

T.R.U.E. Research Foundation

Scientific Misconduct Policy on

Allegations, Investigations and Reporting

POLICY # 15

PURPOSE OF POLICY

This policy presents procedures for reporting and investigating allegations of scientific misconduct, and for the required notifications to federal agencies of such allegations and investigations

BACKGROUND

Each TRUE employee has a responsibility to foster an environment which promotes intellectual honesty and integrity, and which does not tolerate misconduct in any aspect of research endeavor.

Scientific misconduct is extremely troubling - in spite of its infrequency - because when it occurs, it is very destructive of the standards we attempt to instill in our employees, of the esteem in which clinical science in general is held by the public, and of the financial support of the government and other sponsors for clinical scientific enterprise. The importance of integrity in research cannot be overemphasized.

Some federal agencies currently have their own policies regarding scientific misconduct, and require notification to the agency in the event of such an allegation or investigation. At this time, those agencies are the U.S. Public Health Service (PHS) and the National Science Foundation (NSF).

Where required, this notification will be made by the Research Director. While both PHS and NSF recognize that the primary responsibility for the prevention and detection of misconduct, and for the conduct of inquiries and investigations, rests with the awarded institution, they both retain the right to initiate their own investigations at any time.

I. DEFINITIONS

T.R.U.E.'s definition of scientific misconduct, and procedures for investigating and reporting allegations of misconduct, conform to the definitions and regulations of those federal funding agencies which have policies on this subject.

Scientific Misconduct is defined as fabrication, falsification, plagiarism, or other practices that seriously deviate from those commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data.

Also, included as "scientific misconduct" for this purpose is retaliation of any kind against a person who, acting in good faith, reported or provided information about suspected or alleged misconduct. This policy addresses only scientific misconduct.

TRUE's statement on employment practices has been addressed in **Policy # 8** to include such other violations as reckless disregard for accuracy, failure to supervise adequately, and other lapses from professional conduct or neglect of job duties. Allegations or suspicions of misconduct outside the scope of this policy should be directed to the Direct Research Supervisor, Human Resources Director or CEO for investigation, although the process of investigation and reporting obligations may differ from those required for scientific misconduct cases.

An **inquiry** consists of preliminary information-gathering and preliminary fact-finding to determine whether an allegation or an apparent instance of misconduct has substance. The outcome of an inquiry is a determination as to whether or not an investigation is to be conducted.

An **investigation** is a formal examination and evaluation of relevant facts to determine whether or not misconduct has taken place.

II. INDIVIDUAL REPORTING RESPONSIBILITY

Any individuals who believe an act of scientific misconduct has occurred or is occurring should notify the Research Supervisor and/or the RESEARCH DIRECTOR who should immediately begin an inquiry and so inform the appropriate IRB and/or Commander at the site. Reporting such concerns in good faith is a service to the T.R.U.E. organization and to the larger military community, and will not jeopardize anyone's employment.

III. PROCESS AND TIME FRAME FOR RESEARCH Director's REVIEW

The RESEARCH DIRECTOR will immediately contact the research site Commander, Clinical Investigation Department and/or IRB Chair to notify them of the alleged scientific misconduct if such misconduct involves a federal employee. The RESEARCH DIRECTOR will then ask to be a part of the Inquiry and Investigation team so as to report the findings to the appropriate funding agency.

If the alleged scientific misconduct does not involve a military employee and is only against a TRUE employee, then TRUE will notify the Principal Investigator or the Clinical Investigation Department if the Principal Investigator is a TRUE employee and invite them to be a part of the Inquiry and Investigation team.

1. Inquiry: Upon receipt of an allegation of scientific misconduct, the RESEARCH DIRECTOR shall immediately begin an inquiry and shall so inform the Principal Investigator, identifying any outside funding source(s) for the research which is the subject of the inquiry. This inquiry is to determine whether a formal investigation is warranted, and shall be guided by the following:

The accused individual shall be informed of the allegations, and be invited to comment on them. This individual should also be provided with a copy of the draft report of the inquiry, and be given an opportunity to comment on the findings. In so doing, best efforts should be made to protect the confidence of the individual who brought forward the complaint.

Any other relevant individuals, including the individual(s) who raised the concern, if known, should be interviewed.

The final report, including a recommendation as to whether or not a full investigation is warranted, must be submitted by the CEO within 60 days of receipt of the allegation. The final report shall include any comments provided by the accused in response to the draft report. The final report will be presented at the next T.R.U.E. Board of Directors meeting for review and action.

The documentation should include sufficient detail to permit a later assessment of the determination of whether or not a full investigation was warranted. It should describe the information reviewed, include a summary of the interviews conducted, state conclusions reached, and indicate whether or not the RESEARCH DIRECTOR believes an investigation is warranted.

The final report of the inquiry and documentation must be maintained in T.R.U.E. records for three years.

Unless the Board of Directors has further concerns, the Board of Directors recommendation that an internal investigation is not warranted, will be final.

2. Investigation Procedures for T.R.U.E. employees: If the inquiry into a T.R.U.E. employee leads to the conclusion that an investigation is necessary, it will be guided by the following considerations: The formal investigation should begin within 30 days of the completion of the inquiry. The investigation should be completed and the final report sent to the RESEARCH DIRECTOR within 90 days. (If an investigation cannot be completed within this time frame, the RESEARCH DIRECTOR should be notified as soon as possible. In such cases, it may be necessary for the RESEARCH DIRECTOR to request an extension of time from federal funding agencies.)

The investigative process must be thorough, fair and protective of the confidentiality and reputations of all participants.

An investigation should normally include an examination of all documentation, including but not limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls.

Those making accusations, those accused, and those who may have information related to the matter should be interviewed. Complete written summaries of each interview should be provided to the individual being questioned, and any comments should be appended to the summary, or reflected in a revised summary if the interviewer agrees. The summaries must be retained by the CEO.

All significant issues should be pursued until the investigator is reasonably certain that he or she has amassed all necessary and available information, and has consulted with members of the TRUE Board of Directors as to the information.

A draft written report of findings should be made available to the accused. Where identified, those who made the allegations should also receive the portions of the draft

report which concern the role or opinions they had in the investigation. Comments on the draft from the accused or the accusers should be appended to the final report.

NOTE: If there is more than one accused individual, and their involvements are found not to be identical, separate draft reports should be prepared if practical, in order to preserve confidentiality.

In addition to the interview summaries and comments by the accused and accuser(s) on the draft report, the final written report should include:

- 1) a description of the policies and procedures followed
- 2) how and from whom relevant information was obtained
- 3) the findings and basis for them.

If either the CEO or the RESEARCH DIRECTOR considers that sanctions may be warranted, either shall refer the final report to the T.R.U.E. Board of Directors who shall make that determination. The report should be sufficient for the President, or other appropriate T.R.U.E. Board members, to determine whether disciplinary action is called for. If any sanctions result, the RESEARCH DIRECTOR shall be informed, and shall append that information to the final report.

IV. EXTERNAL RESEARCH DIRECTORRDINATION INVOLVING FEDERAL EMPLOYEES

In order to assure compliance with external notification requirements, the RESEARCH DIRECTOR will request the following information from the investigating official or committee at the Military site in a timely manner:

- commencement of an inquiry
- conclusion of an inquiry
- commencement of an investigation
- consultation if an investigation will take more than 90 days to complete
- conclusion of an investigation

If termination of an inquiry or investigation before its completion is contemplated for any reason, this information will also be requested by the RESEARCH DIRECTOR. In addition, the RESEARCH DIRECTOR is to be advised at once if any of the following circumstances are discovered:

- an immediate health hazard
- an immediate need to protect federal or T.R.U.E funds or equipment
- an immediate need to protect those making the allegation, those accused or any of their associates
- likelihood that an alleged incident will be reported publicly
- a reasonable indication of a possible criminal violation

The RESEARCH DIRECTOR shall also take interim action as necessary to protect federal funds and the purposes of the federal grant or contract that may be involved. Such action is administrative and not disciplinary.

If, during an investigation, facts come to light that could affect current or potential funding of the people under investigation, or that may, in the RESEARCH Director's judgment, need to be disclosed in order to ensure proper use of research funds or

protection of the public interest, these facts should be reported to the CEO as they are learned.

V. NOTIFICATION TO EXTERNAL AGENCIES

NOTE: T.R.U.E. Research Foundation will comply with the requirements and regulations of its funding agencies. The following section reflects those requirements as of May 1994. In any particular situation, T.R.U.E. employees working on federally funded studies are advised to review current regulations and requirements.

Under circumstances not involving Public Health Service or other regulated funding agencies, the CEO will make the decision whether information about the charges and their disposition will be disclosed publicly or to specific parties, including the research sponsor. This decision will normally be made upon the conclusion of the final report. However, if required by urgent circumstances, such a disclosure may be made at any time. The CEO will consult with the Board of Directors to the extent feasible and appropriate in such cases.

Absent such urgent need, T.R.U.E. will not make interim reports to outside agencies unless required by external regulation. The Public Health Service requires annual assurances from T.R.U.E. of compliance as well as aggregated information on allegations, inquiries, and investigations. Further, in accord with Public Health Service and National Science Foundation regulations, in cases involving research funded by either of those agencies, the funding agency will be informed in the following situations. Except as specifically described at the end of this section, the following notifications to external agencies will be made only by the RESEARCH DIRECTOR, acting on behalf of the CEO, and on the basis of the information provided by the T.R.U.E. employee:

OUTCOME OF AN INQUIRY

PHS and NSF will be notified of the outcome of an inquiry involving funds from their agency only if that outcome includes the recommendation to conduct a full investigation. (Documentation from inquiries, even those that do not recommend further investigation, will be made available by the RESEARCH DIRECTOR upon an agency's request.)

COMMENCEMENT OF AN INVESTIGATION

Written notification will be provided to PHS or NSF upon determination that an investigation will be conducted. This notice is to be provided on or before the commencement of the investigation, and must include all information required by the agency. In the case of PHS-funded research, this notice must include at least the following: name(s) of the accused individual(s); general nature of the allegation(s); and the PHS proposal or award number involved. Regulations provide that this information will be held in confidence to the extent permitted by law. Note, however, that although the information will not be disclosed to peer reviewers or PHS advisory committees, it may be used by the Secretary of Health and Human Services in making decisions about the award or continuation of funding.

WRITTEN REQUEST FOR A TIME EXTENSION

Although PHS regulations permit 120 days for completion of the investigation and submission of the final report, T.R.U.E. requires that the final report will take no more than 90 days to complete. This allows 30 days for the disciplinary process, if it is decided to pursue one. The final report to PHS must include a statement about the sanction (if any) imposed by the institution. If the investigation and determination of discipline are likely to take more than 120 days to complete, the RESEARCH DIRECTOR will so notify PHS, including reasons for the delay, interim progress reports, the estimated date of completion of the report, and any other necessary information. If an extension is granted, PHS may require the submission of periodic interim reports, or the agency may undertake its own investigation prior to the University's completion of its investigation.

NSF requires completion of the inquiry within 90 days, and completion of the investigation, including submittal of the final report, within 180 days. If completion of either is expected to be delayed, NSF may require submission of periodic status reports.

INTERIM REPORTS

PHS must be apprised during an investigation of facts that may affect current or potential PHS funding of the individual(s) under investigation, or that may need to be disclosed in order to ensure proper use of federal funds or protection of the public interest. Similarly, NSF requires interim reports if the seriousness of the apparent misconduct so warrants; if immediate health hazards are involved; if NSF's resources, reputation, or other interests need protecting; or if federal action may be needed to protect the interests of a subject of the investigation or others potentially affected.

EARLY TERMINATION

PHS must be notified of any decision to terminate an inquiry or investigation prior to the completion of all relevant requirements. This notice must include the reasons for such action. PHS retains the right to investigate the matter further on its own.

FINAL OUTCOME

PHS and NSF will be notified of the final outcome of an investigation involving their funded project(s), and provided with a complete copy of the final report.

SPECIAL EMERGENCY NOTIFICATIONS

In addition, the Public Health Service must be informed at any stage of an inquiry or investigation if any of the following are discovered:

- an immediate health hazard
- an immediate need to protect federal or T.R.U.E. funds or equipment
- an immediate need to protect those making an allegation
- a likelihood that an alleged incident is going to be reported publicly
- a reasonable indication of possible criminal activity. In the case of suspected criminal activity, PHS requires notification within 24 hours.

In special emergency circumstances as defined above, the T.R.U.E. employee or investigating military official or committee at the Military site should attempt to reach the RESEARCH DIRECTOR or CEO (by phone if necessary; in writing, if possible). However, each Military committee or investigating military official may make such reports directly to the agency, and to so inform the RESEARCH DIRECTOR or CEO afterwards, if, in the judgment of the dean, such action is necessary.

VI. DETERMINATION OF DISCIPLINE

The determination as to whether discipline is to be imposed is governed by existing policies. In cases involving TR.U.E. employees, sanctions may only be imposed by the CEO, through the procedures outlined in **Policy #8**. In cases involving Federal employees, T.R.U.E. shall be notified as to whether discipline is to be imposed as governed under Federal law.

Both PHS and NSF have the right to impose additional sanctions, beyond those applied by the institution, upon investigators or institutions, if they deem such action appropriate in situations involving funding from their respective agency.

VII. CAUTIONS AND ASSISTANCE

The gathering and assessing of information in cases of alleged scientific misconduct can be extremely difficult. It is essential to protect the professional reputations of those involved, as well as the interests of the public and of any who might be harmed by the alleged misconduct. In the course of conducting inquiries or investigations, the following provisions are applicable:

Expert assistance should be sought as necessary to conduct a thorough and authoritative evaluation of all evidence.

Precautions should be taken to avoid real or apparent conflicts of interest on the part of those involved in the inquiry or investigation.

The anonymity of accused individuals and, if they wish it, the confidentiality of those who in good faith reported the alleged misconduct, should be protected as much as possible, and care should be taken to protect their positions and reputations. Except as required in the reporting provisions above, only those directly involved in an inquiry or investigation should be aware that the process is being conducted or have any access to information obtained during its course. Where appropriate, efforts should be made to restore the reputations of those accused when allegations are not confirmed.

VIII. DISCLOSURE OF CONFLICTS OF INTEREST

The relationships between T.R.U.E. Research Foundation and outside entities are vital to the technology transfer mission of T.R.U.E., and are encouraged and appreciated. There is in most cases nothing wrong or illegal about having arrangements such as paid consulting for private companies. However, it is T.R.U.E.'s responsibility and in the best interests of our organization, participants and the military (as well as required by law) to maintain an effective disclosure process and to review and manage disclosed conflicts of interest. In an atmosphere of growing scrutiny of industry ties in medicine and

medical research, the time and effort that it takes for employees to disclose outside financial interests and activities is very much appreciated and very important.

Every year, T.R.U.E. requires all active employees and Board of Director members to fill out an **Annual Disclosure Form*** for disclosing financial interests or activities with entities outside T.R.U.E. that relate to professional activities. You may be aware that Federal regulations require that T.R.U.E. ask for these disclosures on a regular basis. Because of T.R.U.E.'s status as a non-profit institution and an applicant for Federal research funds, we are held to a different standard than the private sector in this regard.

REVIEW

The CEO reviews disclosed conflicts of interest and makes the decision whether to approve, disapprove, or suggest alternatives to the conflict of interest situation. In complex cases, or cases where financial interests are large, the Board of Directors will also review and approve the conflict of interest. If action is necessary to mitigate potential conflicts of interest, the employee will be contacted to discuss possible options.

IX. PHS AND NSF REQUIREMENTS REGARDING FINANCIAL DISCLOSURE AND AGENCY NOTIFICATIONS

Effective October 1, 1995 changes were instituted in the regulations of the Public Health Service (PHS), which includes the National Institutes of Health (NIH), and the National Science Foundation (NSF) with regard to the handling of potential conflicts of interest. These changes create added requirements for Principal Investigators applying to either agency for funds. This memo is to advise you of these changes, and to alert you to the way T.R.U.E. will handle them. In addition, it clarifies T.R.U.E.'s requirement to notify agencies in the event a potential conflict is identified.

PRINCIPAL INVESTIGATOR DISCLOSURES

PHS and NSF require that, for EACH proposal, the PI certify that he or she has appropriately disclosed any significant financial interests RELATED TO THAT PROPOSAL. Before an award can be made, T.R.U.E. must determine how any potential conflict will be managed, reduced or eliminated. T.R.U.E. will handle this responsibility for its own PIs.

Please note that both PHS and NSF have now set thresholds for the definition of "significant financial interest" as: "anything of monetary value, including but not limited to:

- salary or other payments for services (e.g. consulting fees or honoraria)
- equity transfers (e.g. stocks, stock options or other ownership interests)
- intellectual property rights (e.g. patents, copyrights and royalties from such rights)."

Such interests become "significant" for PHS or NSF if, for any one enterprise, THE INTEREST HAS A VALUE OF \$10,000 OR MORE OR REPRESENTS MORE THAN 5% OWNERSHIP INTEREST. Note that this threshold applies to the individual or aggregated interests of the PI, spouse or domestic partner, and dependent children.

For every proposal (including continuations and renewals) submitted to either PHS or NSF after October 1, 1995 the following additional questions must be answered by the PI:

Does any Investigator (defined by these agencies to mean Principal Investigator, Co-PI, and others who will be responsible for the design, conduct or reporting of the activities being proposed) or his or her spouse or domestic partner or dependent children, individually or collectively, have significant financial interests (as defined by the agency): that would reasonably appear to be affected by the activities being proposed for funding, or are in entities whose financial interests might be so affected?

Are there other (non-T.R.U.E.) individuals who will be responsible, either as the Investigator or with the Investigator (as defined above) for the design, conduct or reporting of the proposed activities (e.g. subcontractors with significant responsibilities)?

If YES, T.R.U.E. must be assured in writing that the research site complies with the funding agency's regulations. Such written assurance should be provided along with the necessary letter of commitment.

These questions will be incorporated with proposal approvals to either PHS or NSF. Keep in mind what these questions are asking: Would your financial interests appear to be affected by the activities being proposed? You might own a significant amount of IBM stock, and your proposal might include the purchase of a new PC. Such a purchase would not likely affect the financial interests of either you or IBM.

On the other hand, if you have the same dollars invested in a privately-held company with only one product, and your proposal calls for the purchase of equipment from that company, then it might indeed appear that your interests could be affected.

If such interests exist, and have not been disclosed, the PI must submit a confidential letter to T.R.U.E. in which the financial interests are described. Before any award can be finalized, that situation must be reviewed and resolved. Disclosures should be submitted in a sealed envelope to the CEO or RESEARCH DIRECTOR.

AGENCY NOTIFICATIONS (PHS Only)

Upon receipt of an award from the Public Health Service, T.R.U.E. is obligated to notify the sponsoring institute or agency if a potential conflict has been identified in regard to THAT award. If a potential conflict of interest is identified at the time a proposal is submitted, and that proposal is subsequently awarded, the RESEARCH DIRECTOR must prepare a brief notification to the administrative officer for the awarding agency. That notification is to consist of the following:

Re: Agency award number

T.R.U.E. has identified a potential conflict of interest in regard to the subject proposal, and has taken appropriate action to manage, reduce or eliminate that conflict.

The Public Health Service does not require, nor do they want, any explanation of the details of the potential conflict situation. The notification should be signed and transmitted by the CEO. A copy of the notification must be kept with the project records.

Note that this notification requirement applies only to the Public Health Service, including the National Institutes of Health (NIH).

Questions on the interpretation of this policy should be directed to the RESEARCH DIRECTOR and or the CEO.

Approved by TRUE Board of Directors on June 14, 2002

CONFLICT OF INTEREST STATEMENT – ATTACHMENT A

Proposal Title:

1. Does any Investigator (defined by these agencies to mean Principal Investigator, Co-PI, and others who will be responsible for the design, conduct or reporting of the activities being proposed) or his or her spouse or domestic partner or dependent children, individually or collectively, have significant financial interests (as defined by the agency, see **NOTE 1** below):

Yes _____ No _____

If YES, those interests must be disclosed in writing to T.R.U.E. Research Foundation.

Date of submission of disclosure(s) _____

2. Are there other (non-T.R.U.E.) individuals who will be responsible, as the Investigator or with the Investigator (as defined above) for the design, conduct or reporting of the proposed activities (e.g. subcontractors with significant responsibilities)?

Yes _____ No _____

If YES, T.R.U.E. must be assured that the research site complies with the funding agency's regulations. Such written assurance should be provided along with the necessary letter of commitment.

To the best of my knowledge, the above requirements have been met (see **NOTE 2** below).

PI (Please print): _____

Signature: _____

Date: _____

NOTE 1: PHS and NSF define "significant financial interests" as anything of monetary value, including but not limited to, salary or other payments for services (e.g. consulting fees or honoraria), equity interests (e.g. stocks, stock options or other ownership interests) or intellectual property rights. Equity interests become "significant" for PHS or NSF if, FOR ANY ONE ENTERPRISE, THE INTERESTS HAVE A VALUE OF \$10,000 OR MORE or represents more than 5% ownership interest. Note that this threshold applies to the individual or aggregated interests of the Investigator, spouse or domestic partner, and dependent children.

NOTE 2: By signing this, the Principal Investigator is assuring that all Investigators (as defined

by the agencies to include Co-PIs and others who will be responsible for the design, conduct or reporting of proposed activities) have complied with the above requirements for financial disclosure related to this proposal.