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1. PR

2. INTRODUCTION

This document is intended to serve as an overview of patent and copyright matters of interest to Tuskegee University personnel (faculty, staff, students, fellows, and persons and “visiting and adjunct” appointments). The implementation of the policies and procedures outlined in this document should be subordinate to the University’s graduate and undergraduate education, research and service missions.

The policies and procedures cited herein are subject to ongoing reviews and possible future modifications.

The management of patent and copyright processes in a university setting is a complex, highly specialized endeavor. As the need for details regarding policies and procedures arises, University personnel are urged to contact the Office of Grantsmanship and Compliance assistance in the Division of Research and Sponsored Programs.

3. OBJECTIVE OF THIS POLICY

3.1. This policy aims to establish a sound framework for the encouragement of invention, for creative works and technology transfer. In doing so, it seeks to strike a balance between the interests of the University, and its faculty, staff and students.

3.2. The University’s policy objectives in this area include:

- To sustain the climate for innovation and invention;

- To provide a framework where

The advice of the originator (s) of the IP;

Whether protection will be of value to the development and subsequent industrial application of the IP, especially involving mutually beneficial arrangements for the University and industry

Whether there is a possibility of others obtaining protection or commercially valuable IP incorporating the results of work carried out in, and owned by, the University;

Whether protecting IP will inc2 792c b Whether there is a possib7.3(P)-339(b)-9(ETQq0.00000912

Further, any agreements for projects involving University employees, who are to be funded by external sponsors, whether arranged by the individual employee or by Tuskegee University must be pre-cleared. If the end product of any such project includes copyrightable material, any conflict between the sponsor's conditions and Tuskegee University's policies regarding the use of its facilities should be resolved. (If sponsorships solely by Tuskegee University, its employees normally will have no participation in any resultant copyright proceeds. When joint efforts are involved, allocation of interests, and the sponsor's policy guidelines will be observed).

6. POLICIES GOVERNING THE USE OF INTELLECTUAL PROPERTY

6.1. The Intellectual developed by Tuskegee University faculty, staff, or a student is jointly owned by TU and the inventor. When an IP such as a patent is licensed to a third party such as a Start-up Company or major corporation, a return on investment is negotiated between TU and the company. The return on investment is shared by the inventor(s) and TU, according to TU's IP policy.

7. POLICIES GOVERNING PATENTS

7.1. Inventions made within the general scope of employment by Tuskegee University, whether as a part of regular or especially assigned duties, or made in whole or in part with the significant support of Tuskegee University resources or any combination of the above, are property of Tuskegee University and shall be assigned to Tuskegee University or its designee, should the Committee so determine after review. The term "Tuskegee University resources" is used broadly and includes, but is not limited to, advisory time and services of faculty and other staff members, equipment, (by way of illustration only, recording equipment, cameras, computers, machinery and tools,) materials (e.g. tapes, film, canvas, and generally any other physical substances) and funds furnished to the person employed by Tuskegee University, whether as a fellowship or other stipend to enable the employee to create the invention, or as a subsidy for expenses related to making the invention.

If the invention is made under the external grant, contract, or sponsorship, ownership of the invention determined by the governing agreement between Tuskegee University and the external grantor, contract or sponsor.

If the invention is made under funding derived from an external source, but rights to the invention are not governed by an agreement with the external source, the invention shall be considered the property of Tuskegee University unless the Committee, after review, determines otherwise.

Inventions not made within the general scope of em

7.3. Inventions by students made as a consequence of course assignments or as research assistants or significant student use of the University resources in making inventions shall be the property of Tuskegee university, subject to a factual determination of rights by the committee. The Committee shall take into account the terms of any external support, including fellowships and other financial aid, which may be relevant to rights in the invention.

7.4. All faculty, staff, and students, who make inventions, which may be subject to this policy, must make timely and adequate disclosure to the Office of Grantsmanship and Compliance so that a determination of rights, responsibilities and obligations can be made.

8. POLICIES GOVERNING COPYRIGHTS

8.1. The right to copyright an independently created work or to assign this right to a publisher normally rests with author or creator of the work. However, the existence of an

- c. Copyright rights in curriculum material originated and furnished by a faculty member in the Course of instructional work normally will be regarded as belonging to the faculty member.
- d. Faculty members who propose to “test out curriculum material in the course of their

- a. written material (e.g. books, manuals, etc.)
- b. lectures, tests, musical and dramatic composition.
- c. photographs, motion pictures, filmstrip, video recordings, maps, charts and other visual material.
- d. artistic works including sculpture and graphic work.

9. POLICIES GOVERNING TRADEMARKS

9.1. Trademarks or service marks relating to goods or services created or developed by University faculty or staff at the direction of the University or within the general scope of University employment, whether as part or regular or specially assigned duties or with

consultation with all interested parties shall determine distribution in so far as it may be due, to the university itself, its departments and interested faculty, staff or students

13.2. Equities of the participating Parties — An employee who assigns an invention to Tuskegee University or its designee pursuant to this policy will, in the absence of an agreement which specifies otherwise, receive any and all royalties fifty percent (50%) of any and all royalties derived from the licensing or sale of the invention.

14. PATENT AGREEMENTS

14.1. By accepting employment or enrolling as a student, employees and students agree that they are bound by the terms of this policy which vests ownership of inventions in the University under the circumstances outlined herein. All faculty, staff, student employees, graduate students and postdoctoral fellows must also sign the Tuskegee University Patent and Copyright Agreement (See APPENDIX I at the end). In addition, non-employees who participate or intend to participate in research projects at TU must also sign the Patent and Copyright Agreement unless an agreement governing the intellectual property rights of such non-employee has already been executed between Tuskegee University and the individual's employer through the Research & Graduate Studies Office. Each department is responsible for getting

TUSKEGEE UNIVERSITY

Tuskegee, Alabama 36088

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1. Fabrication, falsification, plagiarism, deception or other serious deviation from acceptable practices within the scientific community in proposing, carrying out, or reporting results from research.
2. Intentional failure to comply with federal requirements for protection of research.

Tuskegee University assumes and accepts the responsibility to pursue all allegations of scientific misconduct and will follow through fully to receive questions regarding the integrity of research. Tuskegee University will be alert to questionable academic conduct that might cause legitimate suspicion of fraudulent research. In inquiries and any investigation which may follow, Tuskegee University will focus on the substance of the issue and will be vigilant not to permit personal conflicts between colleagues to obscure the facts.

D. Good faith allegation means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

E. Inquiry means gathering information and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

N. Retaliation means any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

O. Scientific misconduct means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are 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.

P. Informant means a person who makes an allegation of scientific misconduct.

III. RIGHTS AND RESPONSIBILITIES

A. Research Integrity Officer

The President of Tuskegee University will appoint the Research Integrity Officer who will have primary responsibility for implementation of the procedures set forth in this document. The Research Integrity Officer will be an institutional official who is well qualified to handle the procedural requirements involved and is sensitive to the varied demands made on those who conduct research, those who are accused of misconduct, and those who report apparent misconduct in good faith.

The Research Integrity Officer will appoint the inquiry and investigation committees and ensure that necessary and appropriate expertise is secured to carry out a thorough and authoritative evaluation of the relevant evidence in an inquiry or investigation. The Research Integrity Officer will attempt to ensure that confidentiality is maintained.

The Research Integrity Officer will assist inquiry and investigation committees and all institutional personnel in complying with these procedures and with applicable standards imposed by government or external funding sources. The Research Integrity Officer is also responsible for maintaining files of all documents and evidence and for the confidentiality and the security of the files.

The Research Integrity Officer will report to Office of Research Integrity (ORI) as required by regulation and keep ORI apprised of any developments during the course of the inquiry or investigation that may affect current or potential Department of Health and Human Services (DHHS) funding for the individual(s) under investigation or that PHS needs to know to ensure appropriate use of Federal funds and otherwise protect the public interest.

B. Informant

The informant will have [(im)-3i2 79rity Off4 8O s G[(I)13(n)-9(for)6(mant)/ability

investigation, and to be protected from retaliation.

Also, if the Research Integrity Officer has determined that the informant may be able to provide pertinent information on any portions of the draft report; these portions will be given to the informant for comment.

The informant is responsible for making allegations in good faith, maintaining confidentiality, and cooperating with an inquiry or investigation.

C. Respondent

The respondent will be informed of the allegations when an inquiry is opened and notified in writing of the final determinations and resulting actions. The respondent will also have the opportunity to be interviewed by and present evidence to the inquiry and investigation committees, to review the draft inquiry and investigation reports, and to have the advice of counsel.

The respondent is responsible for maintaining confidentiality and cooperating with the conduct of an inquiry or investigation. If the respondent is not found guilty of scientific misconduct, he or she has the right to receive institutional assistance in restoring his or her reputation.

D.

B. Protecting the Informant

The Research Integrity Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The Research Integrity Officer will ensure that these persons will not be retaliated against in the terms and conditions of their

A. Initiation and Purpose of the Inquiry

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the available evidence and testimony of the respondent, informant, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee. The Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

E. Inquiry Process

The inquiry committee will normally interview the informant, the respondent and key witnesses as well as examine relevant research records and materials. Then, the inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

VI. THE INQUIRY REPORT

A. Elements of the Inquiry Report

A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted or not; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency.

B. Comments on the Draft Report by the Respondent and the Informant

The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the informant, if he or she is identifiable, with portions of the draft inquiry report that address the informant's role and opinions in the investigation.

1. Confidentiality

The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

2. Receipt of Comments

Within 14 calendar days of the receipt of the draft report, the informant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the informant or respondent submits on the draft report will become part of the final inquiry

sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry.

C. Appointment of the Investigation Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an investigation committee and the committee chair within 10 days of the notification to the respondent that an investigation is planned or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation. These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert, the Research Integrity Officer will determine whether to replace the challenged member or expert with a qualified substitute.

D. Charge to the Committee and the First Meeting

1. Charge to the Committee

The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and the related issues identified during the inquiry, define scientific misconduct, and identify the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, informant, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report,

5. the allegation involves a public health sensitive issue, e.g., a clinical trial; or
6. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within hours of obtaining that information.

X. INSTITUTIONAL ADMINISTRATIVE ACTIONS

Tuskegee University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

- withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.
- removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;
- restitution of funds as appropriate

XI. OTHER CONSIDERATIONS

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference

to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Informant and Others

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect the informant, who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon completion of an investigation, the Deciding Official will determine, after consulting with the informant, what steps, if any, are needed to restore the position or reputation of the informant. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the informant.

D. Allegations Not Made in Good Faith

If relevant, the Deciding Official will determine whether the informant's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the informant.

E. Interim Administrative Actions

Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.

Record Retention

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

NOTES:

1. 42 C.F.R. § 50.102.
2. 42 C.F.R. § 50.102.
3. 42 C.F.R. § 50.102.
4. 42 C.F.R. § 50.103(d) (12).

29. 42 C.F.R. § 50.104(b)(4).

30. 42 C.F.R. § 50.104(b)(5).

31. 61572792WeNBH/Hf0000000260HTTQQ000000026061572792WeNBH/H0702682.

APPENDIX II

Patent and Copyright Agreement for Tuskegee University Personnel

As required by the Bayh-Dole Act (1980), Tuskegee University (TU) requires the following agreement from its personnel defined by the agreement or the Tuskegee University Intellectual Policy. I understand that, consistent with applicable laws and regulations, Tuskegee University is governed in the handling of intellectual property by its official policies titled Tuskegee University Intellectual Property Policy, and I agree to abide by the terms and conditions of those policies, as they may be amended from time to time. Pursuant to those policies, and in consideration of my employment by TU, the receipt of remuneration from TU, participation in projects administered by TU, access to or use of facilities provided by TU and/or other valuable consideration, I hereby agree as follows:

- 1.** I will disclose to TU all potentially patentable inventions conceived or first reduced to practice in whole or in part in the course of my University responsibilities or with more than incidental use of University resources. I further agree to assign and do hereby assign to TU all my right, title and interest in such potentially patentable inventions and to execute and deliver all documents and do any and all things necessary and proper on my part to effect such assignment
- 2.** I am free to place my inventions in the public domain as long as in so doing neither I nor TU violates the terms of any agreements that governed the workreements that governmect

APPENDIX III

DISCLOSURE FORM

Intellectual Property Disclosure Form
Tuskegee University Office of Grantsmanship and Compliance
(Kenney Hall, Room 44-328(334)727-8985)

I. Description

Please provide a title for your invention and a detailed description. Please provide figures and/or flow charts if necessary. Please provide figures or drawings that show or describe your invention, if applicable. Please describe any difficulties or hurdles that you had to overcome to finalize the invention. Inventions include new processes, products, apparatus, compositions of matter, living organisms, or improvements to (or new uses for) things that already exist. Use additional sheets and attach descriptive materials to expand answers to questions. Sketches, drawings, photos, reports and manuscripts will be helpful.

Invention Title _____

Description _____

What are the immediate and/or future applications of the inventions? In other words, how will this invention likely be commercialized?

Why is the invention better (more advantageous) than present technology? What are its novel and unusual features? What problems does it solve? _____

Note: valid patent protection depends on accurate answers to the following items.

Has the invention been disclosed in an abstract, paper, talk, news story or a thesis?
Yes _____ No _____ (if yes, please provide and if still in progress, please provide the draft.)

Type of disclosure _____ Date of Disclosure _____
(Please enclose a copy)

Is a publication or other disclosure planned in the next six months? Yes _____ No _____

Type of disclosure _____ Date of Disclosure _____
(Please enclose a copy)

Has there been any public use or sale of products embodying the invention? Yes _____ No _____

If yes, describe, giving dates _____

Are you aware of related developments by others? Yes _____ No _____ If yes, please give citations. (Copies of any relevant patents or publications would be appreciated). _____

III. Sponsorship

If the research that led to the invention was sponsored, please fill in the details and attach a copy of the contract or agreement if possible.

Funding Agency _____

Funding Agency contact/grant no. _____ TU Acct. No. _____

Title of Sponsored Project _____

Principal Investigator _____ Phone _____

Has the invention been disclosed to industry representatives? Yes _____ No _____ If yes, please provide details, including the names of companies and their representatives.

IV. For Our Records

Names of inventors

1. _____ Signature _____ Date _____

2. _____ Signature _____ Date _____

Appendix III
