



## UNIVERSITY OF SOUTH ALABAMA

### **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.

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#### **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](#)

Laboratory Notebooks: Best Principles and Best Standards

[USA Records Disposition Authority Policy](#)

[USA Information Systems Security Policy](#)

Written Agreement on Disposition of Data and/or Laboratory Notebook

## Scope

This policy, as amended from time to time, shall apply to all University Affiliated Individuals as defined in the [USA Patent and Invention Policy](#), 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 Data management or management of technical Data, may contain provisions that supersede this policy.

It is vital that University Affiliated Individuals have the capability to document Research results for assisting the University in meeting its legal and scholarly requirements, as well as for more traditional purposes such as determining priority for patentable items and publishing manuscripts. The PI is responsible maintaining appropriate Data and documentation.

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## Definitions

**“Data”** means recorded factual material commonly accepted as necessary to validate Research findings. Research Data covers a broad range of types of information. Digital Data can be structured in a variety of formats. Data differs amongst disciplines and can include but is not limited to: documents, notebooks, Laboratory Notebooks, audiotapes, transcripts, photographs, test responses, slides, and algorithms. In practice, Research Data include intangible (statistics, findings, conclusions, etc.), as well as tangible Data.

**“Laboratory Notebook”** is defined to mean a primary record of Research in any form (e.g. paper notebook, electronic notebook, etc.).

**“Principal Investigator”** means the individual with primary stewardship of Research Data on behalf of the University. In this capacity the Principal Investigator (PI) is responsible for Data collection, recording, storage, access, and retention in keeping with this policy and best practices in the PI’s discipline.

**“Report”** means any summary, statement or description of Research activities published in the open literature or provided to the public, the University, a sponsor, or other Researchers by a University Affiliated Individual.

**“Research”** means a systematic investigation designed to develop or contribute to knowledge and may include the stages of development, testing, and evaluation.

**“Tangible Data”** is defined to include, but is not limited to notebooks, media devices, photographs, films, scans, slides, images, videotapes, gels, blots, spectra, electrophysiological

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 [\*USA Patent and Invention Policy\*](#).

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## **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. Specifically, the University owns all Research Data generated through Research projects performed at or under the auspices of the University regardless of funding source, unless explicit terms of contractual arrangements (including subcontracts), other agreements, or sponsorship declare otherwise. In the event a dispute arises over Data management or ownership, the Vice President of Research and Economic Development will be the deciding official.

### **Custody of Research Data**

On behalf of the University, the PI serves as the custodian of Research Data including the scientific Data and other records of Research generated at or under the auspices of the University. The PI is charged with the preservation and integrity of the original Research Data. In an instance of misconduct, the threat of Data custody or maintenance, or for any other justifiable cause, the University acting through the Vice President for Research and Economic Development or designee, may take immediate custody of Research Data.

### **Access to Research Data**

The University has the right to unfettered access to Research Data for Research performed at the University, supported with University administered funds, or carried out using University facilities. The University’s entitlement to unfettered access to Research Data shall remain irrespective of the responsible University Affiliated Individual’s location. Where necessary to assure needed access, the University may take physical custody of the Data in a manner specified by the Vice President for Research and Economic Development (or a designee).

External sponsoring agencies providing support for Research may have a legal right to access or may request access under the federal Freedom of Information Act (FOIA). When a PI receives a FOIA request for Research Data generated by a federally funded project, the PI should seek

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.

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## **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 [USA Confidential Invention Disclosure](#), form the foundation of proof upon which inventorship is determined.

As per the [USA Patent and Invention Policy](#), “an *Invention Agreement for University Personnel* [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

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 Commercialization and Industry Collaboration. Should such approval be granted, the transfer of the Laboratory Notebook and documents requires, at minimum, a "Written Agreement of Disposition of Data and/or Laboratory Notebook" to be fully executed by the discloser and recipient, including final signing authority of the Director of the Office of Commercialization and Industry Collaboration.

## **Responsible Party**

Vice President Office of Research and Economic Development

## **Next Review Date**

March 2018