University of Pittsburgh

GUIDELINES FOR THE RESPONSIBLE CONDUCT OF RESEARCH

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THE GUIDELINES

The purpose of these guidelines is to provide important University standards for maintaining the integrity and quality of research activities. The ethical conduct of science is a necessary foundation without which progress would not be possible. Attention to best research practices leads to faster progress, improved reproducibility, and more productive collaborations among investigators. The credibility of science with the general public also depends on maintaining the highest ethical standards in research.

Observance of these guidelines will help investigators avoid departures from accepted ethical research practices 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 errors, differences of opinion, or disputes over authorship or credit. Misconduct as defined above is viewed as a serious professional offense and is subject to sanctions imposed by, but not limited to, the University, many professional associations, and funding agencies.

Part I of these guidelines discusses research misconduct. Many other unethical or undesirable activities related to research do not fall under the definition of research misconduct. One example would be 'research improprieties' which are usually failures to meet best practices in the relevant scholarly discipline and standards of the community. University standards for research practices are offered in Part II of these guidelines.

These guidelines provide a common repository of accepted practice for experienced researchers and can also serve as an introduction to responsible conduct of research for those who are just beginning research careers. Although some of these principles apply to all fields, much of what follows deals with scientific research in the physical and medical sciences and 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, several 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 an accompaniment to University-wide policies and procedures governing research, a partial list of which is found in the Appendix. Ethical concerns and best practices in research are also addressed through the Responsible Conduct of Research Course, a self-administered education, testing, and certification program, accessible through the University of Pittsburgh CITI training website.

I. MISCONDUCT IN RESEARCH

Research misconduct is defined as intentional, knowing, or reckless fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results.

Research misconduct does not include honest errors, differences of opinion, or disputes over authorship or credit.

Falsification and Fabrication of Research Results

> Fabrication is making up data or results and recording or reporting them.
>
> Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the experimental outcomes are not accurately represented in the research record.

For example, it is falsification of data to intentionally use image-processing software (e.g., Adobe Photoshop) while preparing a blot for viewing, to add or delete a band, to differentially adjust the intensity or contrast of one or more bands, to splice lanes without using a line indicating the deletion or otherwise revealing the splice, or to juxtapose pieces from different gels onto a single image. It is falsification to label an image from one experiment as representing a different experiment.

Instances of falsification and fabrication leading to findings of research misconduct have been discovered in publications, proposals, annual reports to agencies, research presentations and reports at meetings or at the University. The same standards of accuracy and integrity pertain to grant applications and proposals as those that apply to manuscripts submitted for publication. Reporting of results of experiments not yet performed as evidence in support of 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.

Research integrity requires that reported conclusions are based on accurately recorded data or observations truthfully reported, and that <u>all</u> relevant observations are reported. It is falsification to intentionally delete data or fail to report relevant data in any way that conceals the authentic outcome of an experiment.

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 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 to the original source, at the location in the manuscript of the copied material. 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 long-standing code of conduct governing all scholars and researchers, but in many

cases, it also constitutes 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 they 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 definition of plagiarism applies to grant applications or proposals, including background and research plan sections, as well as to publications.

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, for well-established concepts that are commonly found in textbooks or for phrases describing commonly used methodology. Special rules have been developed for citing electronic information. A citation guidance can be found on the University of Pittsburgh library website.

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 may 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 cannot usually be sustained. Researchers who are excluded from subsequent research are entitled, however, to be considered for co-authorship in publications if their contributions merit it.

Misuse of Privileged Information

Plagiarism includes the unattributed copying of 'privileged information'. Examples of privileged information include ideas, text, or original figures in grant applications or manuscripts received from a funding agency or journal editor for confidential 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.

Reporting Suspected Misconduct

Reporting suspected research misconduct is a shared and important 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 (research.integrity@pitt.edu). Allegations are handled under procedures described in the University Policy RI 07 'Research Integrity'. 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 may be required by law to report findings of misconduct in externally funded research to the funding agency or source, and in some cases an allegation must be reported even before the investigation is completed. 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.

II. BEST PRACTICES AND IMPROPRIETIES IN RESEARCH

Recording, Reporting, and Handling Research Data

Meticulous record-keeping is a sound scientific practice providing 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 the method to other situations. In addition, it is an aid in allowing the eventual sharing of information with others and as documentation that might be useful for disproving any subsequent allegations 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.

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 circumstantial evidence of research misconduct.

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 electronically. 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.

Each investigator has a responsibility to arrange for proper labeling, storage, organization, and backups of media stored electronically.

The use of computers in research laboratories is a necessity, and managing the data generated and stored electronically is becoming a challenge to investigators. 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, backup, and protect 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. Another 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 also provide the ability to add electronic signatures for further validation. The University offers a cloud-based Electronic Research Notebook service, LabArchives, to all University students, faculty, researchers, and staff. LabArchives research notebooks can be used to organize and manage laboratory data safely and conveniently using multiple platforms and devices. (https://www.technology.pitt.edu/services/electronic-lab-notebooks-eln)

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, researchers are often interested in reviewing the coding procedures 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. 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 per the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

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.

Special care must be taken in the use of photo-images not to misrepresent the underlying data. When using image-processing software, like Adobe Photoshop, for example, to prepare 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.

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 responsible for collecting the data. 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 University's Innovation Institute.

Data must be shared with the public in accordance with funding agency requirements and data sharing plans included in a funded proposal. However, selective sharing of unpublished data with a particular entity is generally prohibited. For example, it is unethical and a violation of conflict of interest principles for an investigator to selectively share unpublished data whose collection was funded by the government with a commercial entity with which the investigator has a financial relationship.

A principal investigator who leaves the University must typically leave their original data but is entitled to make a copy of data to take to another institution so as to be able to continue the research. In some cases, they may be permitted 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. The Office of Sponsored Programs (OSP) can assist with processing Material Transfer Agreements (MTAs) and Data Use Agreements (DUAs) for transfer of materials and data. 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 they 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 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, their allocation should be clearly stipulated in the agreement. The Office of Sponsored Programs facilitates the execution of such agreements.

As the scientific enterprise may be a cooperative endeavor encompassing many persons who now or in the future might pursue related research interests, and as 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 may 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.

Storage and Retention of Data

Data should typically be stored securely for at least seven (7) 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, and extended storage of some types of data may be required by laws or regulations. 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 (2) years following final approval of the respective drug or device, which is likely to be substantially longer than seven years after completion of the research project. Human subject research done on children must be retained until all subjects reach the age of 23.

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) has a Data Sharing Policy, effective January 25, 2023, that varies by the type of data collected. The Inter-university Consortium for Political and Social Research has guidelines for preparing data in the social sciences for archiving. It is required by the FDA and expected by many journals that human subject research studies be reported on the ClinicalTrials.gov website. In addition, all NIH-funded recipients and investigators conducting clinical trials, funded in whole or in part by the NIH, must ensure that their clinical trials are registered at, and that summary results information is submitted to ClinicalTrials.gov for public posting. In some research fields, authors are encouraged to create their own Web sites on which they may store extensive data sets for general access.

Some data may fall within the definition of 'Controlled Unclassified Information' and will, therefore, be subject to additional federal regulation. For more information please refer to: https://www.tradecompliance.pitt.edu/procedures/controlled-unclassified-information

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 have sufficient detail to permit other researchers to replicate the results. Publication should be timely but should not be hastened unduly. Haste may increase the risk of not subjecting all results to adequate internal confirmation or of not considering adequately all possible interpretations.

Some data may be sensitive, and a governmental funding agency may require approval to publish particular findings, such as those funded through a proposal with Controlled Unclassified Information (CUI) classification. CUI restrictions are specified in Part 2002 of 32 Code of Federal Regulations. Investigators must abide by any publication restrictions stipulated by regulations pertinent to their work.

A commercial sponsor of a research project may not prevent publication of experimental outcomes, although a delay of publication for an agreed period, not to exceed 90 days, may be allowed in order to permit filing of a patent application (see Corporate Research Agreement Template at: https://www.osp.pitt.edu/osp-teams/clinical-corporate-contract-services/negotiations/corporate-funded-agreements-cras).

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.[1]

[1] *Science* **299**, 1149 (2003)

Criteria for Authorship

Publications must give appropriate credit to all authors for their roles in the research. If more than one person contributes, 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 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. More ideal is to discuss and agree to authorship inclusion and order prior to the start of research and to revisit this subject when new investigators join the project and with any major change to the scope or direction of the research.

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.

Each paper should have designated a corresponding or senior author (often the first or last of the listed names in a multi-authored manuscript) 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. Sometimes two persons are identified as corresponding authors. Any corresponding author has a greater responsibility than other coauthors to vouch for the integrity of the research report and to be prepared to defend every element of the reported research.

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 a galley proof or page proof or a communication from an editor or publisher stating that publication has been approved, subject perhaps only to copyediting.

Duplicate Publication

Researchers should not publish the same article in two different places without legitimate reason and must include appropriate citation in the later publication to the earlier one. In such cases, the editor must be explicitly informed of the prior publication when the manuscript is submitted. The same rules apply to abstracts. If there is unexplained duplication of publications without citation, sometimes referred to as self-plagiarism, a reader may be deceived as to the amount of original research data produced by that investigator.

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 several 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.

Self-plagiarism

'Self-plagiarism' also known as text recycling (https://textrecycling.org/) occurs when an author re-uses previously published text in later publications or manuscripts submitted for publication. Such re-use of one's own words does not fall within the definition of research misconduct and, therefore, would not be investigated under research integrity policy. Generally, duplications of

text describing experimental methods are not considered self-plagiarism. In the background, introduction, research description, results, and discussion sections, however, self-plagiarism is ethically dubious and may constitute a failure to meet the standards of professionalism in some disciplines. Self-plagiarism may also violate copyright law and therefore be subject to legal penalties.

The University expects scholars to follow the guidelines published by the Office of Research Integrity of the Department of Health and Human Services:

> "Guideline 10: Authors who submit a manuscript for publication containing previously disseminated data, reviews, conclusions, etc., must clearly indicate to the editors and readers the nature of the previous dissemination. The provenance of data must never be in doubt."

Further guidelines and examples relevant to the topic of self-plagiarism may be found at this site: https://ori.hhs.gov/why-duplication-and-other-forms-redundancy-must-be-avoided.

Accessibility of Publications

Most research funding agencies have proposed that all publications supported by federal funds be posted within a reasonable time in an electronically accessible form. For example, to advance science and improve human health, NIH makes the peer-reviewed articles it funds publicly available on PubMed Central. The NIH Public Access Policy requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central immediately upon acceptance for publication. The NSF requires that either the version of record or the final accepted manuscript in peer-reviewed scholarly journals and juried conference papers be deposited in a designated public access compliant repository and be available for download, reading and analysis free of charge no later than 12 months after initial publication. It is the investigator's responsibility to be familiar with the accessibility of publication requirements from each of their funding agencies.

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 its publication or a presentation prior to its occurrence. This does not apply to sharing preliminary versions of research papers before peer-review by posting to online preprint servers. Exceptions to the prohibition against advance release may be made if a public health issue is involved and the editor or meeting organizers agree to an advance release.

Interference

Intentional removal of, interference with, damage, or miscalibration of any research-related property, instruments, and other equipment, is improper and could be classified as research misconduct.

Correction of Errors

If an error in data presented is found after publication, whether the error is intentional or inadvertent, or plagiarism should be discovered 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 agreed to by the University and a sponsoring federal agency.

Curriculum Vita, Biographical Sketches for Proposals, and Other Support Disclosures

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. Allegations of such acts will be investigated and censured if warranted.

In listing publications, it is recommended that clearly labeled, separate sections 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.

Grant applications often include sections related to curricula vitae – the Biographical Sketch (Biosketch) and Current and Pending Support sections. Each contributing investigator is responsible for the integrity and completeness of their Biosketch and Other Support sections. Beginning January 25, 2022, NIH requires new formats for both the biosketch and the Other Support documents. For more details about the changes to the NIH biosketch and Other Support, see NIH Notice NOT-OD-21-073, Notice NOT-OD-21-110, Other Support FAQs, and Biosketch FAQs. Effective October 4, 2021, the NSF is requiring the use of new biographical sketch and current and pending support formats, which were updated to incorporate revisions in the Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 22-1). Any error of omission in Other Support information must be reported to the relevant agency office as soon as it becomes known.

Conflict of Interest

Conflicts of interest (COI) exist whenever a University member has personal, professional, commercial, or financial interests or activities outside the University that have the potential to interfere or be perceived to interfere with their University duties or objectivity.

The University Conflict of Interest Policy for Research (Policy RI 01) requires that full-time faculty and University investigators complete an Annual Disclosure Certification in 'MyDisclosures' to disclose any outside interests, activities, or relationships that could create an actual or perceived COI in University research. The disclosures are reviewed by the discloser's supervisor for both

conflict of commitment (COC) and COI and, in some instances, are reviewed by the Conflict of Interest Division (COID) or the Conflict of Interest Committee (COIC).

When a potential COI is identified, a conflict management plan (CMP) is implemented. The purpose of the CMP is to formally identify the COI and to define steps that will mitigate negative effects that might arise from the COI. An example of such negative effects would be unconscious bias, or a perception of unconscious bias, in collecting or interpreting data by an investigator who has a financial interest in the outcome of an experiment. Measures that may be included in a CMP include, but are not limited to, disclosure of the COI in publications and presentations, limitation of the conflicted investigator's role in the research, internal monitoring of the research within the University, and, occasionally, divestiture or elimination of the conflicting interest.

Disclosure typically includes a notice of the conflicted investigator's financial interests in relevant abstracts, publications, presentations, press releases, reports, and human subject research consent forms. A conflicted investigator must also disclose their financial interests in a project to research students and members of the research staff. Separate but related to these disclosure requirements, many journals and funding agencies require disclosure of financial interests or other support when investigators serve as peer reviewers or submit proposals for funding. Authors, grant applicants, and supported investigators should study and learn the specific disclosure requirements of funding agencies and journals relevant to their work.

In some cases, the CMP may require a conflicted investigator's role in the research to be limited to that of a co-investigator rather than principal investigator (PI), a role reduction known as the "PI-Exclusion rule". It is applicable in human subject research when a conflicted investigator has certain significant financial interests (SFIs) that could be affected by the outcome of the study they are conducting. SFIs that trigger PI-exclusion include, but are not limited to, equity in a private for-profit entity, a management, officer, or Board of Directors position or the receipt of payments associated with licensed technology that exceed certain thresholds. For example, a COI that requires implementation of the PI-Exclusion rule would exist when an investigator develops technology through their University research, creates a start-up company that licenses that technology, and then continues to evaluate the licensed technology in their human subject research at the University. While these entrepreneurial activities are encouraged, the COIs they create are subject to oversight and conflict management.

Faculty are encouraged to engage in outside activities such as consulting, founding, and managing new companies, or serving on scientific advisory boards. To do so, however, they must: (1) obtain prior approval from their supervisor; (2) disclose the activity and any compensation in MyDisclosures; and (3) when a COI is identified, adhere to the relevant CMP. University facilities are not 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.

Tenured and tenure stream faculty, but not staff, may spend up to one day per week in outside activities, provided advance approval is obtained and the other previously mentioned requirements are met. Outside activity can create a conflict of commitment (COC) if the outside work interferes or may be perceived to interfere with the individual's performance of their

University responsibilities or interfere with personal objectivity in teaching or research. For a detailed explanation of the 'one day a week' rule, please visit the COI Division's web page: Faculty Use of University Time for Outside Professional Activities.

Separate but related to individual COIs and COCs, an institutional conflict of interest (ICOI) may exist when the University's financial interests, relationships with external entities, or external engagements of Covered University Officials could reasonably be perceived as interfering with its business decisions or core missions of research, scholarship, and teaching (Policy RI 11). An ICOI Committee reviews certain University Threshold Transactions to determine if a potential ICOI exists and, if so, recommends an institutional CMP to relevant Senior Decision Makers. Examples of potential ICOIs include when the University owns equity in a for-profit entity that will sponsor research at the University or when the University has a right to receive payments associated with licensed technology and that technology will be tested or evaluated in University human subject research.

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. They 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 routine 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 regularly report their research progress 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 they 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: https://www.provost.pitt.edu/students/graduate-studies/elements-good-academic-advising.

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

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.

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

Responsibilities to Funding Agencies

Investigators must read and follow all agency policies relevant to the award or grant supporting their research. For example, the National Institutes of Health Grants Policy Statement (NIHGPS) is an essential resource for NIH award recipients. NSF prepares a Proposal & Award Policies & Procedures Guide (PAPPG) (NSF 22-1). Other agencies prepare similar policy documents.

Investigators must submit progress and final research reports to sponsors at times specified in the awards. They 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 Sponsored Programs, should familiarize themselves with the special terms of those agreements, such as those 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.

Special Obligations in Human Subject Research

Research protocols involving human subjects must be approved in advance by the University Institutional Review Board (IRB), the reviewing body for Human Research Protections (HRP), 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(l)].

Human subject means "…a living individual about whom an investigator (whether professional or student) conducting research obtains: (i) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens" [45 CFR 46.102(e)].

There are a number of specific types of projects that no longer meet the definition of human subjects research including scholarly and journalistic activities, public health surveillance activities, and collection and analysis of information, biospecimens, or records by or for a criminal justice agency. In addition, there may be 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 HRP (askirb@pitt.edu) for advice. Alternately, guidance is available on the HRP web site (https://www.hrpo.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 positive determination from the HRP office.

The IRB reviews both the application 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 application submitted to the IRB must include a plan for data and safety monitoring. Applications should also identify the research sponsor. If any investigator has a significant financial conflict of interest, the IRB application should include a plan for managing potential conflicts of interest, approved by the Conflict of Interest Division. 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 consent must be fully compliant with the federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

Every research application 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. However, Department of Defense (DoD) funded or supported studies must have a departmental scientific 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 HRP Division (https://www.hrpo.pitt.edu, irb@pitt.edu) 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 (http://ooas.pitt.edu/corid; 412-802-8280). Depending on the nature of the study, additional approvals must be sought from various offices that are part of the Office of Research Protections. These include institutional biosafety (https://www.ibc.pitt.edu/), radiation safety (https://www.radsafe.pitt.edu/), investigator-sponsored IND and IDE support (https://www.ecshsr.pitt.edu/ind-ide-support), and human stem cell research oversight (https://www.ibc.pitt.edu/human-stem-cell-research-oversight-hscro).

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 necessary to generate reliable and reproducible results. Wherever possible, alternatives not requiring the use of animals must be considered, and if practicable, adopted. Approval must be obtained from the Institutional Animal Care and Use Committee by submitting a protocol through the Animal

Research Online system (ARO, https://www.aro.pitt.edu/) prior to the initiation of any research or teaching that requires the use of animals. The director and attending veterinarian of the Division of Laboratory Animal Resources (dlar@pitt.edu) are available for consultation 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.

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). The IBC website contains information about compliance with NIH guidelines for investigators, and assessment and determination of required biosafety measures.

III. ADDITIONAL UNIVERSITY RESEARCH SUPPORT

Radiation Safety

The University Radiation Safety Division (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 the Radiation Safety Website.

Environmental Health and Safety

The Department of Environmental Health and Safety (EH&S) 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 website and may be requested in hard copy from EH&S.

Intellectual Property and Technology Management

The Office of Innovation and Entrepreneurship 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.

Office of Sponsored Programs

The Office of Sponsored Programs (OSP) 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 Sponsored Programs must approve and sign all such documents as the authorized

University signatory. The functional areas supported by Office of Sponsored Programs staff include information services, project and proposal development assistance, and grants and contracts administration for pre-award and selected post-award tasks

Office of Research, Health Sciences

The Office of Research, Health Sciences, OORHS, mission is to foster both the emerging and the established research enterprises within and across the schools of the Health Sciences at the University of Pittsburgh. These schools are Dental Medicine, Health and Rehabilitation Sciences, Medicine, Nursing, Pharmacy, and Public Health. OORHS serves the University of Pittsburgh Health Sciences community by:

- Providing Information about research funding announcements, federal and University policy changes, and the latest scientific news
- Administering institutional grants programs, such as the Competitive Medical Research Fund (CMRF) and the Health Science Bridge Funding program
- Providing editorial assistance, grantsmanship advice, and scientific review of grant applications for Health Science faculty members
- Facilitating the preparation of multi-investigator and multi-disciplinary grant applications
- Providing guidance to new research faculty in the Schools of the Health Sciences
- Fostering the development and use of research resources and core facilities

Issues or concerns related to biomedical research should be brought to the attention of the Associate Vice Chancellor for Interdisciplinary Research, Health Sciences or its staff.

Investigator-Sponsored IND and IDE Support

The Investigator-Sponsored IND and IDE Support Program (IIS) 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.

Clinical and Translational Science Institute

Pitt's Clinical and Translational Science Institute (CTSI) supports transformation of scientific research and clinical discoveries into modern medical techniques that improve lives. CTSI works directly with researchers in collaboration with regulatory agencies to navigate all necessary regulatory pathways, at any stage of their research. CTSI-supported programs and resources extend to all six of Pitt's schools of the health sciences — and through community engagement efforts — to the Pittsburgh region. Through the establishment of 12 Core divisions, CTSI is building institutional infrastructure, including educational, programmatic, facility, and equipment resources to support a wide range of clinical and translational research.

The Responsible Conduct of Research (RCR) Center provides education on the ethical standards and responsible practices essential for successful scientific research. At any step in the research process, researchers may need to address ethical issues in a thoughtful, responsible manner. The CTSI Responsible Conduct of Research (RCR) Center serves as a resource for researchers at the University of Pittsburgh and the University of Pittsburgh Medical Center (UPMC). Our objective

is to provide education so researchers learn to effectively recognize issues and avoid research misconduct while informing them of the resources that are available to support research. The RCR Center offers workshops that cover subject matter/topics as described in the guidance provided by NIH.

UPMC Clinical Trials Office

The purpose of the Office of Sponsored Programs and Research Support (OSPARS) is to facilitate the implementation and provided institutional oversight of the conduct of industry-initiated and sponsored clinical trials within UPMC. OSPARS facilitates sponsored programs and clinical trials by:

- Assisting in reviewing and endorsing proposals
- Negotiating agreements
- Accepting and authorizing awards
- Interpreting sponsor rules and guidelines
- Providing post-award administration services

All questions and submissions may be directed to OSPARS@upmc.edu.

The Office of Research Protections

The Office of Research Protections (ORP), is the umbrella entity encompassing various units that oversee and facilitate the conduct of ethical and regulation-compliant research. The ORP aids investigators in designing and performing research studies so they meet current ethical standards and conform to all applicable laws and regulations. The units that comprise the ORP accomplish this goal through education, prospective review of research protocols, consultations with investigators, and monitoring of ongoing studies.

IV. APPENDIX

PARTIAL LIST OF RELEVANT UNIVERSITY POLICIES AND PROCEDURES

All University Policies can be accessed online.

Bloodborne Pathogens, CS 01. This document serves to clarify the University program for education, prevention, post-exposure medical treatment and follow-up provided for employees and students who have been exposed to bloodborne pathogens as a part of workplace or other programmed activity.

Conflict of Interest Policy for Research, RI 01. 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.

Copying Copyrighted Material, CS 03. This policy describes procedures for seeking copyrights and specify the relative rights of the author and the University.

Guidelines on Academic Integrity - Student and Faculty Obligations and Hearing Procedures, AC 39. 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.

Guidance on Research Data Management. The University Guidelines on Research Data Management should be reviewed by all research investigators, research coordinators, and department administrators involved in research. All departments engaged in research activities should review their internal data storage and retention practices in conjunction with this guidance. Further information on the NIH guidelines for data management and sharing policy can be found on the HSLS website.

IRB Reference Policies & Procedures, available online or from the Human Research Protection Division (irb@pitt.edu). This is a detailed description of the regulations governing the use of human research subjects and of the procedures for seeking IRB approval.

Innovation Institute Inventors Guide provides online guidance for information on invention disclosures, patent rights and tech transfer intended to help University members better understand some of the terminology and the processes used in moving innovations from the lab to the market of the inventor(s) and the University.

Research Integrity Policy, RI 07. This policy 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.

Responsibilities of Sponsored Research Investigators, RI 08. This document outlines the roles, rights and responsibilities of investigators and provides a mechanism for resolution of disputes.

Use of Animals in Research, Testing, and Teaching. Institutional Animal Care and Use Committee/Education, Compliance and Support – Animal Division (412-383-2008) has listed all policies governing use of animals on its website.