

Intellectual Property Policy and Guidelines

Prepared by

The Office of Grantsmanship and Compliance
Division of Research and Sponsored Programs

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1. PREAMBLE

Tuskegee University, as an institution of higher learning and intellectual endeavors, has as one of its primary functions the continual search for new knowledge in fields in which the university community is active. The University views research by its faculty and within its own community as an important path to the discovery knowledge and its definition informs most useful to the University and the community it serves. Tuskegee University recognizes the creativity of its faculty, staff and students in research, intellectual pursuits

Intellectual property refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce. The Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. It is important, therefore, that there be guidelines for intellectual property policy delineating rights, responsibilities and obligations of the University, the individual members of its community and other interested parties. It is Tuskegee University's desire to ensure that intellectual property rights, which it owns, administers or in which it shares, provide the greatest realizable benefits to the public and the University and provide equitable recognition, return and incentive to individuals in the community which originate them. To achieve its purpose, the Tuskegee University intellectual property policy will be governed in its application by the following general principles:

First, intellectual property rights should be exercised for the public benefit, including the widest appropriate dissemination and use

Second, Intellectual property rights deriving from University Support, resources or employment should be managed to derive maximum, benefit for Tuskegee University.

Third, under circumstances defined by the intellectual property policy, creators of intellectual Property shall be entitled to financial compensation in the form of appropriate royalties and fees where financial profit is realized Tuskegee University through the exercise of its rights to that property. In circumstances where there is no financial profit to the University other forms of recognition may be conferred.

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 whereby faculty, staff, and students are stimulated to identify, protect and develop the commercial value of potentially valuable research results and other creative work engaged successfully in technology transfer;
- To promote a better understanding of the various rights which the law gives for the protection of creative effort and thereby stimulate the proper protection of the university’s economic investment in that effort;
- To provide incentives for individuals and departments to encourage research and development and to pursue commercially valuable projects;
- To recognize students’ rights to intellectual property generated in the course of their study at the University while at the same time asking student researchers, where it is relevant, to assign or license rights to the University in exchange for participation in certain research programs so that the University can properly protect the IP embedded within its research and teaching programs and can range new IP generated through such programs; and
- To protect the rights of faculty, staff, staff, and students with respect to their intellectual achievements.

3.3. The factors relevant to a decision by the University on whether it will take action to protect its IP include:

- The effect on the University’s research program;

- 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 increase its value as a means to attract support for further research and development at the University and/or to provide royalty and other income to the University, faculty, staff, and any students involved;
- Whether such action is desirable for protecting the University's reputation or maintaining the University's interest in the quality and technical efficiency of production under appropriate research and development licensing or joint venture agreements; and
- Whether such action is desirable in the national interest no preserves public equity.

4. DEFINITIONS

4.1. INTELLECTUAL PROPERTY (IP)

Intellectual Property refers to creations of the mind. This can include inventions (typically covered by patents), creative works, music and movies, typically covered by copyrights), and brand names (typically covered by trademarks). IP differs from tangible assets, such as cars, computers or land.

4.2. PATENT

A U.S. patent is a grant issued by the U.S. Government giving an inventor the right to exclude all others from making, using, or selling the invention within the United States, its territories and possessions for a period of 20 years. When a patent application is filed, the U.S. Patent Office reviews it to ascertain if the invention is new, useful, and non-obvious and, if appropriate, grants a patent -- usually two to five years later. Other countries also grant similar patents. Not all patents are necessarily valuable or impervious to challenge.

4.3. INVENTION

An invention is a novel and useful idea relating to processes, machines, manufactures, and compositions of matter. It may cover such things as new or improved devices, systems, circuits, chemical compounds, mixtures, etc. It is probable that an invention has been made when something new and useful has been conceived or developed, or when unusual, unexpected, or nonobvious results have been obtained and can be exploited.

An invention can be made solely or jointly with others as co-inventors. To be recognized legally, a co-inventor must have conceived of an essential element of an invention or contributed substantially to the general concept.

5. ISSUES OF OWNERSHIP - GENERAL CONDITIONS

5.1. Tuskegee University's policies governing the acquisition of IP are intended to provide guidance in defining the interests of the University, its faculty, staff, and students.

5.2. The University shall have the sole and unlimited power, in its discretion, to make all decisions as to whether IP owned or controlled by it in whole or in part under this policy shall be licensed otherwise exploited or used by others and the right without limitation, to waive payment of royalties.

5.3 Any Intellectual Property developed by a student, a faculty member, or staff member employed by TU is awarded 50% by the inventors and 50% by the University.

5.4. Any controversy or claim arising out of or relating to these policies, or any agreement between Tuskegee University employee and Tuskegee University, delineating the respective rights and obligations of the parties, or the breach of such agreement, shall be settled in accordance with the rules using the Policy for Responding to Allegations of Scientific Misconduct attached hereto as Appendix I.

5.5. A committee on intellectual property (the "committee") will review all matters and conducts characterized as IP falling within the scope of this policy statement discovered, made or created by Tuskegee University faculty, staff or students. The Committee will make recommendations to the Vice President for Research and Sponsored Programs on IP acquisition, sharing and disposition. The Vice President for Research and Sponsored Programs will be responsible for the implementation of the University IP policy.

5.6 University faculty, staff, and students shall have the responsibility of reporting to the Office of Grantsmanship and Compliance, invention, discovery, creation or concept which they have made and which may possibly be governed by this policy. They shall execute all documents, which may be deemed necessary to secure the University's full rights that such discovery, creation or concept be assigned to the University or released outright to the employee who has made it for disposition he or she see fit.

5.7. The Committee may advise and assist University faculty and staff who make any discovery, creation or concept not assignable to the University or its designee under this policy, or who have received a release for IP otherwise assignable hereunder. For example, the committee may evaluate an invention and render a report to the inventor including advice and recommendation for securing patent protection and for commercializing the invention. The services or facilities of some other non-profit organization also may be recommended to the inventor.

5.8. Research contracts, granting documents, and other agreements between Tuskegee University and all outside grantors or sponsors of activities likely to give rise to IP rights shall state clearly the obligations and rights of the parties and the procedures to be followed in the event such rights arise. It is preferable that the University be free to negotiate with the outside grantors or sponsors in so far as the disposition of arising IP is concerned.

Further, any arrangements 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 employment Tuskegee University or made significant support of University resources will remain the property of the inventor. A factual determination of rights based on the general scope of employment, including regular or specially assigned duties, and sources of support will be made by the Committee.

7.2. A member of the faculty or staff, who assigns an invention to the University, will in the absence of an agreement, specifying otherwise shall receive 50% of any and all royalties received by Tuskegee University.

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 institutional relationship with Tuskegee University, the use of University resources and other factors may warrant ownership of the work and copyright by the University. The Committee will make determinations of ownership and the right to copyright.

8.2. All faculty, staff and students who author or create works which may be copyrighted and which may be subject to this policy must make timely and adequate disclosure of the work to the Office of Grantsmanship and Compliance so that a determination of rights, responsibilities and obligations can be made. The committee shall be consulted before any independent initiative for publication or other exploitation of copyright rights is undertaken.

8.3. In making determination concerning works subject to copyright, the Committee should take into account the following:

a. The right to claim a copyright for a work will automatically belong to Tuskegee University where:

(1.) A University faculty or staff member creates work within the general scope of employment be Tuskegee University whether as a part regular or specially assigned duties.

(2) A University faculty or staff member creates a work utilizing in the process significant amounts of university resources, and regardless of whether his/her independent initiative is involved. However, should the University at its sole discretion, license or otherwise dispose of its copyright, rights, in this situation, fifty percent of any net proceeds received by Tuskegee University from such license or other disposition will be paid to the creator of the work.

b. University faculty or staff member creating a work through independent initiative working entirely on his/her own time and using entirely his/her own resources will normally retain the right to copyright the work. In this circumstance, the faculty or staff

member will be considered to be using his/her own resources although use is made of Tuskegee University library materials or of University premises in creating the work.

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 teaching duties, with a view to developing such materials into publishable works, shall disclose this to the Office of Grantsmanship and Compliance. If the involvement of University classes and students is significant, an agreement for an equitable sharing of future proceeds with the University shall be researched before such matter is “tested out” in University classes.

e. All rights in any recording (visual, audio, audiovisual or the technical/functional equivalent) of an] type of Tuskegee University event or performance produced with the use of any University resources, personnel and/or financial support shall normally belong to Tuskegee University.

f. Copyrights rights for individual or group student work completed as a part of recourse work, an independent Tuskegee University faculty-supervised study, or as a part of a thesis or dissertation for which the University provided significant financial support beyond the provision of normal coursework, materials, equipment, space and faculty supervision, will remain with the University until the value of that financial support is recouped, At that time the rights will be returned to the student. The student will ordinarily be granted a license for use of the work for any non-income producing purpose while the University holds the con- right.

g. Tuskegee University will normally retain ownership of works by faculty, staff or students, specifically and directly commissioned by the University and for which the University provides substantial support and pays compensation to the creator. The creator any uses the work for non-income producing purposes.

h. Works for non-Tuskegee University from non-employees are owned by the creator unless there is a written agreement to the contrary.

i. Rights in copyright shall remain with the creator unless the work:

a. is a work-for-hire (and copyright therefore vests in the University under copyright law),

b. is supported by a direct allocation of funds through the University for the pursuit of a specific project,

c. is commissioned by the University,

d. makes significant use of University resources or personnel, or

e. is otherwise subject to contractual obligations.

8.4. Where projects involving Tuskegee University faculty, staff or students are to be funded by external grantors, contractors or sponsors and the end product may include copyrightable project must be pre-cleared by the office of Grantsmanship and Compliance whether arranged by individual faculty, staff or students or by the University. Any conflicts between conditions established by the external supporter and the University’s copyright policy should be resolved in advanced by project implementation. The Committee will

decide questions regarding allocation of rights and interests affecting involved University faculty, students, and staff.

8.5. Types of works which may be copyrighted include but are not limited to:

- 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 significant University resource support shall belong to Tuskegee University. Examples include names and symbols associated with University developed computer programs or University activities and events

9.2. Should the University license or otherwise dispose of a trademark it owns for profit and the trademark result from the independent initiative of a faculty or staff member where significant University resource was provided, fifty percent (50%) of any net proceeds received by Tuskegee University from such licenses or other disposition will be paid to the trademark creator.

9.3. The creation of any trademark by a University faculty or staff member shall be timely disclosed to the Office of Grantsmanship and Compliance in all cases where that trademark may be subject to this policy.

10. TRADE SECRETS

10.1. Tuskegee University shall own all trade secrets created, discovered or developed by faculty, staff or students made within the general scope of employment by Tuskegee University, whether as a part of regular or specially assigned duties, discovered or developed in the course of activities which are supported by significant part by Tuskegee University resources. All discoveries, creations, and developments which may be trade secrets and which are covered by this policy must be disclosed to the Office of Grantsmanship and Compliance which will determine their status.

10.2. If a creation, discovery or development is determined by the Committee to be a trade secret, Tuskegee University shall have the right to prohibit its disclosure by an employee to any person agency or entity. In this circumstance, the disclosure shall be prohibited in

the absence of specific University authorization through the Committee and after consultation with Tuskegee University legal counsel.

10.3. Any member of the faculty or staff who discovers, creates or develops a trade secret through independent initiative or research, rather than within the general scope of employment by Tuskegee University, and where Tuskegee University takes or exercises rights of ownership through action or this policy, will in the absence of an agreement specifying otherwise, receive fifty percent 50% of any and all royalties received by University from the licensing or sale of the product or service containing or embodying said trade secret.

11. PROCEDURES GOVERNING ACQUISITION OF INTELLECTUAL PROPERTY RIGHTS

11.1. A faculty, staff member or where indicated, student or at Tuskegee University who discovers, creates, makes or develops a concept, invention or other work in the course of University activities or with the support of any University resources shall timely disclose it to the Office of Grantsmanship and Compliance in writing in a format established by the Committee. The disclosure shall be adequate to allow determination of the applicability of the University Intellectual Policy and determination of ownership and property interests.

11.2. In order to facilitate the timely submission of disclosures, faculty and staff members and, where necessary, students engaged in creative efforts in the course of university responsibilities or with University support shall maintain such logs and records as necessary to support and develop the disclosure.

11.3. The Committee will review disclosures for completeness and substantiation and shall recommend to the Vice President for Research and Sponsored Programs whether to seek or establish proprietary protection for the concept or work disclosed under an appropriate intellectual property category for that disclosure; e.g., patent or trade secret copyright or trademark. The Committee shall consult the creator of the disclosure and concerned University departments in this determination.

11.4. The Vice President for Research and Sponsored Programs, in consultation with the Committee, the University legal counsel, concerned University departments and the creator of the disclosure will be responsible for taking appropriate steps to secure appropriate legal protection.

11.5. The Assistant Director of Grantsmanship and Compliance will prepare records of all disclosures submitted and of its considerations and shall make an annual report of its deliberations and actions to the Senior Vice President of University Advancement through the Vice President for Research and Sponsored Programs.

11.6. Tuskegee University in consultation with the legal counsel will determine such actions as may be appropriate, e.g. giving; the creator or discoverer of the discoverer of the disclosed subject matter a waiver of University interest. The University may also decide

on any University assistance that may be offered to any university faculty or staff member or student in pursuing any rights they may have to the disclosed subject matter.

11.7. The University may seek assistance from patent management firms, patent attorneys, commercial firms and other appropriate entities or person in securing or managing Intellectual Property rights

(a) Patents — In the case of potentially patentable subject matter subject to this policy, the inventor, following the initial disclosure shall keep records of all steps directed to the development and improvement of the invention. The record should be sufficient to indicate the continued exercise of due diligence by the inventor and that there has been no abandonment of the invention

(b) Copyrights — Any requests to record, videotape, broadcast or televise classroom, laboratory or other University sponsored instruction for purposes, other than university educational activities must be approved by the University. The Associated Director of Grantsmanship and Compliance will be responsible for resolving any emerging copyright issues.

(c) Trade Secrets — Tuskegee University faculty and staff may be required to sign appropriate secrecy agreements With respect to trade secrets belonging to the University.

12. EXERCISES OF INTELLECTUAL PROPERTY RIGHTS

12.1. Tuskegee University may exercise its intellectual property rights for its own benefit and to effect transfer off rights for public benefit through:

- License
- Sale
- Assignment

and such other means to achieve its legitimate purposes.

12.2. The University- prefers patent to trade secret protection since patent protection allows the dissemination of knowledge that is a University purpose coupled with the realization of benefit to the University.

12.3. In the case of commercially sponsored research, if it is determined that trade secret protection with rights belonging to the sponsor is required, that portion of the sponsored agreement requiring such protection will be transferred out of the University research agenda as soon as possible, preferably within sixty days. The University have the right to publish research results that occurred prior to the on which the university agreed that patent protection was unavailable after a delay of one year to protect the sponsor's interest.

12.4. No party licensed to make or use an invention owned by Tuskegee University under this policy may use Tuskegee University's name or names of University employees in connection with advertising or promote the invention without having secured the express written consent of the University or its designee.

13. ROYALTY, FEE, AND INCOME DISTRIBUTION

13.1. Royalty, fee, and income distribution arising from the exercise of intellectual property rights under this policy shall be made as set out in this policy. Should circumstances or cases arise where distribution is not apparent from this policy the University after 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 the Patent and Copyright Agreement signed, normally at the time of the individual's initial association with TU.

APPENDIX I

TUSKEGEE UNIVERSITY
Tuskegee, Alabama 36088

Policy for
Responding to Allegations
of Scientific Misconduct

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I. INTRODUCTION

A. General Policy

Tuskegee University defines scientific misconduct as follows:

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.

B. Scope

This policy and the associated procedures apply to all individuals at Tuskegee University engaged in research that is supported by or for which support is requested from the U.S. Public Health Services (PHS). The PHS regulation at 42 C.F.R. Part 50, Subpart A applies to any research, research-training or research-related grant or cooperative agreement with PHS. This policy applies to any person paid by, under the control of, or affiliated with the institution, such as scientists, trainees, technicians and other staff members, students, fellows, guest researchers, or collaborators at Tuskegee University.

The policy and associated procedures will normally be followed when an allegation of possible misconduct in science is received by an institutional official. Particular circumstances in an individual case may dictate variation from the normal procedure deemed in the best interest of Tuskegee University and PHS. Any change from normal procedures also must ensure fair treatment to the subject of the inquiry or investigation. Any significant variation should be approved in advance by the Provost of Tuskegee University.

The procedures outlined in this document also apply to cases of scientific misconduct in dealing with grants, contracts and other sponsored programs funded by the state and other federal agencies, foundations and corporations.

II. DEFINITION

- A. Allegation means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.
- B. Conflict of interest means the real or apparent interference of one person's interests with the interests of another person, where potential bias may occur due to a

prior or existing personal or professional relationship.

C. Deciding Official means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions. At Tuskegee University, the Provost shall serve as the deciding official.

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.

F. Investigation means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

G. ORI means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

H. PHS means the U.S. Public Health Service, an operating component of the DHHS.

I. PHS regulation means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardees and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

J. PHS support means PHS grants, contracts, or cooperative agreements or applications.

K. Research Integrity Officer means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. At Tuskegee University, the Vice President for Research and Sponsored Programs shall serve as the Research Integrity Officer.

L. Research record means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement

records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

M. Respondent means the person against whom an allegation of scientific misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or 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 an opportunity to testify before the inquiry and investigation committees, to review portions of the inquiry and investigation reports pertinent to his/her allegations or testimony, to be informed of the results of the inquiry and 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. Deciding Official

The Deciding Official will receive the inquiry and/or investigation report and any written comments made by the respondent or the informant on the draft report. The Deciding Official will consult with the Research Integrity Officer or other appropriate officials and will determine whether to conduct an investigation, whether misconduct occurred, whether to impose sanctions, or whether to take other appropriate administrative actions [see Section X].

IV. GENERAL POLICIES AND PRINCIPLES

A. Responsibility to Report Misconduct

All employees or individuals associated with Tuskegee University should report observed, suspected, or apparent misconduct in science to the Research Integrity Officer. If an individual is unsure whether a suspected incident falls within the definition of scientific misconduct, he or she may call the Research Integrity Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition of scientific misconduct, the Research Integrity Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the

problem.

At any time, an employee may have confidential discussions and consultations about concerns of possible misconduct with the Research Integrity Officer and will be counseled about appropriate procedures for reporting allegations.

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 employment or other status at the institution and will review instances of alleged retaliation for appropriate action.

Employees should immediately report any alleged or apparent retaliation to the Research Integrity Officer.

Also, Tuskegee University will protect the privacy of those who report misconduct in good faith to the maximum extent possible. For example, if the informant requests anonymity, Tuskegee University will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The informant will be advised that if the matter is referred to an investigation committee and the informant's testimony is required, anonymity may no longer be guaranteed. Institutions are required to undertake diligent efforts to protect the positions and reputations of those persons who, in good faith, make allegations.

C. Protecting the Respondent

Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation.

Institutional employees accused of scientific misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal adviser to interviews or meetings on the case.

D. Cooperation with Inquiries and Investigations

Institutional employees will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations.

E. Preliminary Assessment of Allegations

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

V. CONDUCTING THE INQUIRY

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.

B. Sequestration of the Research Records

After determining that an allegation falls within the definition of misconduct in science and involves PHS funding, the Research Integrity Officer must ensure that all original research records and materials relevant to the allegation are immediately secured. The Research Integrity Officer may consult with ORI for advice and assistance in this regard.

C. Appointment of the Inquiry Committee

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint an inquiry committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of 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 allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside the institution.

The Research Integrity Officer will notify the respondent of the proposed committee membership in 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, 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

The Research Integrity Officer will prepare a charge for the inquiry committee that

describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the 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 as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

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 report and record. Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification

1. Decision by Deciding Official

The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification

The Research Integrity Officer will notify both the respondent and the informant in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report

The inquiry committee will normally complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting, unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent also will be notified of the extension.

VII. CONDUCTING THE INVESTIGATION

A. Purpose of the Investigation

The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope, beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health.

practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records

The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This 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, and the prescribed procedures and standards for the conduct of the investigation, including the necessity for confidentiality and for developing a specific investigation plan. The investigation committee will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

E. Investigation Process

The investigation committee will be appointed and the process initiated within 30 days of the completion of the inquiry, if findings from that inquiry provide a sufficient basis for conducting an investigation.

The investigation will normally involve examination of all documentation including, but not necessarily limited to, relevant research records, computer files, proposals, manuscripts, publications, correspondence, memoranda, and notes of telephone calls. Whenever possible, the committee should interview the informant(s), the respondents(s), and other individuals who might have information regarding aspects of the allegations. Interviews of the respondent should be tape recorded and transcribed. All other interviews should be tape recorded, summarized and transcribed. Summaries or transcripts of the interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory file.

VIII. THE INVESTIGATION REPORT

A. Elements of the Investigation Report

The final report submitted to ORI must describe the policies and procedures, under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report will include the actual text or an accurate summary of the views of any individual(s) found to have engaged in misconduct as well as a description of any sanctions imposed and administrative actions taken by the institution.

B. Comments on the Draft Report

1. Respondent

The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Informant

The Research Integrity Officer will provide the informant, if he or she is identifiable, with those portions of the draft investigation report that address the informant's role and opinions in the investigation. The report should be modified, as appropriate, based on the informant's comments.

3. Institutional Counsel

The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

In distributing the draft report, or portions thereof, to the respondent and informant, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

C. Institutional Review and Decision

Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the informant in writing. In addition, the Deciding Official will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

D. Transmittal of the Final Investigation Report to ORI

After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and informant's comments, to the Deciding

Official, through the Research Integrity Officer.

E. Time Limit for Completing the Investigation Report

An investigation should ordinarily be completed within 120 days of its initiation, with the initiation being defined as the first meeting of the investigation committee. This includes conducting the investigation, preparing the report of findings, making the draft report available to the subject of the investigation for comment, submitting the report to the Deciding Official for approval, and submitting the report to the ORI.

IX. REQUIREMENT FOR REPORTING TO ORI

A. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins. At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved. ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report. Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

B. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.

C. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.

D. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.

E. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:

1. there is an immediate health hazard involved;
2. there is an immediate need to protect Federal funds or equipment

3. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
4. it is probable that the alleged incident is going to be reported publicly; or
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).
5. 42 C.F.R. § 50.103(d)(13).
6. 42 C.F.R. § 50.103(d)(2).
7. 42 C.F.R. § 50.103(d)(13).
8. 42 C.F.R. § 50.103(d)(3).
9. 42 C.F.R. § 50.103(d)(1).
10. 42 C.F.R. § 50.103(d)(1).
11. 42 C.F.R. § 50.103(d)(1).
12. 42 C.F.R. § 50.103(d)(8).
13. 42 C.F.R. § 50.103(d)(7).
14. 42 C.F.R. § 50.103(d)(7).
15. 42 C.F.R. § 50.103(d)(7).
16. 42 C.F.R. § 50.103(d)(7).
17. 42 C.F.R. § 50.104(a)(4); 42 C.F.R. § 50.103(d)(15).
18. 42 C.F.R. § 50.104(a)(2).
19. 42 C.F.R. § 50.104(a)(2).
20. 42 C.F.R. § 50.104(a)(1).
21. 42 C.F.R. § 50.104(a)(1).
22. 42 C.F.R. § 50.103(d)(15).
23. 42 C.F.R. § 50.104(a)(3).
24. 42 C.F.R. § 50.104(a)(5).
25. 42 C.F.R. § 50.104(a)(3).

26. 42 C.F.R. § 50.104(b)(1).
27. 42 C.F.R. § 50.104(b)(2).
28. 42 C.F.R. § 50.104(b)(3).
29. 42 C.F.R. § 50.104(b)(4).
30. 42 C.F.R. § 50.104(b)(5).
31. 42 C.F.R. § 50.103(d)(14).
32. 42 C.F.R. § 50.103(d)(14).
33. 42 C.F.R. § 50.103(d)(11).
34. 42 C.F.R. § 50.103(d)(10).

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 work done.
3. TU policy states that all rights in copyright shall remain with the creator unless the work:
 - a. is a work-for-hire (and copyright therefore vests in the University under copyright law),
 - b. is supported by a direct allocation of funds through the University for the pursuit of a specific project,
 - c. is commissioned by the University,
 - d. makes significant use of University resources or personnel, or
 - e. is otherwise subject to contractual obligations.

I agree to assign and do hereby assign or confirm in writing to TU all my right, title and interest, including associated copyright, in and to copyrightable materials falling under a) through e), above.

4. I am now under no consulting or other obligations to any third person, organization or corporation in respect to rights in inventions or copyrightable materials which are, or could be reasonably construed to be, in conflict with this agreement.

NOTE: *An alternative to this agreement may be appropriate for personnel with a prior existing and conflicting employment agreement that establishes a right to intellectual property in conflict with TU policies. Personnel in this situation must contact the [Office of the Vice President for Research](#).*

5. I will not enter into any agreement creating copyright or patent obligations in conflict with this agreement. This agreement is effective on my date of hire, enrollment, or participation in projects administered by TU, and is binding on me, my estate, heirs and assigns.

[Printed Name] [Job Title] [Signature] [Date]

[Email](#) a scanned copy of your completed Agreement **AND** mail the original signed hard-copy to:

Office of Technology Transfer
Attn: Office of Grantsmanship and Compliance
Kenney Hall Room 44-328
Tuskegee, Alabama 36088
fmossgrant@tuskegee.edu
(334) 727-8985

APPENDIX III

DISCLOSURE FORM

Intellectual Property Disclosure Form
Tuskegee University Office of Grantsmanship and Compliance (Chappie James Center, Room
100 (334) 727-8985

I. Description

Please provide a title for your invention and a brief description. 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? _____

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

Is the work on the invention continuing? Are there limitations to be overcome or other tasks to be done prior to practical application? Are there any test data? _____

Have products, apparatus or compositions, etc. actually been made or tested? _____

II. Publications, Public Use and Sale

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 _____

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 _____

3. _____ Signature _____ Date _____

Contact for more information _____ Phone _____

Mailing Address for inventor(s) _____

Intellectual Property Committee

Reviewer's _____

IPC No. _____ Date _____

Patent Prosecution Road Map

