intermediates in a chemical synthesis, autoradiograms, cell lines, and reagents, items that can be proportioned should be divided among members of a research group at different locations under negotiated terms of material transfer agreements. For non-divisible items, the allocation of the item should be clearly stipulated in the agreement. The Office of Research facilitates the execution of such agreements.

Since the scientific enterprise may be a cooperative endeavor encompassing many persons who now or in the future might pursue related research interests, and since it is in the interest of all to rely on the contributions and findings of others, every investigator has an obligation to the general scientific community to cooperate by sharing of data. Other virtues of sharing data include the facilitation of independent confirmation or refutation of reported outcomes. It is generally accepted that the data underlying a research publication should be made available to other responsible investigators upon request after the research results have been published or accepted for publication. A

researcher who has access to a unique set of experimental or observational data, e.g., from a satellite or from an archeological or paleontological site, has an obligation either to publish research results within a reasonable time or to make the data available to others who will be able to do so.

The National Science Foundation (NSF) has a specific requirement that data, samples, physical collections, and other materials created or gathered in the course of NSF-supported research be shared in a timely manner. The U.S. Public Health Service (PHS) insists that not only data but also unique materials (such as cell lines, cloned DNA, or reagents) developed with PHS funds must be made available to qualified individuals in the scientific community after the associated research results have been published or provided to the sponsoring agency.

d. Storage and Retention of Data

Data should be stored securely for at least seven years after completion of the project, submission of the final report to a sponsoring agency, or publication of the research, whichever comes last. Some agencies that sponsor research may specify a longer period for which data must be retained. For example, the U.S. Food and Drug Administration (FDA) requires that data associated with Phase I-III clinical trials be retained for a minimum of two years following final approval of the respective drug or device, which is likely to be a substantially longer period of time than seven years after completion of the research project. In the absence of a specific agency regulation, a conservative rule is to retain data for as long as there is still scientific interest in the details of the research.

Some types of data are expected to be deposited in a national or international databank, especially when they are so extensive as to preclude publication in a journal of record. Some examples are X-ray crystallographic data on protein structures, human genomic and proteomic data, and DNA microarray data. National Institutes of Health (NIH) requires certain types of data, such as from Genome Wide Association Studies supported by NIH, to be deposited in national databases as soon as the data are cleaned, even before publication. The Interuniversity Consortium for Political and Social Research has prepared guidelines for preparing data in the social sciences for archiving (<http://www.icpsr.umich.edu/icpsrweb/content/deposit/guide/>). A list of Web sites for social science archives is available through the University of California at San Diego at: <http://socsciresearch.com/r6>. In some research fields, authors are encouraged to create their own Web sites on which they may store extensive data sets for general access.

4. Authorship and Other Publication Issues

Publication of research results is important as a means of communicating to the scholarly world so that readers may be informed of research results and other researchers may build on the reported findings. In fact,

it is an ethical obligation for an investigator at the University to make research findings accessible, in a manner consistent with the relevant standards of publication. The reported data and methods should be sufficiently detailed so that other researchers could attempt to replicate the results. Publication should be timely but should not be hastened unduly if premature publication involves a risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations.

A commercial sponsor of a research project may not have a veto over a decision to publish, but a delay of publication for an agreed period, not to exceed six months, may be allowed in order to permit filing of a patent application.

A group of journal editors, acknowledging the potential abuse of published information by perpetrators of bioterrorist acts, have suggested that on occasion the potential harm to society of publication outweighs the potential societal benefits of open publication of research results. Editors concerned about the risk of publication of a submitted manuscript for this reason might advise the authors to modify or withhold publication and communicate their findings to the interested scientific community by other means.²

a. Criteria for Authorship

Publication must give appropriate credit to all authors for their roles in the research. If more than one person contributes significantly, the decision of which names are to be listed as coauthors should reflect the relative contributions of various participants in the research. Many professional associations and research journals have specified criteria for authorship. One common standard appearing in many of these statements is that each author should have participated in formulating the research problem, interpreting the results, and writing the research paper, and should be prepared to defend the publication against criticisms.

Other statements require meeting two or three of the above criteria and, with respect to the last of these requirements, a more limited expectation is often prescribed—that each author should be prepared to defend against criticism those portions of the publication falling within his or her particular area of expertise. A person's name should not be listed as author without his or her knowledge, permission, and review of the final version of the manuscript that includes the names of all coauthors.

A procedure that has been adopted by some journals and some universities or departments is that each author must sign a statement attesting to having read and approved the final manuscript and/or to having made a substantial contribution to the manuscript. Departments or other academic units might

² *Science* **299**, 1149 (2003)

consider drawing up statements of criteria and procedures for certification of authorship appropriate to their own units.

A person whose contribution merits coauthorship should be named even in oral presentations, especially when abstracts or transactions of the proceedings of a conference at which a paper is presented will be published. The entitlement to authorship should be the same whether or not a person is still at the original location of the research when a paper is submitted for publication.

Just as one should include all those who have a right to be listed as coauthors, so one should avoid the listing of so-called honorary authors, who do not meet the criteria for authorship. Many published versions of standards for authorship suggest the use of alternative forms of acknowledgment within the paper for contributions that do not merit coauthorship, e.g., for technical assistance, for providing research materials or facilities, or for meeting some but not all of the stated criteria for authorship. To avoid misunderstandings and even recriminations, the inclusion and exclusion of names of research participants as coauthors should be made clear to all participants in the research prior to submission of the manuscript.

b. Order of Authors

Customs regarding the order in which coauthors' names appear vary with the discipline. Whatever the discipline, it is important that all coauthors understand the basis for assigning an order of names and agree in advance to the assignments.

A corresponding or senior author (usually the first or last of the listed names in a multi-authored manuscript) should be designated for every paper who will be responsible for communicating with the publisher or editor, for informing all coauthors of the status of review and publication, and for ensuring that all listed authors have approved the submitted version of the manuscript. This person has a greater responsibility than other coauthors to vouch for the integrity of the research report and should make every effort to understand and defend every element of the reported research.

c. Self-citations

In citing one's own unpublished work, an author must be careful not to imply an unwarranted status of a manuscript. A paper should not be listed as submitted, in anticipation of expected submission. A paper should not be listed as accepted for publication or in press unless the author has received galley proof or page proof or has received a letter from an editor or publisher stating that publication has been approved, subject perhaps only to copyediting.

d. Duplicate Publication

Researchers should not publish the same article in two different places without very good reason to do so, unless appropriate citation is made in the later publication to the earlier one, and unless the editor is explicitly informed. The same rule applies to abstracts. If there is unexplained duplication of publication without citation, sometimes referred to as self-plagiarism, a reader may be deceived as to the amount of original research data.

It is improper in most fields to allow the same manuscript to be under review by more than one journal at the same time. Very often journals specify that a submitted work should not have been published or submitted for publication elsewhere, and some journals require that a submitted manuscript be accompanied by a statement to that effect.

An author should not divide a research paper that is a self-contained integral whole into a number of smaller papers merely for the sake of expanding the number of items in the author's bibliography.

Publication of two papers representing different interpretations of the same data by different participants in the research is confusing to readers. The participants with differing interpretations of the same data should attempt to reconcile their differences in a single publication or present their alternative interpretations in the same paper.

e. Accessibility of Publications

Some research funding agencies have proposed that all publications supported by federal funds be posted within a reasonable time in an electronically accessible form. A revised NIH Public Access Policy became effective April 7, 2008, requiring all NIH-funded investigators to make their peer-reviewed manuscripts available to the public at the NIH National Library of Medicine's PubMed Central (PMC) immediately after the date of journal publication, or at a later time not exceeding 12 months from the date of publication.

f. Early Release of Information About to be Published

It is unethical to release to the media scientific information contained in an accepted manuscript prior to the publication. An exception may be made if a public health issue is involved and the editor agrees to an advance release.

5. Interference

Not only withholding of data but intentional removal of, interference with, or damage to any research-related property, including instruments and other equipment, is improper and could be classified as research misconduct.

6. Obligation to Report

a. Reporting Suspected Misconduct

Reporting suspected research misconduct is a shared and serious responsibility of all members of the academic community. Any person who suspects research misconduct has an obligation to report the allegation to the dean of the unit in which the suspected misconduct occurred or to the Research Integrity Officer. Allegations are handled under procedures described in the University's Research Integrity Policy. All reports are treated confidentially to the extent possible, and no adverse action will be taken, either directly or indirectly, against a person who makes such an allegation in good faith. Protection of whistleblowers against retaliation is guaranteed under policies of both the University and the federal and state governments.

The Research Integrity Officer must report findings of misconduct in externally funded research to the funding agency, and in some cases an allegation must be reported even before the investigation is completed.

b. Correction of Errors

If a finding of error, either intentional or inadvertent, or of plagiarism should be made subsequent to publication, the investigator has an obligation to submit a correction or retraction in a form specified by the editor or publisher and, in the case of research misconduct, in a form specified by the University and a sponsoring federal agency.

7. Curriculum Vitae

A biographical sketch incorporated into a grant proposal or a curriculum vitae used in an application for a fellowship or any other position must follow the same standards of accuracy as a research publication. Inflated or otherwise inaccurate listings of educational background or academic status with an intent to deceive, including degrees, employment history, and professional accomplishments, are just as reprehensible as irresponsible entries in a list of publications and in some cases could be considered as falsification and be categorized as misconduct.

In listing publications it is recommended that clearly labeled, separate sections should be used for referenced research publications, chapters for books summarizing or reviewing a field, books or monographs, and

abstracts. A separate additional listing of public presentations may be another appropriate category. No item should be listed more than once in the same category. Some schools of the University have established standard formats for curricula vitae.

8. Conflict of Interest

There are some circumstances in which conflicts of interest could compromise the integrity of research or even lead to research misconduct, for example, by the distortion of research outcomes as a result of personal financial interests of a researcher. The annual disclosures of outside interests by researchers required under the University's Conflict of Interest Policy and the review of these disclosures by academic administrators are intended to avoid the escalation of conflicts into improper behavior or misconduct and to avoid even the perception of improper behavior. Possible preventive measures provided under that policy include divestiture, public disclosure of outside interests, reduction of the conflicted researcher's role in the research, and internal monitoring of the research within the University. A notice of conflicting financial interests must be included, possibly as a footnote, in publications, in research proposals (if required by the funding source), in reports, and in clinical research protocols. Many journals and funding agencies require such disclosures. A faculty member must also disclose to research students and members of the research staff the existence of his or her financial interests in activities related to the research. When asked to enter into peer review of a manuscript or proposal, a researcher must disclose any conflict of interest with respect to the matter under review.

The principal investigator of a commercially sponsored study report must have access to all the data underlying a publication and must have full control over the decision to publish. In the case of a multi-site study, the principal investigator of the overall project must have access to data from all sites.

University researchers should not allow their names to be used as "honorary" authors of manuscripts written or provided by commercial sponsors.

In the special case where University researchers are considering or are involved in commercialization of an invention, for example through a start-up company or by licensing technology to an established company, researchers should consult the Conflict of interest Policy for Faculty, Scholars, Researchers, Research Staff/Coordinators. This policy specifies certain limitations on a faculty member's equity holdings and places some restrictions on the faculty member's participatory role in such a company and on that person's role in University research sponsored by the spin-off company. For information relating to commercialization of University technology, contact the University's Office of Technology Management. Oversight of faculty relationships with start-up companies is provided by the Conflict of Interest Committee.

Faculty may be allowed to engage in outside professional activities such as consulting or service on a scientific advisory board, but approval of each such activity from the academic supervisor must be obtained in advance. In no case are University facilities to be used in the conduct of an outside activity, and the University name and logo may be used by outside entities only with permission of designated University business officers. Research performed for an external entity should be conducted by means of a sponsored research contract. In some schools a contract for consulting must be approved in advance to ensure, among other things, that remuneration is related to specific services and that legitimate intellectual property rights of the University are not compromised.

Conflict of commitment must be avoided so as not to threaten a University researcher's primary professional allegiance and responsibility to the University. Faculty, but not staff, may spend up to one day a week in outside activities, and such activities must be approved in advance.

9. Responsibilities of a Research Investigator

An investigator who leads a research group has leadership and supervisory responsibilities with respect to the research performed by members of the group. A principal investigator must not only put together the research group but also arrange for the assembly of an adequate financial and administrative structure to support the research. A supervisor not only provides guidance and advice to individual members of the group in the responsible conduct of the research but also has ultimate responsibility for the scientific integrity of the whole research project. He or she should thus take all reasonable steps to check the details of experimental procedures and the validity of the data or observations reported by members of the group, including periodic reviews of primary data in addition to summary tables, graphs, and oral reports prepared by members of the group. Written policies and procedures for collecting, maintaining, and communicating experimental data within the research group are highly recommended. Close oversight is particularly important during the first few months of participation in the group of a student, junior researcher, or new member of the research group.

An investigator serves not only as a research manager with respect to members of the research group but also as a mentor responsible for the intellectual and professional development of graduate students, postdoctoral fellows, and junior faculty in the group, including awareness and sensitivity to issues in research ethics. Mentors should assist students in defining a thesis or dissertation problem that is intellectually challenging and has a reasonable prospect of being brought to a conclusion within a normal or defined period of time. Encouragement should be given to students and other junior researchers to report their research progress regularly both in oral and written modes and to present completed work at regional or national meetings. Senior investigators must promptly review drafts of student theses or dissertations and provide timely feedback. In order to fulfill all of the inherent role responsibilities, a supervisor

should not have a research group larger than he or she can manage effectively and responsibly. A general compilation, *Elements of Good Academic Advising*, promulgated by the University Council on Graduate Study, may be found at www.pitt.edu/~graduate/advising.html.

Negotiation of sponsored research agreements is not one of the responsibilities of the investigator. That is a function of the Office of Research.

A researcher should be open to collaborative work with investigators having different but complementary skills, whether at the University of Pittsburgh or elsewhere. Early understandings should be reached in any collaboration about sharing of research resources and materials, authorship credit and responsibilities, and entitlement to any revenue from marketing of intellectual property through patents, copyrights, or licensing agreements. (See **3.c.** for requirements and procedures for executing material transfer agreements.)

In many areas of research, including the social sciences, faculty act as independent investigators, without participation of students and even of research assistants. The requirements of ethical behavior are of course just as valid for the lone researcher as for the leader of a group.

10. Responsibilities to Funding Agencies

An investigator should be aware that the same standards of accuracy and integrity pertain to grant applications and proposals as to manuscripts submitted for publication. Reporting of results of experiments not yet performed as evidence in support of the proposed research funding, for example, is considered to be fabrication and is subject to a finding of research misconduct, even if the proposal is subsequently rejected for funding or is withdrawn before full consideration for funding is completed. The same definition of plagiarism applies to an application or proposal, including background and methodological sections, as to a publication.

An investigator must submit progress and final research reports to a sponsor at times specified in the award. He or she must authorize expenditures in a manner consistent with the approved budget and should review financial reports carefully.

Investigators, who enter into agreements with commercial sponsors of research, as negotiated by the Office of Research, should familiarize themselves with the special terms of such agreements, such as those, for example, concerning reporting of results, disclosure of inventions, and confidentiality. Failure to comply with the provisions might sometimes constitute a breach of contract or might compromise the University's claims to intellectual property.

11. Special Obligations in Human Subject Research

Research protocols involving human subjects must be approved in advance by the University Institutional Review Board (IRB), which determines whether risks posed to subjects are acceptable and whether information describing risks and benefits of subject participation is conveyed to subjects in an accurate and intelligible manner. IRB review also ensures that all relevant University, federal and state regulations, and policies are being followed.

The requirement for IRB review applies not only to biomedical and dental research, but also to research projects in the social and behavioral sciences. Furthermore, regardless of where the research is being conducted, if the principal investigator or co-investigator is a University of Pittsburgh faculty member, student, or staff, that research project must be submitted to the University of Pittsburgh IRB, even if it has been reviewed by another IRB.

Special attention must be given to the very specific federal definitions of “research” with “human subjects” as this is important in determining whether, and to what extent, IRB oversight is required.

<http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46>

Research means “...a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” [45 CFR 46.102(d)].

Human subject means “...a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information” [45 CFR 46.102(f)].

There may be a number of scholarly activities (e.g., an oral history project) which may not meet the federal definition of research, or other activities (e.g., secondary data analyses using de-identified data) which may meet the federal definition of research but not meet the federal criteria for the involvement of human subjects. Investigators should contact the IRB (askirb@pitt.edu) for advice. Alternately, guidance is available on the IRB Web site (www.irb.pitt.edu). Regardless of the source of funding, all research activities involving human subjects must undergo IRB review, as per University policy. Those research activities cannot be initiated until the investigator has received a formal determination from the IRB office.

The IRB reviews both the protocol and the informed consent document (consent form) that potential subjects must sign before participating in the research study. Subjects must be informed that they may withdraw from a research program at any time. Research subjects already participating in a protocol by virtue of signing an approved consent document must be informed of any new information

regarding risks and benefits of study participation when such data become available as the study progresses. If a consent document states that subjects will be informed of the research outcomes, the investigator must honor that commitment and so inform the subjects. Any proposed change in the research protocol or consent document must be approved by the IRB in advance of its implementation, and all co-investigators and study staff should be informed by the principal investigator of all relevant modifications.

Every protocol submitted to the IRB must include a plan for data and safety monitoring. Protocols should also identify the research sponsor. If any investigator has a significant financial conflict of interest, the IRB protocol should include a plan for managing potential conflicts of interest, approved by the Conflict of Interest Office. Such a plan may place limits on the role of an investigator who has a conflict. The existence of conflicts should also be disclosed to the research sponsor, to research subjects, and to members of the research team.

The confidentiality of information relating to each subject must be respected and maintained. It is not permissible to collect for research purposes private information that may be linked (e.g., by names, initials, social security numbers, study numbers, or other personal identifiers) to individual subjects without prior written consent of the subjects as approved by the IRB. Data and samples of body tissues or fluids may be used for research only if the subject has provided consent prospectively and in writing, unless otherwise approved by the IRB. Additional requirements must be followed when identifiable medical record information is being used as part of the research; thus the protocol must be fully compliant with the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Every research protocol involving human subjects should receive a formal scientific review, usually at the department or school level, prior to its review by the IRB. This review ordinarily addresses the scientific merit of the study and, depending on the nature of the research project, may also address availability of research subjects, resource utilization, and financial support. Studies that have undergone a scientific review as a condition of funding (e.g., NIH-funded research) will not ordinarily require a departmental review.

The IRB must be notified promptly of any significant adverse reactions or unanticipated problems involving risk to subjects or others. Adverse events discovered in the course of studies involving investigator-sponsored use of investigative drugs, devices, or biological materials must also be reported directly to the FDA.

When large studies are organized as cooperative projects involving many different institutions, the institution that functions as a coordinating center has a special responsibility for developing a monitoring system to check the reliability of data reported from the various data-collecting centers.

The IRB office (412-383-1480) may be consulted for answers to questions involving research with living subjects. Studies using human bodies or tissues following certification of death must receive approval from the Committee for Oversight of Research and Clinical Training Involving Decedents (412-802-8280). Depending on the nature of the study, additional approvals must be sought from various offices that are part of the Research Conduct and Compliance Office (RCCO). These include institutional biosafety, radiation safety, investigator-sponsored IND and IDE support, and human stem cell research oversight.

12. Laboratory Animals in Research

Investigators who use laboratory animals are obliged to follow humane procedures so as to minimize animal pain, suffering, and distress and to use no more animals than absolutely necessary. Wherever possible, alternative protocols which do not require the use of animals should be considered, and if practicable, adopted. Written approval must be obtained from the Institutional Animal Care and Use Committee (IACUC, 412-383-2008) prior to the initiation of any research or teaching that requires the use of animals. The clinical director of the Division of Laboratory Animal Resources (412-648-8950) should be consulted about appropriate procedures with respect to working with animals. The same requirements for disclosure of research sponsorship and conflicts of interest in the use of human subjects in research apply for vertebrate animal research, except that the disclosures in the latter case are made to the IACUC.

13. Research Involving Recombinant DNA (rDNA)

All proposals for work involving gene therapy or recombinant DNA, whether in basic science or pre-clinical research, or in clinical trials, must be submitted for prior approval by the Institutional Biosafety Committee (IBC, 412-383-1768). The IBC maintains a Web site at: www.abc.pitt.edu with information about compliance with NIH guidelines for investigators, and assessment and determination of required biosafety measures.

SOME UNIVERSITY UNITS SUPPORTING RESEARCH

1. Safety

The University Radiation Safety Officer (412-624-2728) oversees the safe use of radioactive isotopes and other sources of ionizing radiation and ensures compliance with federal and state regulations and with institutional licenses. Procedures for obtaining authorizations for the use of sources of ionizing radiation may be found at www.radsafe.pitt.edu.

The Department of Environmental Health and Safety (EH&S, 412-624-9505) is available to assist the research community in all matters related to the safe conduct of research, including the control of hazards such as chemicals, biological

materials including blood-borne pathogens, lasers, and fire. The University's Safety Manual is found at the EH&S Web site, www.ehs.pitt.edu, and may be requested in hard copy from EH&S.

2. Intellectual Property and Technology Management

The Innovation Institute (412-383-7670) provides a comprehensive suite of services for Pitt innovators, from protecting intellectual property to the commercialization of new discoveries through licensing and new enterprise development. The Institute also provides a wealth of educational programming, mentoring and networking for Pitt faculty, students and partners. The Innovation Institute works to create, support and sustain a culture and environment of innovation, entrepreneurship and collaboration on-campus and off-campus for the benefit of the University community, the region and society.

3. University Office of Research

The Office of Research (412-624-7400) is the authorized University business office charged with reviewing, submitting, and endorsing research proposals and budgets for grants and contracts to sponsoring agencies, whether governmental or private. Material transfer agreements, data use agreements, and non-disclosure agreements are also processed through this office. The director of the Office of Research must approve and sign all such documents as the authorized University signatory. The functional areas supported by Office of Research staff include information services, project and proposal development assistance, and grants and contracts administration for pre-award and selected post-award tasks.

4. Office of Research, Health Sciences

The Office of Research, Health Sciences (412-648-2232) has responsibility for overseeing and facilitating biomedical research in the schools of the health sciences. Issues or concerns related to biomedical research should be brought to the attention of the associate vice chancellor for biomedical research or its staff.

5. Office of Clinical Research, Health Sciences

The Office of Clinical Research, Health Sciences (412-648-2332) promotes clinical research within the schools of the health sciences. It promotes an interdisciplinary collaborative environment that fosters the translation of research to the community. It provides research-related resources for participants, investigators, and research staff.

6. Office for Investigator-Sponsored IND and IDE Support

Office for Investigator-Sponsored IND and IDE Support (O3IS, 412-383-1710) assists researchers in the development and submission of investigator-sponsored Investigational New Drug (IND) applications and Investigational Device Exemption (IDE) for acceptance by the FDA and in the conduct of clinical research under such FDA-accepted applications and exemptions (www.o3is.pitt.edu)

7. Clinical and Translational Science Institute

The Clinical and Translational Science Institute (CTSI, 412-864-3474) is an integrative home for clinical and translational scientists across the University, CMU, and UPMC. Its mission is to improve the efficient and effective transforming of the processes of clinical and translational research so as to reach individual patients and the population as a whole. It supports innovative interdisciplinary research initiatives through nine research cores and translation to health practice via a community partnership program and centralization of UPMC's clinical networks. Staff at the Regulatory Knowledge and Support Core can provide hands-on assistance to investigators starting up translational research projects and staff within the Design, Biostatistics, and Clinical Research Ethics Core can help investigators in the design and analysis of their projects.

8. UPMC Clinical Trials Office

The purpose of this office (412-647-4461), part of UPMC's Office of Sponsored Programs and Research Support, is to facilitate the implementation and provide institutional oversight of the conduct of industry-initiated and sponsored clinical trials within UPMC. All questions and submissions may be directed to OSPARS@upmc.edu.

9. The Research Conduct and Compliance Office

The Research Conduct and Compliance Office (RCCO, 412-383-1711) is the umbrella entity encompassing various units that oversee and facilitate the conduct of ethical and regulation-compliant research. The Education and Compliance Office within the RCCO (www.ecohsr.pitt.edu) provides very useful information on study management tools and good research practice education.

APPENDIX

PARTIAL LIST OF RELEVANT UNIVERSITY POLICIES AND PROCEDURES

Numbers and dates refer to the listings in the
University Policy and Procedure Manuals

University Policies can be accessed at www.bc.pitt.edu/policies

Bloodborne Pathogens, 06-01-03, January 31, 1995

Conflict of Interest for Faculty, Scholars, Researchers, Research Staff/Coordinators, 11-01-03, September 24, 2013. This document states University policy for eliminating or dealing with conflict of interest and describes the annual disclosures of outside interests required of all persons involved in research.

Copyrights, 10-04-01, February 14, 1989, and 11-02-02, September 5, 2006. These describe procedures for seeking copyrights and specify the relative rights of the author and the University.

Guidelines on Academic Integrity, 02-03-02, September, 2005. In addition to this University document, each school has its own specific document governing the performance of students in the academic setting—in courses, examinations, and degree-related research, and the responsibilities of faculty with respect to students.

Guidelines on Research Data Management, November 25, 2009, available from the vice provost for research (412-624-0784), or at: www.provost.pitt.edu/documents/rDM_guidelines.pdf.

IRB Reference Policies & Procedures, available from the Institutional Review Board (412-383-1480) or online at: <http://www.irb.pitt.edu/content/policies-and-procedures>. This is a detailed description of the regulations governing the use of human research subjects and of the procedures for seeking IRB approval.

Patent Rights and Technology Transfer, 11-02-01, July 1, 2005. This describes the procedures for applying for patents through the Innovation Institute formerly Office of Technology Management (412-383-7670) and outlines the relative rights and responsibilities of the inventor(s) and the University.

Research Integrity Policy, 11-01-01, October 15, 2008. This defines research misconduct and describes the procedures for conducting inquiries and investigations into allegations of misconduct and for making and appealing decisions related to misconduct.

Rights, Roles, and Responsibilities of Sponsored Research Investigators, 11-01-02, April 3, 1992. This document outlines the rights and responsibilities of investigators and provides a mechanism for resolution of disputes.

Use of Animals in Research, Testing, and Teaching. IACUC (412-383-2008) has listed all policies governing use of animals on its Web Site: <http://www.iacuc.pitt.edu/policies>.



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