Technology Transfer & Commercialization Guide for PASSHE Non-Faculty Personnel

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Additional Materials:
TTC Guidelines for Faculty - See www.passhe.edu/techtransfer
Frequently Asked Questions (FAQ)
Technology Transfer & Commercialization Guide for PASSHE Non-Faculty Personnel

I. Introduction

Universities are major sources of fundamental knowledge underlying the new products and processes essential to economic competitiveness. In this context, facilitating the process whereby university creative and scholarly works may be put to public use and/or commercial application (i.e., "technology transfer") is an important aspect of the service mission of a public university. In turn, the protection of concepts with commercial potential (inventions or creations) via patents and copyrights is an essential aspect of the technology transfer process. Without such protection, companies are unlikely to invest the funds required to commercialize new technology.

This document is intended to serve as a practical guide -- a road map -- on technology transfer as it relates to policies and procedures for PASSHE University non-faculty personnel who may be in a position to make, conceive or otherwise reduce to practice inventions or otherwise develop technology, which includes:

- Staff, including managers, administrators and all other staff classifications (excluding clerical and non-technical personnel); and
- Students who are employed or otherwise compensated at their university through mechanisms such as tuition waivers, wage payroll, graduate assistantships, or other employment classifications used when hiring students, (excluding clerical and non-technical personnel).
- Other Covered Individuals including emeritus/retired faculty, visiting scholars/scientists, contract employees, consultants and others engaged in research at the University who are not permanent or temporary faculty, employees or students.

Students who are not employed or otherwise compensated for services at their university should refer to the "Student Intellectual Property, Technology Transfer & Commercialization Guide" for help with intellectual property policies and procedures related to their academic work.

Definitions of terms used in this document are contained in Appendix A.

A. GOALS

The goal of preparing and distributing these guidelines is fourfold:

1. Assist University personnel in the commercialization of their products.
2. Make inventions and creations resulting from the efforts of University personnel available to industry and the public on an effective and nondiscriminatory basis.
3. Obtain revenue for University personnel, who invent and create and for the PASSHE Universities for use in furthering their educational and research goals.
4. Define the rights and responsibilities of all parties involved in development of Technology Transfer and Commercialization at PASSHE Universities.
This document also provides guidance for compliance with federal patent requirements that are incorporated into all federally funded research grant agreements and contracts. University procedures regarding patent management and technology transfer must be consistent with federal law and policy as set forth in the Bayh-Dole Act of 1980, P.L. 96-517, as amended by P.L. 98-620, implemented by regulations published at 37 CFR Part 401. A synopsis of the Bayh-Dole Act is contained in Appendix B.

The management of patent and copyright processes in a university setting is a complex, highly specialized endeavor. As the need for clarification regarding policies and procedures arises, University personnel are urged to contact their University Authorized Officials (See Appendix C) and their delegates or designees.

Inasmuch as PASSHE only recently initiated a program to enhance its stewardship of its patent and related copyright activities, the policies and procedures cited herein are subject to ongoing review and possible future modification.

B. OVERVIEW OF DISCLOSURE OF INVENTIONS

Inventions with commercial potential may involve novel machines, devices, compositions of matter (compounds, mixtures, genetically engineered cells, plants, animals), genetic forms, software and computer systems, production processes, plant varieties, etc. Such inventions, and the patents and copyrights that reserve rights to them, are the type of Intellectual Property that is the focus of these guidelines.

University personnel will disclose promptly to the University Authorized Official (AO) inventions developed: a) with University resources (intellectual property, facilities, funds, or equipment); or b) within the fields of expertise and/or within the scope of employment for which they are retained by the University. This obligation is required by law in federally-sponsored research. In practice, all inventions must be disclosed to ensure proper management of the patent and proper determination of ownership.
C. OVERVIEW OF OWNERSHIP

The University has the right to claim ownership (rights, title and interest) to inventions and related copyrighted materials made solely or jointly by its non-faculty employees and other covered individuals, as a result of research or investigation conducted by these personnel, which has made ANY use of University resources/support/facilities. Such inventions and related copyrights are to be assigned to the University pursuant to a revenue sharing plan for the inventor(s) that is mutually agreeable.

All inventions developed as part of, or a continuation of, federally funded research will be owned by the University, in accordance with the Bayh-Dole Act. “Ownership” of a patent by the University does not infringe upon the employee’s standing as inventor, as further discussed herein.

The University may contract for sponsored research or investigation with an external sponsor which uses University resources/support/facilities and/or employees’ services in which the ownership of any invention, patent or related copyrightable materials resulting from this work is established in the research grant/agreement/contract and varies from the above terms. In this event, the University AO or designee will notify all employees performing sponsored research of the specific agreement terms.

An invention made by an individual wholly on such individual’s own time, and without the use of University facilities, shall belong to the individual even though it falls within the field of competence relating to the individual’s university position. For purposes of this provision, an individual’s “own time” shall mean time other than that devoted to normal and assigned functions in teaching, university service, direction and conduct of research on university premises and utilizing university facilities. The term “University facilities” shall mean any facility available to the inventor as a direct result of the inventor’s affiliation with the PASSHE University, or any facility available under the University’s policies on co-operative use of research equipment, or policy on use of facilities by emerging technology enterprises, and which would not otherwise be available to a non-PASSHE affiliated individual. However, inventions created on one “own time” without use of “University resources” does not include inventions that are based upon or derived from intellectual property that the University owns or to which it has a potential ownership claim.

In situations of sole individual ownership, University personnel may voluntarily transfer ownership of any patentable process, device, invention and related copyrightable materials to the University as an avenue to protect, license and commercialize the work. In the case of voluntary transfer, the University personnel and the University shall reach mutual agreement on sharing recovered royalties. There is no obligation on the part of the University to accept transfer of ownership of any process, device, invention, or related copyrightable materials created by University personnel.
II. Patent Practice and Procedures

A. INVENTION DISCLOSURES AND OWNERSHIP DETERMINATIONS

1. Prior to Research/Project

University personnel, who anticipate the possibility of creating potentially patentable discoveries and inventions through their research/projects, have the duty to alert University administrators of the possibility at the outset of their project. The method of accomplishing this notification for sponsored proposals is a statement on the proposal routing form, in the form included on Exhibit D-2. For non-sponsored research, the individual will send a similar notice to the University AO via the individual’s Director.

2. At Discovery

University personnel shall immediately notify the University’s Authorized Official (AO) of any inventions developed, a) with University resources/support/facilities (personnel, funds, or equipment), or b) within the fields of expertise and/or within the scope of employment for which they are retained by the University or c) related to, based upon or derived from intellectual property currently owned by the University or to which the University has a potential claim or d) subject to federal grants, contracts or sponsorship agreements; or e) subject to a non-federal grant, contract or other agreement.

In order to properly disclose an invention University personnel will complete an Invention Disclosure Form. The invention disclosure defines the nature of, and provides the basis for a legal claim to, the invention in question. In every case, the invention process must be documented in lab notes, work logs and other appropriate documentation attached to the Disclosure. This documentation will chronicle the contributions of each inventor. The form for the disclosure is attached as Appendix E.

The inventor shall report all use of University facilities, labs, equipment, paid student workers; and amount and source of funds used to support the research leading to the invention. This statement is included on the Invention Disclosure. The University’s will confirm the Inventor’s statement and establish a mechanism to track the institutional support (personnel, cash and in-kind contributions, grants and contracts) of the project, including but not limited to faculty release time, replacement faculty costs, graduate assistants, other student workers, travel funds, supplies, stipends, use of labs and equipment, un-recovered overhead or F&A costs. The University’s Authorized Official (AO) will designate staff responsible for this function. (See Appendix C)

The University AO distributes the disclosure to the University’s CAO, University Legal Counsel (ULC), and the “PASSHE TTO”. The PASSHE TTO is a system-wide, central clearing-house for patent management; it engages the services of Technology Licensing Officers and outside legal counsel to support University patent activity.
Invention disclosures are reviewed and evaluated at the University level to confirm the use of University resources (for purposes of future cost recovery) and for any restrictions imposed by sponsor requirements. The University’s AO shall accept or delegate responsibility for this evaluation and may create a campus committee to do so. This evaluation will determine that the invention falls into one of four classes:

1. External Sponsored Work –

a) Federal Sponsor or Federally Funded

Patents developed in whole or in part under Federally sponsored research, including prior federally sponsored research, are subject to the Bayh-Dole Act, in which case the University will elect to take title.

(b) Non-federal sponsor

Ownership Rights to inventions which are subject to the terms of a non-federally sponsored research or other agreement between the University and a third party are subject to the terms of the applicable agreement and prevailing laws, particularly intellectual property law. All parties should agree to written terms upon award of funding. An agreement shall be executed during the award negotiations and prior to expenditure of funds and shall address ownership and revenue sharing Language, Appendix D, will be incorporated into the research proposal in order to advise the sponsor of the University’s expectations.

c) In the absence of specific sponsor agreement terms, the University will require assignment of title to inventions created by non-faculty personnel for purpose of evaluating and protecting and potentially commercializing the Intellectual Property.

2 Work for Hire – Most if not all work created by non-faculty University personnel will fall within this category., the University owns all rights to non-faculty employee-created copyrightable material that are works made for hire under the Copyright Act. This includes works that are: (1) prepared by an employee within the scope of his or her employment; or (2) specially ordered or commissioned by the University. Ownership and control of works for hire will be governed by federal copyright law. As the employer the University retains the copyrights of works-for-hire, but may grant the creator permission to use the material during the term of his/her employment with the PASSHE/University. Specific Work-for-hire agreements are NOT necessary to secure University ownership of works created by non-faculty employees. “Other covered individuals” shall execute the appropriate agreement, which could include Service Purchase Contracts, or Work-for-Hire agreements or Intellectual Property Agreements prior to the start of work.

C. UNIVERSITY RELEASE OF OWNERSHIP

When the University has rights of ownership to an invention or its related copyrightable materials, as set forth above, and if the University decides that it is not desirable for the University to pursue patent or copyright protection or the University declines to do so, all rights to ownership of the invention or materials will be released to the inventor(s) or developers, to the extent allowed by law of terms of sponsor rights, agreements/contracts. Ownership of federally funded inventions and related copyrightable material revert to the federal agency. Upon request
of the inventor, the University will make written recommendation to the federal agency that ownership rights be vested in the inventor. The inventor(s) or developer(s) would then have the right to pursue a patent or copyright at their own expense. In exploiting or developing any released invention or materials the inventor(s) or developer(s) shall not use University facilities and resources or the name of the University. Even when the University relinquishes its right to pursue a patent or copyright to the inventors or developers, it will retain a non-exclusive, royalty-free license to practice the invention or use the materials for its own purposes.

An assignment to the inventor(s) will require the inventor(s) to, among other things:

1. Accept an equal undivided interest and take responsibility for further assignment of rights to all inventors.
2. Accept responsibility for future patent costs as they are incurred.
3. Exclude “future” or “related inventions” which may arise out of the inventor’s research, or any “background rights” that may be needed to practice the invention.
4. Grant a non-exclusive, royalty-free right to practice the invention and any resulting patents to the University for their own internal, non-commercial research purposes, including the right to sublicense to other research entities.

D. MANAGING PATENTABLE INVENTIONS

Invention Disclosures are forwarded by the University AO to the PASSHE Technology Transfer Office (TTO), a system-wide, central clearinghouse serving all PASSHE Universities. It is the responsibility of the University to maintain and transmit an accurate record of invention, ensuring that the University personnel have agreed to transmit and assign the invention by signing the Intellectual Property Agreement (Appendix F).

The PASSHE TTO evaluates the Invention Disclosure for patentability and market potential. (At this time, these services are contracted to a third-party). A preliminary patent search is generally performed by the PASSHE TTO. If this process suggests that the invention has significant commercial potential, the following sequence is set in motion.

1) The PASSHE TTO, in concert with inventors, will attempt to identify companies whose technology interests coincide with the invention in question. A Technology Licensing Officer (TLO) will be assigned to work with the inventor(s). Non-enabling disclosures are sent to these companies to inform them of the general nature of the invention, without divulging its essential elements. Upon the expressed interest of a potential licensee, additional detailed information about the invention is released following the execution of an appropriate Confidentiality Agreement. The TLO directly negotiates any licensing (and similar) agreements, accepting input and guidance from the University AO, but University personnel do not directly enter into negotiations.

2) In return for rights to an invention, licensees will be expected to file a patent application at their expense in the name of the University. If an invention requires further research to bring it to the point of commercial utilization, companies will be encouraged to provide the necessary research support as part of either a Research and License Agreement, or an Option Agreement. Where an option is involved, companies are offered an exclusive right to negotiate a license in return for a research commitment and/or appropriate payment.
3) The University (that is, the University AO) in consultation with the PASSHE TTO may, under certain circumstances, elect to apply for a patent concurrent with the search for a licensee. This option is very selectively applied as a consequence of the limited funds available for this purpose, and is restricted to unusually promising inventions in dynamic, highly competitive fields. Where this option is contemplated, the results of the preliminary patent search will be submitted to a patent attorney who specializes in the appropriate technical area for a patentability opinion. A decision to proceed will be based on a judgment that the invention is patentable, is not encumbered by other patents, and has sufficient commercial potential to justify patent expense.

4) If, in concert with inventors, the PASSHE TTO is unable to identify a licensee in a timely fashion, the disclosure will typically be returned to the University for further evaluation. The University AO, in consultation with the PASSHE TTO may thereafter elect to accept the disclosure, file a patent application, and initiate the licensing process.

The PASSHE TTO provides monitoring of licensing agreements, including paying all patent maintenance fees, performing due diligence requirements and ensuring licensee obligations are fulfilled.

5) Inventors may petition the University for the assignment of invention ownership rights to them when it

   a) is consistent with the policies and best interests of the University,
   b) would advantage the transfer of technology to the private sector, and
   c) is in accord with the University’s obligations to sponsors and other third parties.

For example, should the PASSHE TTO fail to identify a licensee, and the University AO subsequently elect not to accept the invention, inventors may petition the University for the assignment of invention ownership rights to them as described above.

The foregoing procedure is based on the premise that a close working relationship between University inventors and the PASSHE TTO is important for the successful management of inventions. The reasons are varied. Inventors’ knowledge of their research areas, and of companies active in related technologies, are key elements of the technical and market assessments for an invention, and of the search for licensees. In addition, inventions can serve as powerful catalysts for industrial research support. The search for such support is greatly enhanced by close collaboration between inventors and the PASSHE TTO. Finally, the search for licensees willing to underwrite the cost of concept refinement and/or patent prosecution represents a useful "market test" for an invention.

E. PUBLIC DISCLOSURES

The commercial exploitation of inventions, in the form of products and processes for business and industry, is a highly competitive enterprise. It is therefore critical that inventors begin the University disclosure process as soon as the possibility of an invention becomes evident. Delays give others an opportunity to establish a claim which may deprive an original inventor of his/her rightful recognition and compensation. Some other considerations follow.
In general, it is prudent to delay the oral disclosure or publication of research details that are specific to an invention until such time as the invention has been evaluated and, as appropriate, protected. Such decisions, however, should not be allowed to adversely affect the progress of students toward their degrees. In most cases, the omission of information from publications which would compromise a commercial application does not impede the free flow of fundamental knowledge. In particular, inventions in a University setting are usually practical manifestations of an underlying body of fundamental knowledge. As such, one can frequently engage in the free exchange of basic ideas without compromising the practical application. If inventors have questions about the disclosure or publication of research, they are encouraged to discuss the matter with the Technology Transfer Office.

Public disclosure of a concept in the open literature (in abstracts and texts of presentations at meetings, and in theses, etc.) generally precludes obtaining patent protection in most foreign countries. In the U.S., one may obtain a patent as long as the application is filed within one year of the date of public disclosure. The impact of the waiving of foreign rights for an invention depends upon the size of U.S. and foreign markets, the relative market shares of foreign and domestic companies in the technology in question, etc.

F. SPONSOR AGREEMENTS

1) Industry sponsors

Rights to inventions arising from industrially sponsored research are usually prescribed in a research contract containing a work statement and other terms and conditions of the award. Sponsors generally receive the first option on a license to technology resulting from research which they support. As the contractor for the specified research, the University must ensure that it has not committed rights to technologies to multiple sponsors. In dealing with potential industrial sponsors, University personnel should thus be sensitive to this possibility. The consequences of commingling intellectual property rights between and among sponsors can be substantial. Until such time as they are resolved, disputes over sponsor rights can limit or eliminate opportunities for additional industrial support for promising research areas. Unfortunately, such disputes can last for years.

2) Federal agencies

Federal agencies allow contractors, including universities, to retain ownership of intellectual property arising from research which they sponsor. The government retains non-exclusive rights to such intellectual property for its own purposes. The University has a contractual obligation to inform sponsoring agencies of inventions within two months after they are disclosed to the University Authorized Official (AO) to elect to retain title within two years, and to file a patent within one year of election.

3) Research Consortia

Members of research consortia are typically given non-exclusive rights to inventions conceived in whole or part with consortium funds. Such arrangements can, unfortunately, seriously compromise the commercial potential of an invention. In particular, the
resulting lack of marketplace exclusivity may deter companies from investing in the production facilities and marketing strategies required to commercialize an invention. Faculty concerned about this issue may wish to restrict the use of consortium funds to the support of pre-proprietary research.

G. CONSULTING AGREEMENTS

University personnel shall not enter into private consulting contracts that put at risk of disclosure or loss of protection University-owned Intellectual Property or Intellectual Property that the University has a potential claim to own. University personnel shall not transfer or disclose to a third party any University-owned Intellectual Property or potentially University-owned Intellectual Property through private consulting activities.

Private consulting contracts sometimes contain provisions that limit the disposition of research results, including intellectual property, in promising research areas. University personnel have the duty to ensure that the assignment of rights to intellectual property evolving from consulting activities does not conflict with the ownership rights of the University. In general, University personnel may, within the scope of a private consulting agreement, assign rights to intellectual property in their fields of expertise where organizations engaging their services have legitimate prior claims to the development(s) in question. Examples include consulting activity within a faculty’s field of expertise, which leads to the refinement of an existing product or process, or to a development for which background patents or prior art claims exist (and are held by the consulting client.)

On a related note, University non-faculty personnel may undertake Private Consulting only when it is done without use of University resources, including, but not limited to equipment, staff, laboratories, equipment and computer networks. Employees may not make incidental or substantial use of University resources for fulfillment of a private consulting contract, regardless of the Intellectual Property terms and condition of their contracts. This restriction is necessitated by compliance with conflict of interest and Pennsylvania Employees Ethics Act. However, this restriction does not preclude use of University resources when the University receives fair market value compensation from the employee pursuant to an approved written agreement between the parties; such as a faculty-owned business operating in a University-owned business incubator, paying rent according to a standard lease agreement.
H. CONFIDENTIALITY

1) Material Transfer Agreements

Researchers often share proprietary material with other researchers who are outside the University or PASSHE system. Whether receiving or sending proprietary material to other researchers or companies, a Material Transfer Agreement is often necessary. These agreements are commonly used for the transfer of biological materials, hazardous materials as well as proprietary information and trade secrets. They often address rights to the results of the research in which the material is used, and hence have a significant impact on patent rights. Researchers and University Officials must take care in avoiding agreements with disadvantageous or harmful terms and conditions that restrict IP rights. These agreements can only be signed by University Officials that have contract authority, after the agreement has been reviewed by Legal Counsel. Additional information is included in Appendix G.

2) Non-Disclosure or Confidentiality Agreements

An additional tool to protect patent rights is Non-disclosure or Confidentiality agreements. These agreements are used when providing additional detailed information about inventions to potential licensees. These agreements protect the University and inventors’ rights when it is necessary to disclose enabling details or essential elements about an invention. Model Confidentiality Agreements are available from the PASSHE TTO and ULC.

I. PENNSYLVANIA STATE LAW

Employee-owned companies represent unique issues when it comes to licensing University-owned inventions. The Pennsylvania Adverse Interest Act prohibits Pennsylvania state agencies from entering into contracts with state employees. This Act covers PASSHE Universities as “state agency” and PASSHE faculty as “state employees.” Therefore, a University owned invention cannot be licensed to an employee-owned company. Questions on this point should be referred to University Legal Counsel.

III. Administration

A. TECHNOLOGY TRANSFER OFFICE - FUNCTIONS

Upon receipt of an Invention Disclosure, the Technology Transfer Office assists University administrators and inventors relative to the implementation of patent and copyright policies, and provides counsel on Technology Transfer matters. Mechanisms for assisting University personnel with the patent and copyright processes, and subsequent licensing are described in the PATENT and COPYRIGHT sections of this document.
B. UNIVERSITY AUTHORIZED OFFICIAL - FUNCTIONS

The University Authorized Official (AO) or designee assists University personnel with patent disclosures, ownership determinations and conflict-of-interest issues related to technology transfer and entrepreneurial activities. The University AO has a primary role in monitoring adherence to, and advising personnel on, PASSHE and University procedures in these areas.

To enhance awareness of policies and procedures, the University AO (or designee) shall organize on-campus education and outreach efforts, including collaborative efforts with the PASSHE TTO, such as information meetings on Technology Transfer matters, conflict-of-interest, and technology transfer aspects of outside activities.

The University AO makes the final determination to pursue patent filings and incur the costs associated with such action.

University administrators are encouraged to avail themselves of Technology Transfer Office and University Legal Counsel expertise particularly on the more complex issues.

C. EMPLOYEE ACKNOWLEDGMENTS – RESPONSIBILITIES

The cooperation of all within the University community is an essential element of efforts to protect concepts with commercial potential (inventions or creations) via patents and copyrights, which is an essential aspect of the technology transfer process.

Therefore, all PASSHE employees (as defined in Appendix A) will receive and acknowledge receipt of the PASSHE Technology Transfer Guidelines upon initial hire as a routine part of their orientation. It shall be the responsibility of the appropriate Human Resources executive or administrator to ensure that the PASSHE University Technology Transfer Guidelines are presented to, and the receipt acknowledged by, any covered University employee.

These Guidelines will be distributed to all current PASSHE employees, except clerical and non-technical employees.

All others who may be in a position to make, conceive or reduce to practice inventions or otherwise develop technology, with or without salary or other support, and through the use of University intellectual property, personnel, funds or facilities, will receive and acknowledge receipt of the PASSHE Technology Transfer Guidelines upon initial appointment. This includes but is not limited to, student employees in positions to make inventions, postdoctoral fellows, contract employees, consultants, emeritus or retired faculty, and visiting scholars/scientists. It is the responsibility of the appointing official or administrator, dean or department chair to ensure that the PASSHE University Technology Transfer Guidelines are presented to, and the receipt acknowledged by, Other Covered Individuals.

D. INTELLECTUAL PROPERTY AGREEMENTS - RESPONSIBILITIES

The University Senior Sponsored Research Administrator will ensure that all named project personnel (including staff, consultants and students) shall acknowledge their duty to disclose and assign inventions, as appropriate, when submitting sponsored research proposals for
institutional approvals including internally sponsored projects. Appropriate language is included in Appendix D-2.

The Bayh-Dole Act requires inventor(s) to disclose inventions arising out of federally assisted research to the University, and to assign ownership when the University elects title, so a formal assignment agreement pledging cooperation with these guidelines and the patent process, shall be signed at proposal submission of any federally funded grant or contract proposal, or continuation of prior federally assisted research, or any non-federally sponsored grant or contract proposal. The Senior Sponsored Research Administrator shall ensure these agreements are signed at the time of the proposal submission. (An agreement is included as Appendix F.)

Please Note: The requirement to have individuals identified above, sign an intellectual property acknowledgment and/or agreement arises from: 1) the University's obligations under the federal Bayh-Dole Act to patent and effectively transfer inventions arising from federally sponsored research results to industry for the public benefit and to grant the government a license to use such inventions for government purposes; 2) the University's compliance with contract terms under industry-sponsored research; and 3) the University's responsibility to protect the intellectual property of our personnel. It is not intended to restrict the free exchange of scholarly information or prohibit free and open collaborations between scholars or scientists. It is specifically directed toward those situations in which the development of new technology is targeted.

E. REVENUE DISTRIBUTION

The University will be the licensor for University personnel patents and related copyrights when either a licensee has filed the relevant patent application in the name of the University, or the University has elected to file on its own. After recovery of any financial support, direct patent or copyright prosecution, indirect (or overhead) expenses, maintenance, or infringement litigation costs incurred by the University, royalty revenues are distributed in compliance with mutually agreed schedules allowed under these guidelines.

The University’s share of royalty revenues is utilized to support research, and a portion of the cost of contracting with the Technology Transfer Office. Funds may also be set aside to defray legal expenses associated with infringement actions and product liability litigation accruing to University patents and copyrights. All net royalty revenues received by the PASSHE Universities will be devoted to the support of scientific research and education.

IV. Copyright Practice and Procedures

While the purpose of this document is to provide procedures to manage patentable inventions, a note on copyrights is necessary to distinguish between the two, particularly concerning scholarly work. The University encourages students and other covered individuals to create literary, scholarly, and artistic works. In this context, copyright ownership of such works generally rests with the creator(s). However, works authored by University non-faculty employees (as defined) within the scope of employment belong to the employer – the University.

The University will hold copyright to works created by employees that are generated within the scope of or closely related to the creator’s employment, or commissioned by the University.
The University will hold copyright to all works created by contract employees, and consultants and Other Covered Individuals within the scope of their employment.

Non-faculty employees and other covered individuals may not use University copyright material without specific permission.

Sponsor funding agreements may provide for different ownership and restrictions than those outlined above.

Software

Patentable software developed for any purpose by University personnel is treated as an invention under these guidelines; disclosure is required. Patentable software must meet the definition of an invention: it must be novel, useful and non-obvious.
APPENDIX A

Definition of Terms and Acronyms

Bayh-Dole Act - Enacted on December 12, 1980 The Patent & Trademark Act (Public Law 96-517) created a uniform patent policy among Federal agencies that fund research. Bayh-Dole enables small businesses and non-profit organizations, including universities, to retain title to materials and products they invent under federal funding. Subsequent amendments created uniform licensing guidelines and expanded the law to include all federally funded contractors (Public Law 98-620). The implementing regulations for Bayh-Dole are published at 37 CFR Part 401.

Commissioned work - See work for hire. Commissioned works include, but are not limited to, courseware development specifically assigned or required as part of regular teaching duties.

Copyright- a form of protection that prevents copying of “original works of authorship” that is tangible. These works include literary works, musical works, dramatic works, sculptural works, architectural works, pantomimes, choreography, pictorials, graphics, motion pictures, sound recording and software.

Individual’s “own time” shall mean time other than that devoted to normal and assigned functions in teaching, university service, direction and conduct of research on university premises and utilizing university facilities.

Intellectual property- the term used to describe the patents, copyrights, mask work protection, trade secrets, and plant variety protection certificates that cover or pertain to inventions.

Intellectual Property Agreement is an agreement between the University and University personnel which is signed prior to the start of research or a creative project or at the time of appointment of certain individuals (as outlined in the agreement) which outline specific duties and responsibilities in the event of a discovery or invention and binds the individual to follow these guidelines. The current form of agreement is attached as Appendix F.

Invention- Invention(s) refer to any technical contribution, discovery, process, method, use, design, improvement, modification or combinations thereof, conceived of and reduced to practice during the course of research carried out for or at the University. Includes computer software, novel machines, devices, compositions of matter (compounds, mixtures, genetically engineered cells, plants or animals), genetic forms, mask works, production processes, production methods, plant varieties, etc. that did not exist before.

Invention and Copyright Assignment Agreement is an agreement between the University and the faculty, staff or student inventor(s) or developer(s) which allocates between the University and the inventor, the title, ownership and rights to the invention or materials that results from research carried out at or for the University in exchange for the monetary considerations.
Inventor: One who conceives and either personally or through someone else reduces the invention to practice. The conception of an invention is complete if the inventor is able to make a disclosure that would enable someone skilled in the art to make the invention without extensive research or experimentation. Someone who constructs the invention based on the inventor’s conception or who merely assists in the reduction to practice of an invention is not an inventor. Failure to name the correct inventors can result in invalidation of the patent. It is the obligation of all inventors to adequately document their inventive contributions in laboratory notebooks. Inventorship is distinct from authorship and ownership.

Materials refer to those items which arise from work performed by faculty, staff or students which can lead to copyright protection and could include course work, books, films, recordings, grants, software and other publications developed outside of those needed for individual classroom instruction as defined in Article 39, Paragraph B. 2. of the APSCUF Collective Bargaining Agreement. This should not be confused with research materials described under Material Transfer Agreements.

Material Transfer Agreements are mechanisms for obtaining needed research materials, including but not limited to biological material. They are frequently required when a provider of material or data deems it necessary in the following circumstances:
- The material and/or information is proprietary;
- The material or information is being maintained as a trade secret;
- The material is infectious, hazardous or subject to special regulations;
- The provider is concerned about potential liability; and/or
- The provider wishes to obtain rights to the results of the research in which the material or information is to be used (COGR, 2003)

Only University officials who have contract authority can sign material Transfer Agreements after legal review.

Net Income, is the total income generated by the licensing, sale, distribution or commercialization of an invention, less the direct and indirect expenses incurred by the University.

Other Covered Individuals - Individuals who are required to sign Intellectual Property Agreements, but are not official employees or students of the University are considered “Other Covered Individuals.” This includes emeritus/retired faculty, visiting scholars/scientists, contract employees, consultants and others engaged in research at the University who are not employees or students.

Patent- a grant to the owner or assignee of the patent the right to exclude others from making, using or selling the invention for a term of twenty years from the date of the patent application. Provisional patents are typically filed as a “placeholder” for one year; non-provisional patents are examined and patents issued by the US Patent Office.
Patentable invention - a novel, non-obvious, and useful discovery. It can be: a device, a manufactureable article, a machine, a composition of matter, a process or method, or a new, useful improvement. It excludes printed matter and pure algorithms.

Technology transfer - the process whereby University creative and scholarly works may be put to public use and/or commercial application.

TLO – Technology Licensing Officer. TLO’s evaluate inventions for commercialization potential and negotiates licensing agreements, among other duties.

TTO – PASSHE Technology Transfer Office, system-wide, central clearing-house for patent management for all PASSHE Universities. The TTO engages the services of Technology Licensing Offices and outside legal counsel.

ULC – University Legal Counsel

University AO - University Authorized Official.

University employee refers to part-time and full-time faculty, part-time and full-time staff and administrators, paid or otherwise compensated undergraduate and graduate students and others with a defined relation to the University. Students who receive a tuition waiver conditioned on work or service hours are considered University employees for purposes of this policy.

University personnel - includes University employees and other covered individuals, which are: visiting scholars/scientists and contract employees and consultants and others engaged in research at the University who are not employees or students.

University facilities shall mean any facility available to the inventor as a direct result of the inventor’s affiliation with the PASSHE University, or any facility available under the University’s policies on co-operative use of research equipment, or policy on use of facilities by emerging technology enterprises, and which would not otherwise be available to a non-PASSHE affiliated individual.

University-sponsored Research - includes research covered under an official University research contract and any research- like activity or other creative endeavor carried out by employees in the course of their official duties or responsibilities.

Work for Hire - The U.S. Copyright Act defines a “work made for hire” as (1) a work prepared by an employee within the scope of his her employment; or (2) a work specially ordered or commissioned for use as a contribution to a collective work, as a part of a motion picture or other audiovisual work, as a translation, as a supplementary work, as a compilation, as an instructional text, as a test, as answer material for a test, or as an atlas, if the parties expressly agree in a written instrument signed by them that the work shall be considered a work made for hire. For the purpose of the foregoing sentence, a “supplementary work” is a work prepared for publication as a secondary adjunct to a work by another author for the purpose of introducing, concluding, illustrating, explaining, revising, commenting upon, or assisting in the use of the other work, such as forewords, afterwords, pictorial illustrations, maps, charts, tables, editorial notes, musical arrangements, answer material for tests, bibliographies, appendixes, and indexes, and an “instructional text” is a literary, pictorial, or graphic work prepared for publication and with the purpose of use in systematic
instructional activities. An operational definition for these guidelines is: work commissioned by the University and developed by faculty under campus consulting, extra service or technical assistance agreements regardless of the form of compensation, or work completed by non-faculty employees and personnel as part of the scope of employment.
Appendix B

University obligations under the Bayh-Dole Act

Bayh-Dole permits universities, other nonprofits such as teaching hospitals, and, in most cases, commercial federal contractors to retain title to inventions that are conceived or first reduced to practice in the performance of a federal grant, contract, or cooperative agreement in exchange for certain obligations on the part of the contractor.

In considering Bayh-Dole’s implications and requirements, it is important to keep in mind the objectives of Act as established in its preamble. They are to:

- promote the utilization of inventions arising from federally supported research and development programs;
- encourage maximum participation of small business firms in federally supported research and development efforts;
- promote collaboration between commercial concerns and nonprofit organizations;
- ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise;
- promote the commercialization and public availability of inventions made in the U.S. by U.S. industry and labor;
- ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and
- minimize the costs of administering policies in this area.

By accepting federal funds in support of a research project, recipient institutions assume responsibility for complying with the requirements of the Act. In general, the institutions are required to:

- obtain written agreements from all employees (except clerical and non-technical personnel) recognizing their obligations to report inventions developed under federally funded programs to the appropriate university office and assign them to the institution;
- disclose an invention to the federal agency supporting the applicable research program within two months after the inventor discloses an invention in writing to the institution;
- elect title to the invention within two years after disclosing the invention to the federal agency but no later than 60 days before the end of any statutory period in which valid patent protection can be obtained in the U.S.;
- file a patent application within one year after election of title, but no later than the end of any statutory period in which valid patent protection can be obtained in the U.S.;
- include at the beginning of the U.S. patent application and patent a statement that the U.S. Government has rights in the invention and identifying the sponsoring agency and the number of the funding award;
- submit to the funding agency a confirmatory license for each U.S. patent application;
- notify the funding agency within 10 months after filing the initial patent application whether and in which countries corresponding foreign applications will be filed;
• submit periodic reports, no more frequently than once a year, regarding the utilization of the invention as requested by the funding agency;
• notify the funding agency at least 30 days before statutory deadlines if a patent application or patent will be abandoned;
• give preference to issuing licenses to small business firms if they show they have the resources and capability to bring the invention to practical application;
• except with permission of the funding agency, not assign rights to inventions to third parties (except to patent management firms), including to the inventor;
• require any exclusive licensee to substantially manufacture in the U.S. any products that will be sold in the U.S., unless this requirement is waived by the funding agency;
• share with the inventor(s) of the invention a portion of any income the institution receives from the licensing of the invention;
• use the balance of income received from the licensing of the invention (after costs associated with patenting and licensing are reimbursed) to support education and scientific research.

These obligations are not trivial. They explain why universities and non-profit institutions must make serious resource commitments to supporting the personnel and infrastructure required to comply with the federal regulations that implement the Bayh-Dole Act.

Source: A Tutorial on Technology Transfer in U.S. Colleges and Universities, Council on Governmental Relations, September 2000
## Appendix C

<table>
<thead>
<tr>
<th>PASSHE University</th>
<th>University Authorized Official</th>
<th>Designee to monitor Substantial Use</th>
<th>Official to sign License Agreements</th>
<th>Senior Sponsored Research Administrator</th>
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Appendix D-1

Intellectual Property policy statement for proposals for non-federal grants/contracts; to be used primarily in proposals to foundations and corporations.

I. Publications
The University’s research activities are an integral part of the total educational program, and much of it forms the basis for articles in professional Journals, seminar reports, presentations at professional society meetings, and student dissertations and theses.

To fulfill the University’s obligations as a publicly-aided educational institution, University research should serve a public rather than a private purpose, and the results should be disseminated on a non-discriminatory basis. The University encourages studies whose results can be freely published.

The University recognizes that the legitimate proprietary concerns of private research sponsors and the effective commercialization of research outcomes may require limited delays in publication. Where appropriate, publications can be deferred for a negotiated period of time in order to protect patent rights. Similarly, on those occasions where the University has accepted a sponsor’s proprietary information as necessary background data for a research project, the sponsor may review proposed publications in order to identify any inadvertent disclosure of those specific data.

II. Patents and Copyrights
The University’s policy with regard to inventions and creations resulting from research reflects the view that a university by its nature has an obligation to serve the public interest by ensuring that inventions are developed to the point of maximum utilization and availability to the public. The University, therefore, retains title to inventions and creations made under its sponsored programs with the understanding that it will license them in the public interest under an active inventions/creations management program in which licensing of industrial research sponsors is an important part. The University and the inventor share in the proceeds of royalty-bearing licenses. The licensing program includes a wide range of options depending on the circumstances. In some cases, where required for effective development of the invention, exclusive licenses for a limited term may be negotiated.

III. Use of Names
Research sponsors may not use the University's name in advertising or other product promotion activities without the University's prior written approval. Similarly, the University will not use the name of the sponsor in publicity releases without the sponsor's approval.
Appendix D-2

Statement for Inclusion on Proposal or Contract/Agreement Submittal/Routing Form

It is understood that all discoveries and inventions made or conceived in performance of work on this project will be the property of University of Pennsylvania or in accordance with the contract terms for this project; and the Principal Investigator(s) will furnish prompt and full disclosure of inventions made during performance of this project to the University’s Authorized Official. I have read the PASSHE Technology Transfer and Commercialization Guide for Faculty, and Other Employees and understand my obligations.

I, the project director, (check one): anticipate □ do not anticipate □ developing Intellectual Property during this research/project. The anticipated Intellectual Property is (check all that apply)
Publications/presentations □
Software □
Inventions or discoveries □

Describe above IP:__________________________________________________________

NOTE: The above statement is to be incorporated into each proposal or contract/ agreement submittal form that is transmitted to the CAO of each University. This statement should be signed by all faculty and staff members who will be participating in the project.
Appendix E -1 – Invention Disclosure (use new PDF)

INVENTION DISCLOSURE
University, Pennsylvania State System of Higher Education

Original Form should be submitted to the University Authorized Official via the Dean or Director at least FOUR weeks prior to public disclosure.
Completion of this invention disclosure form does not abrogate faculty rights accrued under Article 39 of the collective bargaining agreement.

1. Title of Invention:

2. **Inventor Identification:** (Attach separate sheets to accommodate more than six inventors).

<table>
<thead>
<tr>
<th>Inventor Name</th>
<th>Inventor Title</th>
<th>Affiliation (University/Company)</th>
<th>Department Address</th>
<th>Home Address</th>
<th>E-mail Address</th>
<th>Work Ph</th>
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3. **Execution of Disclosure:** This disclosure must be (1) signed and dated by all inventors, (2) read, understood, and signed by one technically qualified non-inventor witness (e.g. department head), and (3) read and signed by the University Authorized Official.

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<th>Inventor Signature:</th>
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Name University Authorized Official
The University Authorized Official must notify the affiliated institutions of co-inventors.

Inventor: is defined as is one who conceives and either personally or through someone else reduces the invention to practice. The conception of an invention is complete if the inventor is able to make a disclosure that would enable someone skilled in the art to make the invention without extensive research or experimentation. Someone who constructs the invention based on the inventor's conception or who merely assists in the reduction to practice of an invention is not an inventor. Failure to name the correct inventors can result in invalidation of the patent. It is the obligation of all inventors to adequately document their inventive contributions in laboratory notebooks. Inventorship is distinct from authorship and ownership.

4. Percent (%) Contribution of Each Inventor:

5. Obligations to Third Parties:
   A. Is this invention a result of sponsored research?
      No ☐ Yes ☐
      Sponsor:
      Grant No.:
      Fund/Budget num
      Principal Investigator:
   B. Are you a party to any other agreement(s) pertaining to the invention? (Agreements of: consulting, confidentiality, materials bailement, materials transfer, grant-in-aid, etc.)
      No ☐ Yes ☐
      Agreement Type:
      Name of Other Party:
      Please provide copies of agreements pertaining to the invention.

6. Record of Invention:

<table>
<thead>
<tr>
<th>Event</th>
<th>Date</th>
<th>References (include lab book numbers, models, and drawings. Attach separate sheets if necessary.)</th>
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<tbody>
<tr>
<td>A. Initial Concept</td>
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<td>B. Reduction to Practice:</td>
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<tr>
<td>C. Development or Improvement of invention:</td>
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7. Detailed Description of Invention:
   Provide a detailed description of the invention that describes clearly and concisely:
   A. The object of the invention (i.e. the problem it solves)
   B. The solution to the problem that the invention provides
   C. Similar inventions in current, and disadvantages of current practice that the invention overcomes
   D. Emphasize the key aspects of the invention that make it unique and non-obvious.

8. Public Disclosures:
   Past Disclosures:
   Has the invention been disclosed (i.e. have you told anyone about it?)
   No ☐ Yes ☐
   (If the invention was disclosed in writing, provide a copy of the disclosure.)
   - Date of Disclosure:
   - To whom the disclosure was made:
Future Print Disclosures.
- Date of proposal or manuscript submission to a journal, publisher, etc.: 
- Date of Publication

Future Oral Disclosures.
- Date of conference, convention, speech, etc.: 

Electronic Disclosure (See guidelines.)
- Date of Electronic Publication:

9. What University resources/support/facilities (including external, University-administered resources) were utilized in the research leading to this invention?

Grants/contract value:

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Student Assistants:

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Staff Assistants:

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Computer Network: Time Period:  

Other:  

INVENTION DISCLOSURE Instructions (Page 3)
Original Form should be submitted to the Authorized University Official via the Dean or Director at least FOUR weeks prior to public disclosure (i.e. presentations or publications)

The University Authorized Official and the PASSHE TTO assesses each invention for its patentability, enforceability, and its likelihood for commercial success. The patent process represents a significant University investment in the invention. The cost of a United State patent application ranges from $15,000 to $25,000, while international patent applications often total over $100,000.

A provisional patent application provides protection for the invention for one (1) year from the filing date of the provisional, and such an application will be reviewed by the University Authorized Official and the PASSHE TTO to determine whether it will be converted to a non-provisional patent application, filed, and prosecuted.

Since you, the inventor, are the expert in your field and on the new technology, we ask your assistance in describing the competing technologies, the invention’s state of development, and the potential commercial market for the invention. The bulleted lists are intended as guidelines to outline your answers, which will be presented to the University Authorized Official and the PASSHE TTO. For the purposes of this document “the invention” shall mean the disclosed invention.

Competing Technologies
What technologies compete with the invention? Describe:
- current practices/methods/technologies that accomplish the same task or solve the same problem as the invention,
- shortcomings or disadvantages of competing technology and the invention’s improvement over these disadvantages (Is the invention easier, more cost efficient, smaller, or faster than the current technology?),
- the type of change an invention brings to its field (Does the invention create a revolution or an evolution?),
- patents or technical papers embodying similar technology,
- patents or technical papers embodying any part of the invention,
- the degree of research interest in the invention’s field. (Is the field heavily researched?).

Invention Development
What is the status of the invention’s development? Describe:
- the invention’s reduction to practice (Does a working model, prototype, or biological strain exist that proves the concept is successful?),
- additional steps required to advance the invention toward commercialization (For example, does the invention require government agency approval, human tests or independent trials to determine its success?),
- approximate funding required to advance the invention toward commercialization,
- approximate time required to advance the invention toward commercialization,
- known industrial support or alliances that could provide further funding (Include contact information if available),
- companies (especially in Pennsylvania) that you think would be interested in the invention if it were brought to their attention,
- the inventor’s motivation or interest in commercialization of the invention,
- the inventor’s preferred method of commercializing the invention.

Market Conditions
What are the market conditions surrounding the invention? Describe to the best of your ability:
- market need(s) satisfied by the invention,
- possible processes or products that could result from the invention,
- the customers or “end-uses” of a product based on the invention,
- potential markets, their sizes and possible growth rates (Include citations for market information).
Apprendix E-2

UNIVERSITY OF PENNSYLVANIA
PENNSYLVANIA STATE SYSTEM OF HIGHER EDUCATION

SOFTWARE DISCLOSURE

Use this form to disclose software inventions to the University’s Authorized Official. Prompt disclosure allows the University to secure intellectual property rights as appropriate and to fulfill obligations to external sponsors of research. Completion of this software disclosure form does not abrogate faculty rights accrued under Article 39 of the collective bargaining agreement.

1. Title of Software:

2. Description – Briefly describe general nature, primary functions, and areas of principal use (Attach additional page if necessary):

3. Further development necessary before licensing: (Attach additional page if necessary)

4. Names and addresses (if known) of potential licenses (especially in PA):

5. Estimated price range of product:

6. Funding Source(s) – Was work leading to the invention supported by:
   A. Internal University Funds:
      Project
      Title:

   B. External Funds from: Federal Agencies? Yes☐ No☐ Corporate Sponsors: Yes☐ No☐
      Sponsor:
      Sponsor:
      Grant/Contract #
      Grant/Contract #

7. Principal Developer(s) – List those making substantial contributions (use second page if necessary):
   a. Name
      Title
      Dept.
      Campus Address

      Work Phone
      Home Address
8. **Contribution** of each co-developer:
9. Remarks:

__________________________________________________________
Signature of Discloser(s)                                      Date

__________________________________________________________

__________________________________________________________

__________________________________________________________

__________________________________________________________

*indicate discloser to be contacted for additional information
Appendix F – Intellectual Property Agreement
PASSHE NON-FACULTY PERSONNEL

UNIVERSITY INTELLECTUAL PROPERTY AGREEMENT

Purpose: This form is required to be completed and signed by University employees and other individuals engaged in covered research. Covered research includes
(1) any federal grant or contract proposal,
(2) any non-federal grant or contract proposal with applicable sponsor requirements,
(3) continuation of prior federally assisted research, or
(4) any independent, non-sponsored, self-directed research involving the use of University facilities research that may be within an individual’s field of expertise and/or scope of employment for which they are retained, or a work-for-hire. University non-faculty personnel include: staff, graduate assistants and paid student workers, postdoctoral fellows, contract employees, consultants, emeritus/retired faculty, visiting scholars/scientists, and others, who may be in a position to make, conceive or reduce to practice inventions or otherwise develop technology. This agreement must be signed prior to the initiation of covered research or a work-for-hire, therefore it should be signed by personnel at the time of proposal submission for sponsored research awards, including internally sponsored research, or at the time of appointment of undergraduate/graduate students assisting research, postdoctoral fellows, contract employees, consultants, emeritus/retired faculty, visiting scholars/scientists, or prior to commencement of research that uses University intellectual property facilities and/or resources, including faculty time..

Instructions: The original signed agreement should be returned to the Sponsored Research Office or equivalent via your department of employment or matriculation.

I agree, as a condition of my association on the following project ______________ to abide by the terms of the PASSHE Technology Transfer Guidelines currently in effect, as well as any subsequent revisions thereto. In so agreeing, I especially note the responsibilities set forth below.

(1) to submit invention disclosures to the University promptly following the completion of conception or the first reduction-to-practice of any inventions, discoveries, rights of patent therein, or software (Hereinafter “University Intellectual Property”);

(2) to assign to the University (or its designee) all rights which I have or may acquire in inventions, discoveries, rights of patent therein, or software which are conceived, reduced-to-practice by me:

(a) with the use of University facilities or in the field of expertise and/or within the scope of responsibilities covered by my employment/appointment/association with the University, or
(b) with the assistance of federal funds and/or the continuation of a previously federally funded research, or
(c) completed under a Work-for-Hire agreement.

(3) to do whatever is required to enable the University (or its designee), at its expense, to protect the University Intellectual Property whether by patent, copyright or otherwise; including:

(a) making myself available to meet with patent attorney and provide necessary documentation, data and research results to support the filing or prosecution of patent applications or
(b) reviewing and signing documents from patent attorney retained by ______________ University (or its designee) to seek protection of ______________ University Intellectual Property, or
(c) to assist the University (or its designee) in seeking licensees to commercialize ______________ University inventions;
(4) to maintain laboratory documentation, including laboratory notebooks, where appropriate, to adequately demonstrate that inventions or discoveries were conceived or first reduced-to-practice by me including clear identification of any sponsorship;

(5) prior to completion of my association with work contracted pursuant to contracts or grants, a complete disclosure of all software, instructional materials, inventions or discoveries conceived or first reduced-to-practice by me with the utilization of time, money or facilities charged to contracts or grants, and copyrightable works vested there under, must be submitted to the University.

(6) If I serve as a principal investigator or director of a University research, development, or other type of project, I will determine whether each person who performs any part of the research or development work on the project for which I am responsible has signed an appropriate Intellectual Property Agreement; and if not, will obtain such additional Intellectual Property Agreements as are necessary, and forward them to the University Authorized Official.

I agree it is my responsibility to read and understand PASSHE policies governing IP, including University policies.

I understand that this agreement is part of the terms of my association with the above stated project and is limited to University IP resulting from such project.
My responsibility set forth in Section (3), will continue after termination of my association with the University.

I intend to be legally bound by this agreement.

PLEASE CHECK CURRENT STATUS AND SIGN:

☐ /STAFF ☐ VISITING SCIENTIST
☐ GRAD ASST/FELLOW ☐ EMERITUS/RETIRED FACULTY
☐ GRADUATE STUDENT ☐ NON-DEGREE STUDENT
☐ UNDERGRADUATE STUDENT ☐ OTHER

Printed Name ___________________________ University ID # or Individual Taxpayer Identification Number ___________________________

Signature ___________________________ Date ___________________________

Witness ___________________________ Signature ___________________________
Appendix G – Guidance on Material Transfer

Introduction

Materials transfer agreements (MTAs) are agreements between researchers, other scientist(s), and their respective institutions. An MTA allows researchers to share research materials, such as a cell line, plant germplasm, a chemical compound or a polymer, with another scientist for research purposes, while protecting the intellectual property rights to the materials.

A material transfer agreement (MTA), signed by the University, must always be in place before a principal investigator (PI) at a PASSHE University receives material from an outside source or, in some cases, sends it to an outside source.

The terms and conditions of an MTA for receipt of material from an outside source are generally defined by three parameters:

- the organizational characteristics of the material provider;
- the actual or potential value of the material to the provider; and
- the source of funding that will support the work with the material

Material Incoming from an Educational or Non-Profit Organization

Many research institutions and non-profit organizations are generally willing to transfer material under the terms of the Uniform Biological Material Transfer Agreement (UBMTA), which was developed on a collaborative basis to facilitate the exchange of research material for non-commercial purposes. An "Implementing Letter" is used to confirm that the recipient has signed the UBMTA and is accepting material under UBMTA terms and conditions.

PASSHE is not a signatory to the UBMTA; therefore it uses a Simple Material Transfer Agreement, a brief, straightforward document which incorporates the essential terms of the UBMTA. Researchers should consult with the University Authorized Official (or designee) to initiate a Simple Material Transfer Agreement to receive material. The Simple Agreement must be reviewed by University Legal Counsel and signed by a University official that has contract authority.

Material Incoming from a For-Profit Entity

Most for-profit material providers have their own MTA templates, which they offer to PASSHE Universities as a starting point for negotiations. Finalizing terms with a for-profit material provider can be a complex and time-consuming process, particularly if the provider wants to protect the material (and associated confidential information) from further disclosure or wants to secure rights to inventions that may result from PASSHE’s researchers’ use of its material. In transactions with for-profit entities, PASSHE’s approach to intellectual property issues depends in large part on the source of funding that will support our planned research with the material.
If research work with a provider's material will be supported by a federal grant, contract or cooperative agreement, the University is required to follow the provisions of the Bayh-Dole Act (35 U.S.C. secs. 200-212), and its associated regulations (37 C.F.R. Part 401). Under Bayh-Dole, PASSHE Universities must either elect title to inventions that arise from research activities supported in whole or in part by federal funds, or convey title to those inventions back to the federal funding agency. PASSHE Universities may not assign title to such inventions to any party. Bayh-Dole also requires PASSHE Universities to:

- provide the federal government with a non-exclusive, royalty free license to practice the invention;
- share royalties with the inventor(s); and
- use the remaining proceeds to fund further research.

If a PI's work with material from an outside source is federally funded, it is the position of PASSHE that a for-profit material provider can receive a ninety-day option to secure a non-exclusive, royalty bearing license to inventions that incorporate the original materials, progeny and unmodified derivatives that directly result from the PI's work with the provider's material. Any arrangement more beneficial to the material provider can be accepted by PASSHE only after the University Authorized Official is included in the negotiations. At a minimum, the university must be able to recover any costs that would be associated with meeting their obligations under an MTA (for example, the costs of obtaining a patent in order to grant rights to the material provider).

If the work will be supported by a private (i.e., non-federal) funding source, PASSHE Universities may be willing to accept intellectual property provisions that are more advantageous to the material provider, up to and including the transfer of title to inventions that include the original materials, progeny and unmodified derivatives. In such cases:

- the University Authorized Official has a role in arranging the disposition of inventions; and
- PASSHE will attempt to protect the PI's ability to publish and to conduct future research by seeking to avoid an overly broad grant of patent rights to the material provider.

Negotiations with for-profit material providers are sometimes also complicated by confidentiality provisions, liability provisions and insurance requirements, or requests for publication delays that exceed thirty, or even ninety days. These matters are seldom an issue in transactions with educational and non-profit organizations.

To secure material from a for-profit entity:

1. obtain the provider’s MTA;
2. complete an *Inbound Material Form* and forward the form and the Provider’s MTA to the University Authorized Official or designee [insert position] through the researcher’s chair and dean.
3. The University Authorized Official will consult with Legal Counsel and negotiate with the Provider if necessary
4. MTA’s must be signed by a University official that has contract authority and by the
researcher receiving the material.

Once the agreement is finalized, the researcher will receive a copy back for their use. The researcher(s) may not accept or use the material until an MTA is fully signed by all parties.

Material Incoming from the U.S. Government

Some materials can be procured from federal agencies such as the National Institutes of Health (NIH). Material transfer agreements from agency providers usually have terms that are consistent with the UBMTA, and are therefore acceptable to PASSHE. Such agreements must be reviewed by University Legal Counsel and signed by a University official that has contract authority.

Outgoing Material Transfers

When a PASSHE University researcher wants to share material with someone off campus, the transaction is an "outgoing material transfer." The key factor in outgoing transfers is ownership of the underlying intellectual property. If the material to be transferred is part of a pending or issued University patent, or a pending or completed University invention disclosure, then the researcher must follow PASSHE guidelines for material transfers.

In such cases the University will use the Simple Material Transfer Agreement, which incorporates terms consistent with the UBMTA and preserves certain intellectual property rights of the institution and the researcher. In order to facilitate an outgoing material transfer, the University Authorized Official can designate personnel to sign the Simple Material Transfer Agreement. The University does not, however, have the personnel resources to review, negotiate or sign other forms of MTAs for outgoing material transfers. The University has the right to refuse to transfer the material.

If the material to be transferred is subject to an incoming MTA or a third-party patent, then the PI will be severely restricted in his/her ability to share the material. The prudent and expedient course, in this instance, is to refer the material requester to the original source of the material.

If the PASSHE University, has no current or potential claims to the material, and there are no other potential or existing constraints on distribution, such as an existing MTA or a third-party patent, then a PASSHE University researcher may share his or her material with outside parties, including for-profit as well as educational or non-profit entities. The University does require the PI to confirm in writing with the University Authorized Official (or designee) that the material is not subject to any known restrictions.

WARNING: “Shrink-wrap” or Zip-lock” MTA

A “shrink-wrap” or “zip-lock” material transfer agreement is one that accompanies delivery of a product and essentially states by opening the package the recipient accepts the terms of the material transfer agreement that is enclosed within the package. These agreements may also be called license agreements. The agreements may be problematic for several reasons. PI's do not have authority to agree to terms than bind the University. The terms are often unacceptable to the University and the PI, such as indemnifications, limits on
publishing, ownership of data and research results, ownership of derivative intellectual property and so forth. Upon receipt of a product containing such an agreement, the PI should immediately consult with ________________(University official)

adapted from Wisconsin Alumni Research Foundation web site.
Simple Material Transfer Agreement (Incoming/Outgoing) to Not-for-Profit Institutions

The Provider's proprietary material, __________________ ("Material"), created by __________________ ("Scientist"), has been requested by __________________ ("Recipient"), on behalf of their investigator, __________________ ("Investigator"), for the following use: __________________ ("Research").

As of ____________ ("Effective Date") and in consideration for receiving Material, Recipient agrees to the following:

1. Material is for use by Investigator for research and experimental purposes only. Material shall not be used in humans.
   Material may not be used for any commercial purpose, including but not limited to research conducted under any sponsored research agreement, except for the following sponsored research project: __________________ (This sponsored research agreement is attached as Attachment A). Material is to be used solely by Investigator and his/her collaborators under Investigator’s direct supervision and is not to be distributed to other parties, either on or off of the Recipient’s campus.

2. No invention that contains or incorporates said Material, any unmodified derivatives thereof, or the use of Material or unmodified derivatives thereof shall be commercialized without Provider's written consent. Subject to the rights granted hereunder, Recipient agrees that no other rights are given or implied by this Agreement.

3. The Provider shall be free, in its sole discretion, to distribute the Material to others and to use it for its own purposes.

4. The Material is experimental in nature and it is provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESS OR IMPLIED. Provider MAKES NO REPRESENTATION OR WARRANTY THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT. Recipient shall use Material in an appropriate safe manner in compliance with all applicable Federal, State, and local laws, regulations and guidelines.

5. Except for use in the Research and Teaching, Recipient agrees to hold in confidence any and all information disclosed to Recipient and further agrees not to disclose such information to third parties or use such information for five (5) years from the date of receipt, unless such information: (a) was in the public domain at the time of disclosure; (b) later became part of the public domain through no act or omission of the Recipient, its employees, agents, successors or assigns; (c) was lawfully disclosed to the Recipient by a third party having the right to disclose it; (d) was already known by the Recipient at the time of disclosure; (e) was independently developed by the Recipient or (f) is required by law or court order to be disclosed; provided, however, Recipient shall provide notice to the recipient of any such required disclosure in to the academic association prior to such required disclosure in order to allow Provider to seek to prevent or limit such disclosure.

6. In no event shall the Provider be liable for any use by Investigator or Recipient of the Material or any loss, claim, damage or liability, of whatsoever kind or nature, which may arise from or in connection with this Agreement or the use, handling or storage of the Material. Except where limited by Federal law, or to the extent authorized by the constitutions and laws of the state governing the Recipient, the Recipient, if Recipient is not a PASSHE University, agrees to indemnify and hold harmless the System, Provider, their trustees, officers, agents and employees, from any liability, loss or damage they may suffer as a result of claims, demands, costs or judgments against them arising out of the activities to be carried out pursuant to this Agreement and the use by Recipient of the results obtained from Research.

7. Any publication containing experimental results obtained with the use of Material shall acknowledge the source of Material, in a scientifically appropriate manner, and a copy of any such publication shall be provided to the Scientist.

8. This Agreement shall terminate years after the Effective Date. Upon such termination, Recipient shall destroy all unused Material.

9. The Agreement will be governed under the laws of the State of Pennsylvania and is not assignable.

10. The Material contains third party rights as outlined in Attachment(s) A [B, and C] that is [are] attached and incorporated into this Agreement. [add any other third party issues here]

11. If [animals, include the following] The Material is an animal and can be cross-bred. Any cross-bred progeny and descendants of the cross-bred progeny are not included in the term “Material”. Inventorship of any cross-bred Material shall be determined in accordance with U.S. patent law. It is understood and agreed that Provider retains sole ownership of the Material contained in any such cross-bred animals.

The parties have executed this Agreement as of the Effective Date.

Provider Official:

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Recipient Official:

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
</table>

Address:

Read and Understood by:
Investigator:

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
</tr>
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</table>

Reviewed:
University Legal Counsel:

<table>
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<tr>
<th>Printed Name</th>
<th>Title</th>
<th>Signature</th>
<th>Date</th>
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</thead>
</table>
MATERIAL TRANSFER AGREEMENT (MTA) INBOUND MATERIAL FORM

For use when routing “for profit” entity MTA’s

PLEASE SEND COMPLETED FORM TO University Authorized Official via your Dean or Department Chair

Please submit (1) this form, (2) a brief description of your research in which the requested material will be used, (3) the Provider’s MTA, if they sent one to you, and (4) any correspondence you received from the Provider to your University Authorized Official (or designee) via your dean or department head.

The MTA will be reviewed for compliance with PASSHE policy and applicable laws. If the MTA is acceptable, the University will sign and send it to the Provider. If not, the University will negotiate the MTA terms with the Provider. Once the MTA has been signed by all the required Parties, an original will be kept in the University’s files and a copy will be sent to the PI as a record of the transaction and to refer to throughout the research project. Researchers may not accept or use the material until the MTA is fully signed by all parties.

<table>
<thead>
<tr>
<th>Name and email of University Principal Investigator (PI) requesting the material:</th>
<th>PI’s Phone:</th>
<th>Material being requested from Provider:</th>
</tr>
</thead>
<tbody>
<tr>
<td>University:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of University or Company providing you with the Materials, and name/email of the provider’s contact person:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Is the Material of human origin or obtained from a human specimen? Yes ___ No ___

If yes, please attach a copy of your IRB approval letter.

Will you be modifying the Material? Yes ___ No ___

If yes, how?
(Report derivative property)

Please specify the funding source(s) to be used for your research (check all that apply):
- Industry sponsor name(s):
- Federal contract(s) or grant(s); sponsor name(s)
- Nonprofit grant; grantor name(s):
- Gift funds; giver name(s):
- Other

If the NIH is listed as a funding source above, does your grant require submission of (a) an intellectual property management plan, (b) a data sharing plan, or (c) a model organism sharing plan? Yes ___ No ___

Will the Material be used in conjunction with other materials from commercial parties? Yes ___ No ___

If yes, what are these other materials and who provided them?

Please identify any existing commitments made to third parties regarding this research project not already disclosed above.

Will you use this material or technology in teaching? Yes ___ No ___

Will you need to receive any confidential information from the Provider about this Material? Yes ___ No ___

If the Provider requires you to send them a copy of your manuscript before it is published, what is the maximum number of days you will allow them to review/comment on your manuscript before submitting for publication?

Is the Material commercially available for purchase? Yes ___ No ___

PI Signature: ________________________________

Date: ________________________________
Standard Terms and Conditions for PASSHE University
Incoming Material Transfer Agreements

The following is the language that is generally acceptable to PASSHE in an MTA that does NOT use the Simple Agreement. It is a starting point for negotiations.

1. Publication

"Investigators will have the right to publish and disclose the results of the Research. In order to balance this right with Provider's proprietary interests, investigators will submit any and all proposed disclosures to Provider for its review at least thirty (30) days prior to the scheduled disclosure of the results to any third party (including, without limitation, to any journal for review). Provider will complete its review within thirty (30) days of receipt of the submitted documents. Provider may request that investigators delete from the documents any reference to Provider's Confidential Information. If, during its thirty (30) day review period, Provider notifies University and/or investigators that it desires to file patent applications on any inventions disclosed in the documents, investigators will defer publication/disclosure for up to sixty (60) additional days from the date of submission of the document to Provider."

2. Definition of “Materials"

"Materials" means the provided materials and any Progeny and Unmodified Derivatives thereof. Progeny is an unmodified descendant from the provided materials, such as virus from virus, cell from cell, or organism from organism. Unmodified Derivatives are substances created by the investigator which constitute an unmodified functional subunit or product expressed by the provided materials, such as subclones of unmodified eel/lines, purified or fractionated subsets of the provided materials, proteins expressed by DNA/RNA supplied by the Provider, or monoclonal antibodies secreted by a hybridoma cell-line. Materials shall not include: (a) Modifications, or (b) other substances created by the investigator through the use of the Materials which are not Modifications, Progeny, or Unmodified Derivatives. Modifications are materials made by the investigator which contain/incorporate the Materials.

3. Licensing

"UNIVERSITY and investigators agree to grant to Provider (a) a non-exclusive, royalty-free license to inventions for internal research purposes and (b) an exclusive option to obtain an exclusive, royalty-bearing license to any and all of UNIVERSITY's and investigators' interests in the inventions with the right to grant sublicenses. The parties agree to negotiate in good faith the commercially reasonable terms and conditions of such an exclusive license, or any such royalty payments, that may arise out of this Agreement. Provider shall exercise its (a) right and (b) exclusive option by
notifying UNIVERSITY and investigators in writing of those inventions that Provider intends to license within ninety (90) days of Provider's receipt of a report or manuscript describing such inventions. Any such license will be subject to (i) rights retained by the United States government in accordance with 35 USC sections 200-212, 37 CFR section 401, and UNIVERSITY's obligations regarding the NIH guidelines for Obtaining and Disseminating Biomedical Research Resources, when research is funded by the U. S. government, including, but not limited to, the obligation to ensure that research tools will be available to the academic research community on reasonable terms, and (ii) the retained right of UNIVERSITY to make, have made, provide and use for its internal purposes."

4. **Patent Prosecution**

"Any patent applications necessary to protect the proprietary positions of the parties in any of the inventions may be prepared and filed by UNIVERSITY and/or investigators (jointly in Provider's and UNIVERSITY'S/investigators' names, if jointly invented, with expenses shared equally by Provider and UNIVERSITY and/or investigators; solely in UNIVERSITY's and/or investigators' name, if solely invented, with expenses paid by UNIVERSITY and/or investigators). If UNIVERSITY and/or investigators elect not to file or maintain an application or patent arising from any invention, UNIVERSITY and/or investigators shall promptly notify Provider, and Provider shall have the right to file or maintain the applications or patents, at Provider's expense. Any such patent applications will be subject to any third party rights, including, but not limited to, those rights retained by the U. S. government and/or other sponsors of the Research. Inventorship will be determined according to U. S. patent law, with ownership to follow inventorship".

5. **Confidential Information**

"Confidential Information shall mean proprietary and confidential information of the Provider which is related to the Materials and is provided to UNIVERSITY and indicated as confidential or proprietary at the time of disclosure or in the case of oral disclosures, indicated in writing within thirty (30) days of disclosure."

Confidential Information shall not include information which:

a) was in UNIVERSITY's possession prior to receipt from Provider;
b) was in the public domain at the time of receipt from Provider;
c) becomes part of the public domain through no fault of UNIVERSITY;
d) was lawfully received by UNIVERSITY from a third party having a right to disclose it to UNIVERSITY;
e) is subsequently and independently developed by employees of UNIVERSITY who had no knowledge of the Confidential information disclosed; or
f) is required by law to be disclosed.

"UNIVERSITY agrees that Confidential Information shall be used solely for the research with the Materials and that the Confidential Information will
not be disclosed to anyone except those employees of UNIVERSITY working under the direct supervision of the Recipient Scientist who have a need to know for the purposes of the research utilizing the Materials and who are bound by the terms of this agreement as an employee of UNIVERSITY."

"UNIVERSITY's obligations with respect to Confidential Information as set forth in this Paragraph shall remain in effect for a period of five (5) years following the Effective Date of this Agreement."

6. **Data**

"UNIVERSITY agrees to provide the Provider with a summary of any data resulting from the use of the Materials (the "Data"). UNIVERSITY shall own all Data. The Provider agrees to use the Data solely for research and regulatory purposes, and not to use the Data in support of a patent application without UNIVERSITY's prior knowledge and only after the UNIVERSITY has reviewed the application and had the ability to assert any claims to inventorship. The Provider also agrees not to use the Data for any marketing or promotional purposes without the UNIVERSITY's prior written approval."

7. **Use of Name**

"Neither party shall use the name of the other or any contraction or derivative thereof or the names( s) of the other party's faculty members, employees, or students, as applicable, in any advertising, promotional, sales literature, or fundraising documents without prior written consent from the other party."

8. **Liability**

"Neither of the parties shall assume any liabilities to each other. As to liability to each other or death to persons, or damages to property, the parties do not waive any defense as a result of entering into this agreement. This provision shall not be construed to limit the Commonwealth's rights, claims or defenses which arise as a matter of law or pursuant to any provisions of this agreement. This provision shall not be construed to limit the sovereign immunity of the Commonwealth or of the State System of Higher Education or the university."