Responsible Authorship and Publication Practices

1 Criteria for Authorship – General

- "Authorship of original research papers is an important indicator of accomplishment, priority, and prestige within the scientific community."

  Panel on Scientific Responsibility and the Conduct of Research: Responsible Science: Ensuring the Integrity of the Research Process, Vol. I, National Academy Press, Washington, 1992, p. 52

- Because of the complex nature of contemporary research, many researchers are often involved in the preparation of a single manuscript, and questions arise as to who is entitled to be listed as an author.

- The names listed as author or authors of a research publication should reflect both credit and responsibility for the manuscript.

- Some journal editors, professional associations, and research institutions have specified criteria for listing as an author.

- Traditions with respect to co-authorship are often discipline-specific. For example, in complex experiments in high-energy physics that require the use of national or international facilities such as accelerators or radiation sources and the cooperation of researchers from many institutions, it is not uncommon to list the names of several hundred co-authors for a single paper.

- Many journals limit the number of authors listed in the Table of Contents, and many of the computerized databases limit the number of authors included.

- There is a growing tendency to discourage "honorary authorship.," a term often used for the routine listing of an administrator, such as a laboratory head or department chair, as a co-author of all papers emanating from a given laboratory or department, regardless of whether that administrator has met the generally acknowledged criteria for authorship.

  - Attention must also be placed on the importance of including as co-authors everyone who has met all the criteria. Sometimes, the name of a student or postdoctoral fellow is improperly excluded. Improper exclusions should be examined also in the case of oral presentations.

2 Criteria for Authorship - Uniform Requirements for Biomedical Journals

- The International Committee of Medical Journal Editors has developed Uniform Requirements for Manuscripts Submitted to Biomedical Journals, updated in 2004 and accepted by over 500 journals, with the following criteria for listed authorship:

  http://www.icmje.org/ index.html

- Substantial contributions to conception and design or acquisition of data, or analysis and interpretation of data; and

- substantial contributions to drafting the article or revising it critically for important intellectual content; and

- final approval of the version to be published.

- The following explanatory notes to these criteria are given:

- A role solely in acquisition of funding or collection of data does not justify authorship.

- General supervision of the research group alone is not sufficient for authorship.

- Any part of the article critical to its main conclusions must be the responsibility of at least one author.

- Each author should have participated sufficiently to take public responsibility for appropriate parts of the content.

- Some journals require that at least one author takes responsibility for the integrity of the work as a whole.

3 Certification of Authorship

- One author should be designated as the corresponding author, who will conduct correspondence with the editor, inform all authors about the status of the manuscript through the review process to the scheduling of the publication date, and receive requests for reprints or technical queries.

- The corresponding author may be required to provide assurance that each author has read the submitted version of the manuscript and approves it.

- Some journals and some research institutions require that each author sign a certification statement indicating which of the criteria that author has met and/or what the specific role of that author was in the reported research and the manuscript.

- Some journals use the same certification document to disclose any financial or management connection with a company whose product is being evaluated in the manuscript. (See Sections 4.7 and 4.9.)

4 Alternate Forms of Acknowledgment

- The contributions to a research project of participants who do not qualify for co-authorship may be recognized in a number of alternate ways.

- Acknowledgements in a manuscript are sometimes made as footnotes to the title page, as part of a special paragraph at the end of the manuscript, or as an appendix.

- Technical help can be acknowledged in the manuscript.

- Sources of special materials used in the research, such as reagents or specialized instruments, can be acknowledged in the body of the manuscript.

- Intellectual contributions to the conceptualization or analysis of the research can be cited in the manuscript, either as a reference to a publication or as an acknowledgment in the manuscript.

- Any person acknowledged in the manuscript should be informed in advance and asked for written consent to being so recognized.

- Acknowledgment of general support, such as from a department chair, or for financial support, may be made in the manuscript.

- Recognition can always be given to staff members of the research organization through the regular personnel evaluation process.

5 Order of Listing Co-Authors

- The order of listing co-authors should be determined by the authors well in advance of submission of the manuscript.

- The meaning of the listed order of authors is not the same for all fields or for all research groups. For example, the principal author is listed first in

some fields and last in others. A suggestion has been made that the significance of the order of listing be explained by a brief note or footnote, if the journal allows this.

- The problem of ordering the names is avoided in some disciplines by listing the co-authors in alphabetical order.

6 Agreements Concerning Authorship

- Discussions about listing of co-authors and ordering the names of co-authors should be held within the research group as soon as possible as the research project and conceptualization of the manuscript develop.

- Controversies about listing and ordering the names of co-authors can be bitter. If the issues cannot be resolved amicably within the research group, it is sometimes helpful to ask an objective party, such as a division chief, department chair or dean, to mediate the dispute.

7 Competing Manuscripts

- If different collaborating researchers have different interpretations of the data, they should make every effort to resolve their differences before submitting a manuscript.

- If they cannot resolve their differences, they may consider including both sets of interpretations in the manuscript.

- In the case of competing submitted manuscripts from the same institution, the editor sometimes refers the matter to a senior administrator of the originating institution, such as a dean, for guidance as to which interpretation to accept. The administrator, in such a case, may invoke some internal review procedure to resolve the controversy.

- The editor may print one manuscript and invite the disagreeing author to submit a letter to the editor following the publication of that manuscript.

- If the disagreement is over facts to be reported, an editor will normally not accept any manuscript until the matter is resolved at the institutional level, since the disagreement might imply an allegation by one group of researchers of misconduct on the part of another group.

8 Redundant Publication

- A manuscript should not be submitted to a journal if it substantially repeats a paper of the author(s) previously published.

- An exception may be made if the author and editor both knowingly want to repeat a publication, and if the fact of republication is clearly stated in the manuscript.

- One basis for such an exception might be that the readerships of the two journals are different.

- It is not inappropriate to submit a complete report that follows a preliminary presentation, such as an abstract or poster presented at a professional meeting. If the abstracts of the meeting are published, a citation to that publication should be given in the complete report.

- A manuscript should not be submitted to one journal while it is under consideration elsewhere, unless both editors are made aware of and are in agreement with the simultaneous submissions.

- If a submitted paper contains data that had been printed previously, particularly data about human subjects, reference should be made to the previous publication and an appropriate citation should be made.

- It is improper to divide what is essentially one study into two or more fragmented or overlapping publications for the sake of expanding an author's bibliography.

  Angell M and Relman AS. Editorial. N Engl J Med 1989;320:1212-3

9 Pre-publication Release of Findings

- It is unethical to release to the media scientific information contained in an accepted paper prior to the publication.

- An exception to the above rule may be made if there is a public health issue involved and if the editor agrees to an advance release.

- A press release may be circulated with an embargo date coinciding with the date of publication.

- Press conferences or press releases of oral or poster presentations at open meetings are permitted, but the material disclosed to the media should not go beyond what was presented at the meeting.

- Circulation of pre-publication manuscripts among colleagues in either print or electronic mode is permitted if it is made clear that the manuscript has not yet been published and is not to be publicly disseminated.

- Universal rules governing electronic publication of non-refereed papers have yet to be worked out, as of the date (2005) of the most recent revision of this module.

10 Correction of Errors

- An author who discovers an error in his or her published paper should inform the editor and, depending on the traditions of the particular journal, submit a correction in the form of an erratum or a letter to the editor.

- The correction should include the full reference to the paper being corrected, including authors, title, and journal citation.

- The communication should indicate the reasons for the correction.

- Many journals arrange to have the reference to the correcting erratum included with the reference to the original paper in bibliographic searching tools.

- Development of new information in the course of further research that may change the interpretations contained in a paper should not be submitted as an erratum. This is an example of the self-correcting nature of research. The new information should be reported in a separate publication.

- If a reported result is erroneous because of research misconduct, it is the obligation of the institution (i.e., the University of Pittsburgh) to arrange for the submission of the necessary correction or disclaimer, either by the author or by a University administrator.

- If an error is discovered prior to publication, the paper should be be withdrawn if at all possible to allow for necessary corrections.

Data

1 The Nature and Recording of Data

- By data we mean recorded information, regardless of the medium of recording.

- Data may include, but are not limited to contents of notebooks, computer or instrument printouts, disks, slides, autoradiograms and questionnaire forms; among other forms of data are statistical compilations, models and their testing, and other material relevant to the research project.

- The recorded data should contain enough information to allow the researcher to reconstruct the history and details of the experiment even after the lapse of some time, to allow another researcher to replicate the research, to confirm the validity of the conclusions, to enable the researcher to respond to questions or criticisms of the findings. and to establish priority in case of a future patent application.

- In many fields of investigation, the common primary repository of experimental data is a bound notebook with consecutively numbered pages.

- Notebook entries should include a description of the methodological procedures, materials used and the nature of the observational technique, calculational and statistical treatments of the observations, results, and conclusions. Reference should be made to the location of samples or of data that cannot be recorded in the notebook.

- Each page of the notebook should be dated and initialed. When possible, printouts, tables, graphs, and photographs should be pasted into the notebook.

- Data should be recorded directly into the notebook, not through temporary slips of paper. A notebook entry should be made permanent, preferably in blue or black ink and not with red or felt-tip pens. Corrections should not be made by erasure, blackouts, or whiteouts, but by drawing a thin line through the entry to be corrected with the correcting entry above or in a nearby margin, initialed and dated, with a notation for the reason for the change, e.g., eie (error in entry).

- Refer to the Human Subjects module for recommended forms of documentation in clinical studies.

- Certain clinical studies may require the establishment of independent Data and Safety Monitoring Boards (DSMBs) that will oversee and monitor such studies to ensure the safety of participants and the validity and integrity of the data.

- NIH requires that a DSMB be established for all NIH-funded Phase III clinical trials.

- For NIH-funded Phase I and Phase II clinical trials, investigators are required to submit a general description of the data and monitoring safety plan as part of the protocol submitted to the IRB and as part of a research grant application.

- The FDA or NIH may require a DSMB for some Phase I or Phase II studies, including research on medical products intended to be marketed or studies having multiple clinical sites or involving high-risk interventions or vulnerable populations.

2 Abuse or Misuse of Data

- In general, all observed data should be included in the data analysis.

- Data should be excluded from analysis only for good reason, explained in the notebook or as part of the data analysis itself. Some acceptable reasons for exclusion might include instrumental breakdown, accidental disruption of the procedure, deterioration of an essential reagent, or irrelevance of some sections of the data, as in epidemiological studies, to the hypothesis being tested.

- Outliers, or data points that do not fit a smooth curve that goes through or near most data points, should not be excluded simply because of poor fit. Exclusions should be made only with regard to pre-defined statistical criteria included in the experimental design.

3 Confidentiality of Data

- In the case of clinical studies or surveys, primary data are associated with individuals and may convey information about the health or behavioral characteristics of individuals. The confidentiality of these data must be assured.

- A fine balance must be struck between the need to protect sensitive information that identifies individuals and the need to provide researchers with access to the information in a manner that will permit them to do their work.

- Codes should be used to identify individual research subjects, and the identification of the code name with the subject's name should be maintained in a secure place and should be available only to a small number of individuals.

- Names, addresses, birth dates, social security numbers and other identifiers should not be used in the code name.

- For further details, see the Human Subjects and HIPAA modules - 2, 6, 7 and 8.

4 Retention and Storage of Data

- Data should be stored in a safe place for as long as the research project is underway. The University has mandated a minimum retention time of five years after the final reporting or publication of the project. Since several federal agencies sponsoring or regulating research have adopted seven-year rules for data retention, the University will probably increase its mandated retention time.

- See Guidelines on Data Retention and Access, http://www.pitt.edu/~provost/retention.html.

- Beyond the five years (or longer if mandated by a sponsor), data should be retained long enough to support any patent applications and to allow the resolution of any questions about the research raised during the minimum retention period.

- Data should be suitably indexed so that they may easily be called up when necessary.

- National and international data banks exist in some fields, into which all researchers are expected to deposit their data. Some examples are X-ray crystallographic data and human genomic data. The Inter-University Consortium for Political and Social Research has prepared guidelines for preparing data for archiving. See http://www.icpsr.umich.edu/ACCESS/dpm.html

- Some journals may require that extensive data supporting a manuscript accepted for publication be deposited in an archive or at a website.

- A list of websites for social science data archives is available through the University of California at San Diego at http://odwin.ucsd.edu/idata.

5 Ownership and Access to Data

- Legal title to data acquired in University research projects rests with the University, not with the individual researcher or with the principal investigator. If any problem should be found with the data, such as an allegation that is the subject of a law suit or a research misconduct proceeding, the University has the primary responsibility to respond to the charges.

- The University may assert the right to copyright or patent products of research conducted by University researchers, in accordance with University policies and procedures dealing with intellectual property, allowing, among other features, the sharing of licensing, sale, or royalty revenues between the inventor(s) and the University.

  For Patent Policy, see:
  http://www.pitt.edu/HOME/PP/policies/11/11-02-01.html

- A researcher who has made a finding that may be patentable should file a Disclosure of Invention to the Office of Technology Management (OTM).

  For on-line filing, see the OTM website:
  http://tech-link.tt.pitt.edu

- A principal investigator who leaves the University of Pittsburgh may continue to maintain access to the data by leaving the original copy at the University and taking a copy to another institution, or by taking the original data on long-term loan with a written commitment to provide the University with access to the data at any future time within the retention period.

- If the data to be taken to another institution are governed by confidentiality restrictions, a confidentiality agreement may be executed through the Office of Research.

- Students or other investigators in a project may access those data which they have been responsible for collecting.

- The University does not normally assert its legal ownership of the literary, artistic, or scholarly work of its faculty and staff, with respect to copyright, unless the preparation of the particular work was a specific assignment as an employee of the University.

- The University does assert legal ownership to intellectual property in the form of software (other than educational software to be used only within the University) developed at least in part with the University's computer facilities. The University's ownership of software, except for software

created as a work for hire, is subject to a royalty-sharing agreement with the programmer.

- The federal government has the right of access to any data acquired under a government-sponsored research project.

- In the interest of openness, data supporting research which has been published, as well as unusual or unique materials created during the research such as DNA sequences or cell lines, should be made available to any qualified researcher who makes a reasonable request. Such professions as the American Psychology Association and the American Sociology Association have supported sharing or archiving of data.This principle has been upheld by the National Science Foundation, the National Institutes of Health and other federal agencies with respect to data generated in research supported by those agencies. An agreement should be executed for transfer of research of materials.

  For a model form for handling voluntary transfer of research materials, see: http://www.pitt.edu/~offres/proposal/mtainter.html

- Federal regulations are being developed which might require releasing to the public, in some cases, data collected in federally funded research in general and specifically when used to support federal rules and regulations, in response to a request under the Freedom of Information Act.

- There have been instances in which research data have been subpoenaed by the courts. The case law is not firmly established in this regard, and inquiries with respect to specific instances should be directed to the Office of the General Counsel.

Mentoring

1 Orientation of Staff and Students

- The mentor is usually either the prinicipal investigator or co-investigator of a research project or the designated adviser in a student's academic program.
- A mentor is responsible for introducing students, postdocs, and staff to what is in many cases their first research experience.
- A basic orientation is often needed in how to conduct and record experiments.
- Bibliographical and library practices are important components of the orientation, including development of habits of keeping up with the current literature, possibly through journal clubs.
- Graduate students, and sometimes postdocs, select their research problems, but the mentor can help in the selection process.
- The goals of the mentorship should be discussed prior to initiating the relationship or during the orientation.
- The traditions of the particular discipline, of the particular laboratory, and of the particular research project must be introduced, including the details of research protocols and research tools.
- Regular group or one-on-one mentor-trainee meetings can provide a setting for ongoing orientation.
- Safety and confidentiality issues specific to the research should be included in the ongoing training.
- Compliance issues related to governmental regulations and specific to the research area should be included in the training. (Compare, for example, modules on Human Subjects, Animal Care and Use, Conflict of Interest, Human Embryonic and Fetal Stem Cell Research and HIPAA Privacy Requirements.)

2 Oversight

- The student or postdoc should report progress regularly to the mentor.

- The mentor's oversight should not be restricted to research summaries but should cover primary data as well, at least on some random basis. The mentor cannot assume the integrity of the work he/she directs without thorough familiarization with the details.

- From time to time the mentor should directly, or through an experienced member of the research group, monitor experiments or observations of junior personnel or confirm results, particularly in the early stages of the trainee's work in the group, partly to strengthen the professional development of the trainee and partly to assure quality control.

- If the research is part of a group effort, frequent group meetings should be held at which results are presented to, and discussed by the group.

- Discussion of research ethics, including research misconduct and conflict of interest issues, should be part of the ongoing interaction between mentor and trainee.

3 Professional Development

- Keep in mind the goal of developing a student or postdoc into an independent creative researcher. You may have your own goals of advancing your particular research project, but you should not use the person you are mentoring merely as another pair of hands to help you satisfy your own agenda.

- A postdoc should be treated as a colleague and should be given leeway to develop an independent approach to a problem you suggest or even to embark on a new problem, consistent with the requirements of the funding source.

- A trainee should be encouraged by allocation of time and/or money to acquire skills or special techniques outside the mentor's own research group.

- The junior researcher should be encouraged to develop oral communicative skills by reporting research results or journal club assignments orally to a group.

- The mentor should encourage the development of skills in preparing funding proposals, perhaps through applications for traineeship, fellowship or travel awards or through submission of drafts for sections of the mentor's grant proposals.

- The mentor should encourage the student or postdoc to attend professional society meetings, both regional and national.

- The mentor should introduce trainees to colleagues from other institutions working in similar fields.

- When feasible, the mentor should encourage the student or postdoc to write abstracts and then make presentations at professional society meetings.

- The mentor should communicate deadlines for the trainee's completion of certain tasks such as preparing papers for publication.

- The mentor should review and critique promptly drafts of dissertations, or papers prepared in whole or part by students or postdocs.

- The mentor should give advice on the selection of a journal to which a paper should be submitted.

4 Respective Roles of Mentor and Trainee

- The mentor should be a role model for those being mentored, not only in matters of approaches to research but also in matters of professional ethics and responsibility.

- There should be early discussions about the criteria for naming authors or co-authors for publications that will emerge from the research. These discussions should include the order of listing of multiple authors. The mentor should not hesitate to grant authorship or co-authorship when it is deserved.

- There should be frank discussions about the assignment of royalty or licensing rights for any copyrights or patents that might be issued on the basis of the student's or postdoc's work.

- The mentor should be friendly and encourage the development of social graces by students and postdocs, but at some point it may be necessary to establish a professional objectivity or even distance.

- A mentor should have frank discussions with students or postdocs about their respective intentions with respect to following up on the research after the trainees leave the research group. A mutual understanding on who will continue each line of research can avoid bitterness in the future.

- A mentor should be frank about his or her expectations of including or not including a student or postdoc in a future research grant, especially if the trainee has been asked to write a portion of the funding proposal.

- The mentor must be careful that his or her behavior toward a trainee cannot be interpreted as sexual harassment.

  For University policy on sexual harassment, see:
  http://www.pitt.edu/HOME/PP/policies/07/07-06-04.html

- The mentor has an opportunity to benefit from experiences with the trainee, learning from what special skills and insights the latter brings to the shared enterprise and from what the trainee will accomplish after beginning to funcion more independently.

5 Career Guidance

- The mentor should initiate frank and helpful guidance about career options early in the relationship with students or postdocs. Realistic considerations should be given to the trainee's interests and abilities and to the state of the market.

- A mentor who does not think that a trainee's career choice is a good match with his or her abilities should offer constructive alternative choices. Also, a mentor who would not write a positive recommendation for a particular type of position should be frank with the trainee in this regard.

- The mentor should be helpful in guiding a student or postdoc to prospective employers and should make a personal contact if the prospective employer is a part of the mentor's professional network.

- A mentor should keep in touch with former students and postdocs and should try to be helpful in locating a "second" position if necessary, such as a more permanent position following a postdoctoral appointment.

6 Dangers of Exploitation

- A mentor should not let a student start on a dissertation project that has little probability of a successful outcome within a reasonable time, regardless of the contribution the work on that project may make to the mentor's larger research program.

- A mentor may feel very comfortable about having a student remain as part of an active research group and may, consciously or unconsciously, want to prolong the student's stay beyond what is needed for completion of a

dissertation. The mentor should realize, however, that the student's interest is usually to complete the degree as soon as possible and move on to a new position.

- A mentor may be very pleased with the work of a postdoc, not only in research but in overseeing the research of others. A postdoc who is kept on past several years should be considered for some additional recognition in terms of salary and/or rank, such as research associate or research assistant professor.

- The assignment to a student of a dissertation topic related to financial or outside management interests of the mentor is an invitation to trouble.

  See Sections 4.3 and 4.9.

- The mentor should not expect that a student or postdoc will voluntarily perform personal services such as baby-sitting, gardening, or automobile repair, unrelated to the research.

- The mentor should be considerate of the needs of students and postdocs related to disabilities, family responsibilities or serious medical problems.

- A mentor who has taken on more students or postdocs than can be effectively managed is exploiting one or more of the trainees for whom the mentor is responsible.

- A mentor who leaves the campus on a sabbatical or other leave must allow for some suitable oversight of the students and postdocs.

Conflict of Interest

1 Conflict of Interest

A conflict of interest arises from a situation in which commitments and obligations to the University or to widely recognized professional norms are likely to be compromised by a person's other interests or commitments, especially economic, particularly if those interests or commitments are not disclosed.

- Participation by a researcher in an activity that provides personal gain does not in itself constitute unacceptable behavior.
- Possible intrusions on research integrity could occur if the outside interests of a researcher, financial or otherwise, affect the design, conduct, or reporting of professional activity.
- Each instance of a researcher's involvement in outside activities must be examined on a case-by-case basis for the existence of a conflict of interest. (See Section 4.6.)
- This module deals with conflict of interest mainly with respect to research and teaching. Conflicts related to University business decisions, including purchasing, are dealt with in a separate University Policy #07-05-02, Conflict of Interest for Designated Administrators and Staff.
- Conflict of interest is the subject of a more detailed treatment in Module 4.

2 University Policies on Conflict of Interest

- University policies on conflict of interest are compatible with requirements of federal agencies sponsoring and regulating research.
- The policies are summarized in the Faculty Handbook and may be accessed as indicated in the References section for this chapter.
- In addition, participation by researchers in technology transfer, including formation of start-up companies to commercialize research, may give rise to special conflict of interest concerns. (See Section 4.9.)
- All researchers are required to make periodic disclosures, at least annually, of outside remunerative activities related to their University responsibilities. (See Sections 4.4 and 4.5.)

- There is a separate University policy on conflict of interest for consultants. This may be accessed as indicated in the References section for this chapter.

- University researchers who use outside consultants on their projects must call the attention of these consultants to the Policy for Consultants and arrange for the consultants to make the required disclosures called for in that Policy.

3 Examples of Potential Conflict

- Accepting gratuities or special favors from companies doing business or sponsoring research at the University

- Accepting over-scale honoraria for lectures at companies

- Performing evaluative research for a company in which the investigator has a financial interest

- Accepting a paid consultancy with a company having an interest in the faculty's research

- Being a paid member of a speakers' bureau for a company

- Using students to perform company services

- Assigning as a required text a book for which the instructor receives royalties

- Accepting a research contract with a restricted publication clause

- Providing privileged access to information developed with University or independent sponsors to a favored company

- Purchasing materials from a company in which the investigator has an interest

- Influencing the negotiation of contracts, including research contracts or licensing contracts, between the University and a company in which the investigator has an interest

4 Required Disclosure, Part I

Faculty members, administrators, and researchers are required to make regular, timely, and full confidential disclosures to their superiors (usually a department

chair or dean) of all outside remunerative activities related to their teaching, research, or administrative activities.

- The disclosure must be submitted electronically on the Conflict of Interest Superform , accessible on the web at http://www.coi.pitt.edu.
- The form should be submitted at the time of appointment and before April 15 of each subsequent year.
- A disclosure should also be made at other times of the year if new relevant facts develop.
- Disclosures submitted on the Conflict of Interest Superform are entered automatically onto a Conflict of Interest Database maintained by the Research Conduct and Compliance Office (RCCO).
- No grant or contract proposal will be processed through the Office of Research unless a current copy of the disclosure form of the investigator appears in the Conflict of Interest Database.
- Some categories of outside interests and activities to be disclosed pertain also to members of the declarer's immediate family (dependents, spouse, and members of the household).
- In the case of some special circumstance such as a potential conflict of interest on the part of a department chair, the initial disclosure may be submitted directly to the dean rather than to the chair.
- Investigators in clinical research or pre-clinical animal research must also declare any significant financial interest in the sponsor or technology of a protocol when submitting the protocol for approval by the Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) . (See Modules 2 and 3.)
- Research relations with a start-up company in which the researcher has an interest must be reviewed by the Entrepreneurial Oversight Committee (EOC). (See Section 4.9.)

4.1.1 Required Disclosure, Part I - Outside Interests to be Declared

The Superform requires researchers to answer Yes or No with respect to the following categories.

- Ownership interests in an organization in your field of research when aggregated for you and members of your immediate family exceeding $10,000 or 5% of the organization's outstanding equity.

- Offices, board memberships, employee or management positions in such an outside organization held by you or a member of your immediate family

- Remuneration from any single outside organization exceeding 1% of your University salary or $10,000 when aggregated for you, your spouse and dependent children

- Engagement in research that could affect a company in which you have a financial interest

- Employment by you of a University student or staff in an outside company

- Interest in a contract or sale to which the University was a party

- Interest in intellectual property by reason of your (or your spouse's or dependent child's) being inventor of a technology related to your research for which an invention disclosure has been filed or is being developed or evaluated

5 Required Disclosure, Part II

Part II is to be completed only if you responded positively to one of the categories listed in Part I.

- You are to list details of your relationships to outside organizations for which you indicated positive answers in Part I.

- In addition, you are to list research grants that might reasonably appear to affect the company in which you disclosed an interest.

- Generally, if you receive an economic benefit from a company with an interest in your research, you should disclose that benefit in any publications, presentations, or grant proposals related to the research. Examples of benefits to you might include:

    1. sponsorship of the research,
    2. a consulting or lecturing agreement you have with the company,
    3. a salary or stipend you receive as an officer, employee, or member of the board or scientific advisory committee of the company,
    4. stock you may own in the company, or
    5. royalties you receive from the company.

5.1.1 Required Disclosure, Part II - Examples of Conflicts

Examples of Conflicts That Require Management

- Conflicts that must be eliminated or managed are those that place the researchers at risk of jeopardizing the integrity of the research, such as the following:

- Holding of an office in, or receipt of remuneration or equity from a company having an interest in your University research (See Section 4.9.)

- Conducting experiments that measure, test, or exploit the effectiveness of the product of a company in which you have an interest

- Sale to the University of a product or service of a company in which you have an interest

5.1.2 Examples of Situations Not Requiring Management

- Aggregated ownership (by you and your immediate family) of less than 5% of the equity in an organization in your field of research, and less than $10,000.

- Remuneration of less than $10,000 per year from a company having an interest in your research.

- Ownership of equity in a publicly traded corporation whose only connection with your research is the manufacture of an instrument used in your work, if there is no other source of that type of instrument, unless one purpose of your research is to test the effectiveness of the instrument

- Remuneration from service on a panel or committee of a government agency or other non-profit entity

6 Procedures for Reviewing Disclosures

Aim: to manage, reduce, or eliminate the conflicting interest

- After completing the Superform, you should print out the Detached Signature Page, sign it, and give it to your supervisor (e/g/, department chair, dean).

- If you were required to complete Part II, your supervisor will meet with you so as to determine whether any steps beyond disclosure are needed to

eliminate, reduce, or manage the potential or actual conflict and, if so to prepare a Management Reporting Form

- The supervisor shall forward to the dean or campus president for additional review all Detached Signature Pages from persons who were required to complete Part II. Each Detached Signature Page is to be accompanied by the corresponding Management Reporting Form.

- The dean or campus president shall forward to the Provost or Senior Vice Chancellor for Health Sciences, as appropriate, a copy of each reviewed Detached Signature Page with its accompanying Management Reporting Form.

- The Provost or Senior Vice Chancellor for Health Sciences will also review the material, modify the management plan if necessary, and forward a copy of each Detached Signature Page with its Management Reporting Form to the University Conflict of Interest Office.

- Sanctions may be applied for failure to follow a recommended procedure for dealing with the matter.

- A conflict that cannot be resolved may be referred to the Conflict of Interest Committee for recommendation of a resolution by the Provost or Senior Vice Chancellor for Health Sciences.

7 Managing Conflicting Interests - General Considerations

- Researchers must make full and accurate disclosures to their supervisors, as required by University policy.

- Supervisors shall maintain confidentiality with respect to disclosures by investigators, and the contained information shall be disclosed only to the extent necessary for review, management of any conflicts, or compliance with requirements of reporting to a federal sponsoring or regulatory agency.

- All research results shall be published or publicly disclosed with reasonable promptness, whether the results are favorable or unfavorable to the interests of any sponsor or to the outside interests of the researcher.

- Students and postdoctoral fellows shall not be exploited or their training compromised in the service of sponsored research or the financial gain of the supervisor.

- *A disclosure of outside interests impacting research should be provided to students and postdocs engaged in the research.

- In the case of a presentation or publication which deals at least in part with the evaluation of the effectiveness or risk of using a substance, device, or service sold or provided by a commercial organization with which the researcher has a connection or by a commercial organization competitive with one with which the researcher has a connection, that presentation or publication must contain a statement disclosing the researcher's connection.

8 Managing Conflicting Interests - Some Specific Management Tools

- Disclosure of the potentially conflicting relationship

- Monitoring and oversight of research by an independent committee

- Modification of the research plan

- Disqualification from participation in all or part of the research

- Full or partial divestiture of significant financial interests

- Resignation from management or board positions

- Severance of the conflicting relationships

9 Special Requirements with Respect to Start-up Companies

General Reference to University Policy:

11-02-03 Commercialization of Inventions through Independent Companies

http://www.pitt.edu/HOME/PP/policies/11/11-02-03.html

Administration of the Policy:

Chair of the Entrepreneurial Oversight Committee , 412-383-1774

- To help to address the economic, scientific, and technological development of the region and the nation, researchers are encouraged to explore options to commercialize inventions through licensing arrangements with existing companies or by formation of independent

(start-up) companies based on the science or technology that has been developed in their laboratories.

- Disclosures of inventions, applications for patents and arrangements for commercialization must be made through the Office of Technology Management.

- No more than 20% of stock in a start-up company may be held in the aggregate by all University faculty, staff, and students, and members of their immediate families. Exceptions may be considered for companies in a developmental stage that do not have products in clinical trials or products being sold.

- Faculty, staff, and students may not hold management, board, or operating positions in the company.

- Proposals for sponsorship of university research by start-up companies must be reviewed by the department chair or dean, and by the Entrepreneurial Oversight Committee (EOC), to whom regular reports must be made on the research methodologies and results.

- No faculty, staff, or student holding equity in, or receiving financial benefits from the success of a start-up company can be the principal investigator for a University research project sponsored by that company or be the attending physician or record patient data in a clinical study sponsored by the company. Such a faculty, staff, or student shall not negotiate the research grant or contract.

- Prior approval must be obtained from the department chair and dean on the use of students in projects sponsored by start-up companies.

- Investigators must disclose to students any significant financial interest related to the students' research.

- Stock in a start-up company may not be sold or traded by a University faculty, staff, or student, or by members of their immediate families unless general and specific guidelines established by the EOC are followed.

- University resources and facilities may not be used in the operation of start-up companies, including telephone, e-mail, and computers.

10 Conflict of Commitment

- The University recognizes the value both to the institution and to the faculty of consulting and other outside professional activities by individual faculty members. The institutional constraints on such outside activities

are described in the policy, Outside Employment, summarized in the Faculty Handbook and accessed as: http://www.pitt.edu/HOME/PP/policies/02/02-06-01.html

- The outside activities must not conflict with the individual's responsibilities to the University.
- The name, property, and facilities of the University may not be used in the work for which the individual receives personal payment.
- The time given to such activities should not exceed an average of one day per week.
- The fee for outside work must be commensurate with the individual's professional standing.
- The individual must receive permission from the department chair or dean to engage in such outside activities.
- Some professional schools have more restrictive requirements concerning the amount of time spent and the amount and distribution of fees earned, including the possibility that fees be shared or turned over completely to the academic unit.
- Pro bono professional service is encouraged, such as membership on advisory committees for government, non-governmental non-profit organizations, or for professional associations. Extensive activities of this type, however, should be cleared with department chairs or deans to insure that faculty responsibilities to the University are not compromised.
- Clinical activities in department- or school-approved practice plans are separately regulated and are not necessarily subject to the one-day-a-week limitation.

Other Investigator Responsibilities

1 General Responsibilities of an Investigator on a Sponsored Project

The following are among the responsibilities of an investigator on a sponsored project:

- To create the project
- To obtain assurance of the availability of the facilities needed to conduct the research
- To write the funding proposals in accordance with University and agency requirements
- To assemble the necessary staff to conduct and complete the project
- To maintain academic and research integrity and conduct the research in a timely and professional manner and in compliance with the specific terms of the grant or contract
- To ensure that the research is conducted in compliance with University and government regulations, including concern for health and safety, human subjects, and animals used in research, and avoidance of conflict of interest
- To conduct the project in a manner consistent with the teaching and research mission of the University
- To authorize expenditures in a manner consistent with the approved budget for the project
- To review carefully the financial reports
- To submit progress and final reports as may be required under the terms of the award
- To report patentable and commercially valuable findings to the Office of Technology Management
- To acknowledge all sponsors of the research project in any publication, presentation, or other public communication regarding the research

2 Responsibilities to the Scholarly Community

The following are among the responsibilities of an investigator to the scholarly community:

- To publish research findings in a timely manner
- To screen papers voluntarily for security risks by refraining from publication of information that could be useful to bioterrorists or developers of bioweapons working for rogue nations. The report of the panel of the National Research Council that made this recommendation may be accessed as a 2004 book, Biotechnology Research in an Age of Terrorism, at http://www.nap.edu/catalog/10827.html. Many biological journals are assuming the role of screening manuscripts from this point of view.
- To accept requests to participate, when possible, in the peer review process that judges the quality of manuscripts submitted for publication and proposals submitted for research funding
- To make timely, objective, and non-biased judgments during peer review
- To maintain the confidentiality of the peer review process
- To refrain from utilizing the material in a reviewed manuscript for one's own research until the original material is published or presented publicly.
- To publish negative as well as positive results, if the findings are conclusive
- To submit, in the case of NIH-funded research, manuscripts accepted for publication to a free searchable archive

3 Collaborative Research

- A researcher should be open to collaborative work with researchers having different but complementary special skills and disciplinary backgrounds, whether at the University of Pittsburgh, elsewhere in the United States, or even in foreign countries.
- Clear understandings should be made near the beginning of any collaboration of the respective roles of the partners, of the credit each partner will receive through authorship of joint papers and royalties from any patents, and of the responsibility of each collaborator in presentation and defense of the ultimate research findings.

- In the event of a break-up of the collaboration, attempts should be made to negotiate amicably the respective future tracks the partners will follow in continuing the work.

- Early agreements should be made about each partner's share of research materials and access to the data. (See Sections 1.6 and 2.5.)

Research Misconduct

1 Definitions of Research Misconduct

Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

- Federal Policy on Research Misconduct

Office of Science and Technology Policy (OSTP), December 6, 2000, 65 FR 76260

- *Research, as defined herein, includes all basic, applied, and demonstration research in all fields. This includes, but is not limited to, research in economics, education, linguistics, medicine, psychology, social sciences, statistics, and research involving human subjects or animals.

- The University of Pittsburgh definition of misconduct includes misrepresentation of credentials.

- Other unethical or sloppy research practices are often referred to as research impropriety.

1.1 Definitions of Research Misconduct – Fabrication

Fabrication is making up data or results and recording or reporting them

OSTP Policy

- Do not fake an experimental result in order to substantiate your hypothesis.

- Do not be tempted to inflate your results so as to have a good case to make in a grant proposal or in a dossier for promotion or a job application.

- Do not anticipate results when preparing an abstract or grant proposal in the expectation that your predicted results will be achieved before the conference presentation is made or the grant proposal is reviewed.

- Do not cover up the absence of results of a required pre-admission test in a clinical trial by making up test results.

- Do not forge a clinical subject's response to a questionnaire in a misguided attempt to avoid burdening the subject.

1.2 Definitions of Research Misconduct – Falsification

Falsification is manipulating research materials, equipment or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

OSTP Policy

- The research record is defined as the record of data or results from the research and includes, for example, laboratory records, both physical and electronic, research proposals, progress reports, abstracts, theses, oral presentations, internal reports, journal articles, and books.
- Negative results, as well as positive, should be reported.
- Selection of collected data for analysis must be based on a statistical protocol prepared before data are collected.
- Purposely altering an instrument to give incorrect readings, for your experiments or for those of another researcher, is as serious an offense as purposely writing down erroneous observations.
- Misrepresentation of one's educational background is considered to be falsification.
- Exaggeration of one's bibliography by claiming unpublished work as a publication is considered to be falsification.
- Papers should not be listed in a manuscript or proposal as submitted unless they have actually been submitted, not merely on the basis of expectation of submitting.
- Papers should not be listed as in press unless they have passed all editorial review and have been scheduled for publication.
- The use of data from a subject found retrospectively not to have satisfied all the protocol requirements for admission to a clinical study may be made only in accordance with validated biostatistical criteria, and the use of these data must be justified in any report or publication.
- Photo-images must not be manipulated without clear explanations of what was done.

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- Photo-images must not be manipulated without clear explanations of what was done.

1.4 Definitions of Research Misconduct – Plagiarism

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

OSTP Policy

- The ideas, results, or words of another should be clearly attributed in your manuscript.
- Citation to the work of another should be made at the point where the work is cited and should not be relegated to a non-footnoted general reference in the bibliography.
- Extensive use of the words of another author should be enclosed with quotation marks or should be formatted in indented paragraphs, with appropriate citation.
- It is improper to plagiarize an historical introduction, a review article, or methodological background from another author as well as to plagiarize research results.
- You may not use for your own purposes the ideas you find in a proposal or manuscript that you are reviewing.
- The publication by a supervisor of the work of a junior colleague or part of a student's thesis or dissertation, without attribution, is plagiarism.
- The editor of a collection of individually written chapters does not have the right to use the contributions of the individual authors without attribution.
- It is improper to include in a manuscript findings previously published by the same author or the same research group without citing the earlier publication.
- The concept of plagiarism may be applied not only to research but also to educational or other scholarly activity.

2 Standards of Proof

A finding of research misconduct requires that:

- There be a significant departure from accepted practices of the relevant research community.
- The misconduct be committed intentionally, or knowingly, or recklessly.

- The allegation be proven by a preponderance of the evidence.
- Research misconduct does not include honest error or differences of opinion.

3 Locus for Dealing with Allegations of Misconduct

3.1 U.S. GOVERNMENT

Office of Research Integrity (ORI), Public Health Service -

For policies and reports, consult: http://ori.dhhs.gov

Office of Inspector General, National Science Foundation -

For reports, consult:

http://www.nsf.gov/publications; Under Publication Types select Reports; Under NSF Organizations, select Office of Inspector General. Click View, and find Semiannual Reports to Congress.

Other Sponsoring Agencies:

3.2 UNIVERSITY OF PITTSBURGH

Academic Deans

Research Integrity Officer

1710 Cathedral of Learning

Phone: 412-624-3007

Fax: 412-624-1606

- The University's Research Integrity Officer is the designated institutional liaison with all federal agencies on research misconduct matters.

4 Duty to Report

- Reporting suspected misconduct is a shared and serious responsibility of all members of the academic community.

- Reporting is not an act of betrayal but is a positive act performed in an attempt to contribute to the quality and integrity of scholarship.

- Allegations shall not be made capriciously, but symptoms of evidence of misconduct shall not be ignored.

- Allegations of misconduct shall be communicated confidentially, and preferably in writing, to the dean of the school in which the misconduct is suspected or to the Research Integrity Officer (RIO).

- It is not the obligation of the complainant (whistleblower) to prove the allegation. If the matter deserves follow-up, an appropriately constituted panel will be designated to conduct the inquiry or investigation.

- Alleged violations of regulations designed to protect human subjects in research should be reported to the Institutional Review Board (IRB), at 412-383-1480.

- Alleged violations of regulations designed to protect animals used in experimentation should be reported to the Institutional Animal Care and Use Committee (IACUC), 412-383-2014, and/or the Director of the Division of Laboratory Animal Resources (DLAR), 412-648-8950.

- Problems initially reported to the IRB that may have implications of possible research misconduct may be reported by the IRB to the RIO or to the relevant dean.

- Problems uncovered in an internal Quality Assurance or external audit may be referred to the RIO if there are implications of possible research misconduct.

5 Protection of a Complainant (Whistleblower)

- The University will exercise all reasonable measures to provide protection against retaliation for a complainant who makes a good-faith allegation or engages in good-faith cooperation with the investigation of such allegations.

- *Good faith means having a belief in the truth of one's allegation or testimony that a reasonable person in the complainant's or witness' position could have based upon the information known to the complainant or witness at the time the allegation was made. An allegation or cooperation with an investigation is not in good faith if made with knowing or reckless disregard of information that would negate the allegation or testimony.

- For a Whistleblower Bill of Rights, recommended by the federal Commission on Research Integrity (1995), see Section II.D. of the Commission Report, at:

- http://ori.dhhs.gov/documents/report_commission.pdf

- Anyone who feels that retaliatory action has been taken against him/her for having lodged a complaint or cooperated with an inquiry or investigation may invoke the first step in the University Grievance Procedures

  http://www.pitt.edu/HOME/PP/policies/02/02-03-01.html

- If a settlement is not achieved in the first step, the grievant may request the appointment of a Grievance Panel by presenting a written complaint to the Research Integrity Officer.

- If there is a finding of retaliation, the Provost shall take corrective action, which may include redress of any disadvantage suffered by the grievant and sanctions against the person(s) found to have committed the retaliation.

- Disciplinary action may be taken against a complainant who is found by the dean to have made an allegation not in good faith but out of capriciousness or malice or with reckless disregard of known facts that would disprove the allegation. The dean's finding may be appealed.

6 Procedures for Dealing with Allegations - The Inquiry

- The Research Integrity Officer, in consultation with the dean, shall make a preliminary assessment of the allegation to determine whether it falls within the definition of Research Misconduct.

- A matter that does not fall within the definition of Research Misconduct but concerns alleged violations of other regulations may be dealt with directly by the dean or may be referred to another office that could have jurisdiction, such as the IRB or IACUC.

- If the allegation falls within the definition of Research Misconduct and sufficient evidence exists or may be obtained to warrant an inquiry the dean, in consultation with the Research Integrity Officer, shall appoint and charge one or more qualified and objective persons (the Inquiry Panel) to conduct a confidential inquiry.

- The inquiry consists of information-gathering and preliminary fact-finding to determine whether a formal investigation is warranted. Primary research records may be examined, experts may be consulted, and witnesses may be invited to give testimony. After receiving the report of the inquiry report and any written comments from the respondent (the accused), the dean recommends either that a formal investigation be conducted or that the matter be closed without a finding of misconduct.

- If the activities of the respondent are found to involve research impropriety but not misconduct, the dean will take corrective or disciplinary measures.

- The individual or office, such as the IRB or IACUC, that initially reported the possibility of research misconduct will be notified of the outcome of the inquiry.

7 Procedures for Dealing with Allegations -The Investigation

- An investigative panel consists of five objective peers, a majority of whom come from a school other than that in which the respondent holds a primary appointment.

- The respondent shall be informed of the allegations.

- The panel may examine the research records and consult witnesses at a hearing. Confidentiality is maintained throughout, except that the respondent has an opportunity to question witnesses who are called to give testimony.

- The respondent may be accompanied to the hearing by an adviser, who may but need not be a lawyer, who may consult with him but may not present the case to the panel.

- The respondent may question witnesses and may present evidence in defense against the allegations.

- An audiotape or stenographic record of the hearing procedures shall be made.

- The investigative panel writes a report to the dean, with a copy to the respondent, and recommends whether a finding of research misconduct be made. The respondent may make written comments on the report before the dean makes a final decision.

Follow-Up

- Absent a finding of misconduct, the matter is closed.
- If research impropriety is found but not research misconduct, the dean may take corrective or disciplinary measures.
- If misconduct is found, the respondent is subject to sanctions following a short period of time to allow for an appeal. (See Sections 6.8 and 6.9.)
- The complainant shall be informed of the outcome related to the complainant's role and information supplied.
- It is the responsibility of the Research Integrity Officer to report to the federal sponsoring agency the initiation of an investigation (but not of an inquiry), the findings of an investigation, and the final administrative actions taken as a result of the investigation. Relevant regulatory agencies, such as the FDA and OHRP, will also be notified in accordance with their requirements.

8 Internal Sanctions for Misconduct

Sanctions may include but are not limited to the following:

- A reprimand
- A requirement that letters of apology be written.
- Notification of editors and withdrawal or correction of abstracts, manuscripts, or papers
- Monitoring of future research
- Required participation in an educational program
- Removal from the project in question
- Notification and restitution to a sponsoring agency as appropriate
- Limitations on future role as an investigator
- Notification of future or prospective employers
- Notification of the IRB or IACUC, as appropriate
- Notification of affected institutions of the respondent's previous or current affiliation, co-authors, or other affected third parties

- Probation, suspension, or salary adjustment
- Notification of state or professional licensing boards
- Initiation of steps that could lead to a change of student or employment status including dismissal from a degree program or loss of tenure, or to revocation of a degree

9 External Sanctions for Misconduct

A sponsoring or regulatory federal agency , after allowing for appeal, may impose additional sanctions:

- Publication of a summary of the case in the Federal Register and/or other publications
- Prohibition from serving on advisory panels for a stated period
- Restrictions on role in future federally-supported research
- Debarment from receiving federal research funds
- Assessment of a fine
- Imprisonment for fraud