Tangible Research Property Policy

EFFECTIVE DATE: October 2016

Policy Statement and Purpose

This policy sets forth the rights and responsibilities of the University and all University Affiliated Individuals regarding ownership, management, access, and distribution of Tangible Research Property arising at or under the auspices of the University.

The creation of Tangible Research Property is a product of conducting research. The University and Principal Investigators endeavor to make Tangible Research Property available to the research community on a reasonable basis, consistent with other University policies, procedures and legal obligations regarding:

- Promoting the principles of openness in research and complying with sharing guidelines generally accepted in the scientific community as described in federal granting agency guidelines and scientific journal policies;
- Complying with the terms of sponsored project agreements;
- Ensuring the appropriate transfer of biological materials (e.g. animals, human tissue, recombinant DNA, disease-causing agents), radioactive materials, and the like;
- Supporting University personnel in securing and protecting intellectual property rights;
- Complying with the terms of managed conflicts of interest that may arise when University Principal Investigators have outside financial interests; and
- Guiding the appropriate transfer of Tangible Research Property for both research and commercial uses.

This policy is designed to complement and not supersede, or expand upon, the USA Patent and Invention Policy or the USA Copyright Policy.
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Related Documents and Information

**USA Copyright Policy**
**USA Patent and Invention Policy**
**USA Faculty Handbook: Section 4.1.2 Academic Freedom**

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**Scope**

This policy, as amended from time to time, shall apply to all University Affiliated Individuals, which includes but is not limited to: faculty, students, graduate students, post-doctoral fellows and support staff, who are involved in the design, conduct or reporting of funded or unfunded research or sponsored projects. Research or a sponsored project with the University that is funded through a grant or contract which includes specified provisions regarding Tangible Research Property, may contain provisions that supersede this policy.

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**Definitions**

**“Adjusted Net Income”** means Net Income from Tangible Research Property, less any Tangible Research Property Direct Generation Cost.

**“Invention”** is defined in the **USA Patent and Invention Policy**

**“Material Transfer Agreement” (MTA)** is a contract that governs the transfer of tangible research property between two organizations when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the recipient with respect to the materials and any derivatives.

**“Net Income”** means the gross revenues actually received from the sale, assignment, license or other commercial development of TRP (including royalties, licensing fees, milestone payments, equity shares in a company or other similar consideration but excluding any external research funding designated for support of research on TRP or for support of other University research programs) less the deduction for Tangible Research Property Direct Generation Cost.

**“Other Research Contributor” (Contributor)** means any persons other than a *University Affiliated Individual* who have made a substantial contribution to the conception, design, or creation of Tangible Research Property.
“Principal Investigator” (PI) means the individual with primary stewardship of TRP on behalf of the University. In this capacity the PI is responsible for ensuring collection, recording, storage, access, and retention in keeping with this policy and best practices in the PI’s discipline.

“Tangible Research Property” (TRP) means, for the purpose of this policy, unique research products or items produced in the course of research projects, whether or not funded by external sponsor(s), at or under the auspices of University of South Alabama, whether or not patentable or otherwise protectable using intellectual property law. TRP includes such items as: biological materials, chemical compounds, physical samples, integrated circuit chips, prototype devices, and equipment. Categories of biological materials include organisms, cells, viruses, cell products, cloned DNA, as well as DNA sequencing, mapping information and crystallographic coordinates. Categories of chemical moieties or engineered products include sample compounds, reagents, intermediates, models, sensors, devices, equipment, computer hardware or firmware, diagrams, or computer media. TRP does not include intangible property as defined in the USA Patent and Invention Policy.

“Tangible Research Property Direct Generation Cost” means all of the documented and verifiable direct costs and expenses attributable or allocated to the generation of the quantities of TRP distributed which led to the receipt of Net Income from such TRP. As an example only, the costs of raw materials, supplies, reagents, specialized equipment, and other direct costs and expenses necessary to generate the quantity of TRP constitutes Tangible Research Property Direct Generation Cost. Salaries, overhead, and equipment which were otherwise used for teaching or numerous research purposes are not part of Tangible Research Property Direct Generation Cost.

“University” is defined in the USA Patent and Invention Policy.

“University Affiliated Individual” is defined in the USA Patent and Invention Policy.

Policy

Tangible Research Property Ownership

TRP made by University Affiliated Individuals is the property of the University.

Custody of Tangible Research Property

TRP will normally be retained in the laboratory or unit where it was produced. The ultimate disposal of TRP is at the discretion of the PI and his or her department or work unit head, subject to provisions of relevant grants and contracts.

It is the responsibility of the PI (or other responsible party in the case of TRP developed in the normal course of University activity) to control the maintenance and distribution of TRP made in
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the course of research activity. Such control includes determining if and when distribution of the TRP is to be made beyond the laboratory for others’ scientific or commercial use, subject to provisions of relevant grants or contracts and University policy.

Access to Tangible Research Property

The USA Faculty Handbook: Section 4.1.2 Academic Freedom expresses our commitment to the principle of freedom of access by all interested persons to the underlying data, to the process, and to the final results of research, including TRP. Consistent with such policy, it is the University’s practice to promote the prompt and open exchange of TRP and associated research data with scientific colleagues outside the PI's immediate laboratory.

Commercial Consideration of Tangible Research Property

Because TRP may have potential commercial value as well as scientific value, the PI may wish to make TRP broadly available for others' scientific use by means which do not diminish its value or inhibit its commercial development or public use. Although valid non-commercial reasons may exist for the temporary delay of TRP distribution outside the laboratory for others' scientific use (e.g., safety factors or the need to more fully characterize the TRP prior to distribution, etc.) scientific exchanges should not be inhibited due to potential commercial considerations.

Transfer of Tangible Research Property

All transfers of TRP from the University to other organizations should be accomplished using a Material Transfer Agreement (MTA), signed by an authorized University official. Obligations to distribute TRP are not intended to supersede the PI’s right to keep TRP proprietary until the results of the research have been published. Transfer of human tissues and specimens may be limited by University policies and federal regulations governing human subject research.

Distribution of TRP to Outside Academic Investigators: The University follows the research resource sharing guidelines of the National Institute of Health (NIH), other federal agencies, and many journals to make unique research resources available to academic colleagues for research use. These guidelines provide for the transfer of published TRP under standard MTAs such as the NIH Simple Letter and the Universal Biological Material Transfer Agreement. Although valid non-commercial reasons may exist for the temporary delay of TRP distribution outside the laboratory for others' scientific use (e.g., safety factors or the need to more fully characterize the TRP prior to distribution, etc.), scientific exchanges should not be inhibited due to potential commercial considerations.

Distribution of TRP to Industry Investigators: The University, with consent of the PI, may make TRP available to industry scientists for research purposes. Company requests for TRP for commercial purposes must be managed by the University’s Office of Commercialization and Industry Collaboration (OCIC). Fulfillment of such requests by
the OCIC may be subject to existing license agreements and/or material transfer agreements, and will typically involve licensing fees and/or cost recovery.

Special considerations will apply to avoid conflicts of interest for transfers of TRP to a company from an investigator who has a conflict of interest management plan for that company. Transfer in these instances, if allowed, will require Dean’s office approval and at minimum, full cost recovery.

Transfer of TRP when the PI Leaves the University of South Alabama: When a PI moves to another institution the PI will typically be able to take TRP (a portion or all) with him/her. The following will apply:

- The University reserves the right to retain portions or all of the TRP if the TRP has special value to the University and/or University Affiliated Individuals.
- The transfer the TRP will be subject to an MTA.
- The TRP will be described with enough detail to allow identification of what items are being transferred as deemed appropriate by the PI and approved by the department chair.
- Documentation of the transfer is sufficient to comply with the USA Faculty Handbook: Section 4.1.2 Academic Freedom.
- Further transfer for commercial use would require consultation with the University’s OCIC.

Transfer of TRP when a Contributor Leaves University of South Alabama: When visiting researchers leave the University, they may, only with approval of the PI and department chair transfer a portion of their TRP to their new institution. Such transfer is subject to review and approval by the University’s OCIC, and requires a MTA.

Income from Transfer of Tangible Research Property

Unless prohibited by law or the terms of a grant, award or contract under which TRP is developed:

- If the TRP is protected by one or more issued patent(s) anywhere in the world, or OCIC has filed one or more patent application(s) anywhere in the world claiming patent protection for an aspect of such TRP, or non-patented TRP with significant commercial potential, as determined by the OCIC, then such TRP shall be treated as much as possible as an Invention for purposes of this Policy, and all Net Income from such TRP shall be distributed pursuant to the USA Patent and Invention Policy as if such TRP were an Invention.

- In any case not governed by the aforementioned (for example, where OCIC did not file any patent application anywhere in the world claiming patent protection for an aspect of
the TRP, OCIC shall determine the Net Income for the TRP. Then, Net Income for the TRP shall be distributed as follows:

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<th>PI’s Laboratory</th>
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**Program Income and Sponsored Awards**

Investigators and OCIC shall report any Net Income from TRP to the Department of Grants and Contract Accounting for a determination whether such revenues must be reported to a funding agency or sponsor as Program Income. In those circumstances in which Net Income from TRP may be considered Program Income under federal law, or grant, award or contract terms, or where the distribution formula set forth above would cause the University to violate law or grant, award or contract terms, the University will comply with applicable law and the sponsor’s terms in the use and/or distribution of any Net Income from TRP due to OCIC as Program Income or otherwise, and otherwise equitably share any Adjusted OCIC Income Revenue for such TRP, if any.

**RESPONBIBLE PARTY:** Director of the Office of Commercialization and Industry Collaboration

**REVIEW DATE:** October, 2018