

Research Integrity Policy & Procedures

Approved by:

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Introduction

Healthcare Platform Institute (HPI) expects the highest standards of professional conduct from each employee in all activities they perform. Moreover, the area of scientific research relies upon the trust and confidence of both the scientific community and the public at large. Unethical behavior undermines confidence in the reliability of science and the integrity of the Institute. For these reasons, the Institute considers misconduct a betrayal of fundamental scientific principles and shall deal with all instances of possible misconduct firmly in accordance with the *HPI's Research Integrity Policy and Procedures*. The Institute shall process situations that may constitute research misconduct (such as intentional or reckless fabrication, falsification or plagiarism). Situations that do not result in a finding of this policy may be reviewed under the Institute's other policies of the institute.

Prevention

The Institute expects intellectual honesty in all its endeavors. Employees should maintain open communication, submit work for peer review, comply with the Institute's policies and procedures, disclose and cooperate in the management of conflicts of interest, commit to self-regulation, and comply with the Institute's processes for the disclosure and management of conflicts of interest. The Institute shall inform employees regarding its ethical standards, its guidelines for conducting and reporting research, its philosophy and policy for dealing with and reporting possible misconduct, and the importance of complying with the relevant policies and procedures.

As a regular element of its policy of maintaining the highest possible standard of productivity, the Institute will continue to maintain a regular and rigorous system of review of the quality of the work of its employees and internal affiliates.

The Institute shall periodically evaluate its policy and procedures for educating its staff about the proper conduct of research and assess whether additional efforts are necessary.

The purpose of this policy is:

- ✓ To set forth research integrity principles and practices.

- ✓ To ensure that the employees of the Institute are informed of institutional and governmental regulations relevant to their work.
- ✓ To establish procedures designed to promote research integrity.

Procedure(s) for Research Supervisors

Primary investigators are responsible for the careful supervision of their trainees and other research personnel. The complexity of scientific methods and the need for careful experimental design, caution in interpreting possibly ambiguous data, and advanced statistical analysis all require that the primary investigator assumes an active role of guidance and supervision. Primary investigators should be prepared to give additional attention to other members of research team who arrives in a research division without substantial experience.

Rules

Responsibility for research team members must be assigned to a specific primary investigator. For particular research projects, supervision should be carried out by the responsible primary investigator.

As a part of its orientation program for new members of the research teams, the Institute will provide each new employee a copy of this Policy. Primary investigators should familiarize team members with relevant governmental and institutional requirements for conduct of studies involving human research participants.

Recommendations

The degree of supervision by the primary investigators should take into account the experience and skill of other personnel with the research team. Primary investigators should help trainees develop good research practices and technical expertise, as well as good research ethics.

Primary investigators should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting, and storing data. The editing of manuscripts alone does not constitute adequate supervision by the primary investigator.

Primary investigators should have realistic expectations regarding the performance of team members and other research personnel and should inform them of these expectations.

Collegial discussions among all primary investigators and trainees constituting a research division should be held regularly both to contribute to the scientific efforts of the members of the group and to provide informal peer review.

Primary investigators should be alert to behavioral changes in the research team members or other research personnel that may indicate inordinate personal or academic stresses or substance abuse. Stresses are particularly likely to occur at times of transition or as deadlines approach. Since the care with which research activities are conducted may be adversely affected by stress, members or employee may need closer supervision at such times.

Data Gathering, Storage and Retention

The retention of accurately recorded results is of utmost importance for the progress of scientific research. Original data must be retrievable not only to answer scientific questions but also to respond to questions that may arise about the propriety of research conduct. Moreover, a common denominator in most cases of alleged research fraud has been the absence of a complete set of verifiable data. The rules and recommendations in this section are designed to ensure that all research data are recorded appropriately and that access to them will be available when necessary.

The Institute is aware that scientific investigation may be impeded if undue conditions are placed on the ability of departing investigators to retain custody of original data generated in the course of work performed here. Nevertheless, there are pragmatic reasons for preserving the Institute's ready access to original data. For example, access to original data may be necessary if the Institute is to render the most effective assistance in rebutting unjustified claims of fraud made against its researchers. The Institute is also responsible for promoting the collective reputation for integrity of its researchers with public and private granting agencies. The inability to produce original data tends to place the integrity of research in question. Moreover, original data is always considered the best evidence for the purposes of avoiding questions of admissibility in administrative or judicial proceedings. When an investigator is departing the Institute, he or she may enter into a written agreement with the director of his or her research division with regard to original data.

While what constitutes "original" or "primary" data may differ depending on the technology used, in every instance an investigator is expected to maintain an accurate record of experimental data that is as close to the original form of the data as is practical. When the "original" data are so voluminous or are collected and/or modified in atypical ways (for example, in the case of data collected by computer), individual investigators should seek concurrence of their Division Director, or his or her designee, in deciding what aspect of their research will constitute primary data, bearing in mind the possible future need to support reported findings.

Rules

Custody of all original data must be retained by the institute's research division. An investigator who moves to another institution must submit to the head of the division, or his or her designee, a written request to remove original data from the Institute. This request must contain an itemized description of the data and must specify where the data will be located in the future. In granting such requests, the Division Director, or his or her designee, must remind the researcher that legally the data are the property of the Institute; that any inventions made here must be disclosed to the research division the Institute; and that original data must be made available for review if questions of research misconduct should arise. If the head of research division, or his or her designee, does not approve of the removal of data, an appeal may be made to the president of the institute.

Investigators are required to retain research records in accordance with legal requirements, institutional policies and contractual obligations to research sponsors. The data stored must be kept in accordance with institutional policy. For instance, human subject information must be kept in secure, protected locations.

Legal Requirements

For research involving protected health information or other confidential information protected by federal or regional laws, study records should be kept for at least seven years after the last subject has completed the study. For all other research, the Institute will require that original data be retained for at least seven years from the date of publication. Beyond that, where questions have been raised regarding the validity of the published data, investigators must preserve original data until such questions have been resolved to the satisfaction of the Institute and any involved government agencies. Then, each head of research division must decide whether to preserve original data for a given number of additional years or for the life of the division.

Recommendations

Original experimental results should be kept in an orderly fashion in such a way that they are accessible and can be easily reviewed by peers. Records should identify when experiments were done and by whom.

To ensure against the loss of primary data that are stored electronically, such data should be backed up on a central server and/or on disks or CDs. Hard copies of primary data that are used in publications, presentations and funding applications should be generated and maintained as noted above.

Authorship

Two critical safeguards in the publication of accurate scientific reports are the active participation of each co-author in verifying any part of a manuscript that falls within his or her specialty area and the designation of one author who is responsible for obtaining co-author verification.

Rules

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

Recommendations

Criteria for authorship of a manuscript should be determined and announced by each research division, and in advance when possible. Authorship should be given generously, but only to those who have contributed significantly and substantially to the research, are prepared to stand behind their findings, and have reviewed the entire manuscript. The referral of participants included in a research study does not, in and of itself, constitute a significant contribution warranting co-authorship status. All publications should credit research findings appropriately by citing relevant observations of others, as well as by recognizing the work and input of all contributors in their own environments.

Publication Practices

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

Recommendations

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

Reporting Misconduct

The trust and good faith firmly associated with the Institute will flourish only if every member of this community bears responsibility for upholding the highest standards of integrity. Should misconduct occur, early identification and intervention are in the best interests of everyone. Steps to be taken by anyone who suspects that another's conduct has been improper are detailed in the procedures below. The Institute recognizes the risks to persons who report apparent misconduct and has made every effort to protect them as well as those who might be accused in error. It is a professional obligation of every employee and internal affiliates to inform either his or her superiors, the Institute executive team, or the Institute's research division, or his or her designee, if the person has reservations about the integrity of the work of another member of this community.

Institutional Actions in Response to Final Findings of Misconduct

Violations of this Research Integrity Policy and Procedures may result in discipline up to and including termination of employment.