Data Management and Laboratory Notebook Ownership Policy

EFFECTIVE DATE: June, 2016

Policy Statement and Purpose

This policy sets forth the rights and responsibilities of the University and all University Affiliated Individuals regarding access and maintenance of original Research Data generated in association with the design, conduct and reporting of Research performed at or under the auspices of the University. Additionally this document sets forth the policy regarding ownership and disposition of Laboratory Notebooks

Maintaining accurate and appropriate Research records is a fundamental component of any Research project. It is necessary to support and authenticate findings, to protect intellectual property rights, and to ensure compliance with federal regulations and other University policies.

This policy does not supersede, or expand upon, the USA Patent and Invention Policy or the USA Copyright Policy.

Related Documents and Information

USA Copyright Policy

USA Data Management Best Practices: Collection and Retention of Data

Office of Management and Budget Circular A-110

USA Patent and Invention Policy

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recordings, samples, specimens, IRB consent forms, Research reports, analysis, Data included in theses and dissertations, and any other materials relevant to the Research or sponsored project.

"University" is defined to mean all units of the University of South Alabama, including schools, colleges, hospitals, clinics, institutes, programs, centers and any other components not otherwise listed.

"University Affiliated Individual" is defined in the <u>USA Patent and Invention Policy</u>.

Policy

Data Ownership

In accordance with federal policy and the common practice of higher education institutions, the primary owner of Research records is the University.

guidance by directing the request to the Office of University Counsel and the Vice President for Research and Economic Development to determine an appropriate response. The National Institutes of Health and the National Science Foundation have policies that govern the sharing of Data and the dissemination of Research results. When requested and unless restricted as confidential, University Affiliated Individuals are generally expected to share all Research Data involving their published works.

Data Transfer

In the event a University Affiliated Individual leaves the University, a "Written Agreement of Disposition of Data and/or Laboratory Notebook" may be negotiated between the University Affiliated Individual and the University. Should Research Data leave the University with the University Affiliated Individual, it will be solely in a custodial manner. The University's rights to access the Data shall remain preserved. Written approval granted to transfer Data shall be on a case by case basis and is at the sole discretion of the Dean from which such Data originated and the Director of the Office of Commercialization and Industry Collaboration.

Data Security

Some Research Data may include protected health information (PHI) or personally identifiable information such as social security numbers or personal financial information, etc. To safeguard this information, PIs should apply specific federal laws, state laws, and institutional policies. The Institutional Review Board governing review and approval of human subject's Research adheres to the HIPAA Security Rule. PIs conducting human subject's Research must comply with institutional policies for safeguarding electronic PHI.

Laboratory Notebook Ownership

USA advances its mission in part by generating knowledge through research. An important outcome of Research may be the development of inventions with significant public benefit. The transfer of inventions to the private sector, and the securing of patents when appropriate, provides the means for disseminating new discoveries to the general public through the free enterprise system.

While anyone can apply for a patent to protect an invention, the named applicant(s) must be the true inventors. Laboratory Notebooks, along with a fully completed <u>USA Confidential Invention</u> <u>Disclosure</u>, form the foundation of proof upon which inventorship is determined.

As per the <u>USA Patent and Invention Policy</u>, "an <u>Invention Agreement for University Personnel</u> [IAUP] will be signed at the time of employment or affiliation with the University, or if already employed or affiliated, prior to the use of any USA facilities which might result in an invention or discovery". Ownership of such inventions flows from the inventor-employee to USA as a result of inventor-employee executing the IAUP. Accordingly, **inventions** which are conceived or first actually reduced to practice in the course of employment or affiliation with the USA, or

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through participation in sponsored Research made available by USA, or with the use of the funds, resources or facilities administered by the USA, **shall be the property of USA**. As a natural consequence of this, USA also asserts ownership of any and all documents upon which proof of inventorship is based, e.g., Laboratory Notebooks.

Laboratory Notebooks and any and all documents upon which proof of inventorship is based remain the property of USA even in the event where a University Affiliated Individual's employment with USA is terminated. In such an event, the Laboratory Notebook must remain with the laboratory. Express written approval may be granted to transfer said Laboratory Notebooks and documents. However, this approval is at the sole discretion of the Dean from which the Laboratory Notebook is being requested, and the Director of the Office of