1.0 POLICY

1.1 Background.

1.1.1 Scientists performing secondary analyses of existing data may wish to use restricted access (confidential) data. **Restricted access data sets** are those cannot be released directly to the public because of risks to study participants and the confidentiality promised to them. Commonly restricted data elements include detailed geography that would allow identification of participants, DNA or other personally identifiable medical data, and administrative data from federal agencies such as the Social Security Administration or Medicare. Such files are available to researchers from a data collection agency or authorized supplier and must be used only under formal agreements for their use and maintenance of confidentiality.

1.1.2 Most data sources require IRB approval of the investigator’s research plan and the data use agreement before granting access to the data.

1.1.3 Major sources of restricted-access data in the social sciences include (but are not limited to) the following:

1.1.3.1 National Center for Education Statistics, Institute for Educational Sciences. **NCES IES Restricted Use Data License Procedures**;

1.1.3.2 U.S. Census Bureau Research Data Center. **Census Bureau Research Data Center Research Proposal Guidelines**;

1.1.3.3 U.S. Bureau of Labor Statistics. **Researcher Access to Confidential Data Files at the BLS**.

1.1.3.4 Panel Study of Income Dynamics (PSID) (University of Michigan). **PSID FAQ**.

1.1.3.5 The National Longitudinal Study of Adolescent Health (Add Health) (University of North Carolina). **About Restricted Use of Contractual Data (Add Health)**.

1.1.3.6 National Archive of Criminal Justice Data (Inter-University Consortium for Political and Social Research). **NACJD Restricted Data**.

1.1.3.7 National Center for Health Statistics (NCHS) Research Data Center. **NCHS Research Data Center Procedures**.
1.2 Policy Statement

1.2.1 It is the policy of the University of Alabama IRB that the use of restricted-access data provided by a data-collection agency or authorized supplier must be used with formal confidentiality protections specified in a data transfer agreement. Acquisition of such data requires a contractual agreement between The University of Alabama and the data provider accepting those terms and detailing the security protocol to be used to ensure those confidentiality protections.

1.2.2 University of Alabama researchers must also meet internal institutional requirements to employ restricted-access data. Typically, a researcher must obtain approval to do research involving human subjects from the IRB and then submit the data transfer agreement to The Office for Research for review, negotiation and/or signature.

1.3 Objective

1.3.1 Implementation of this policy will ensure protection of the privacy of human research participants in UA research and compliance with the HIPAA privacy rule.

1.4 Responsibility

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance, Research Compliance staff, IRB members and chairs, investigators, the University Privacy Officer, and the Director of Information Security and Compliance/ISO.

2.0 PROCEDURE

2.1 Investigator Application for Use of A Restricted Data Set

2.1.1 The investigator prepares an IRB application that, in addition to standard elements, includes the following:

2.1.1.1 The name and source of the data set sought for use;

2.1.1.2 A detailed description of why public-use data is insufficient for the inquiry and why access to restricted access data is essential;

2.1.1.3 A description of the data source’s requirements for access to the data;

2.1.1.4 A description of how the restricted-use data will be protected. This includes storage, access limitations, and other measures intended to prevent unauthorized use of the data.

2.1.1.5 A copy of the proposed data transfer agreement should be appended.
2.1.2 Following IRB approval of the research plan and data transfer agreement, the investigator submits the data transfer agreement to the Office For Research for review, negotiation, and signature.

2.2 IRB Review of Application for Use of a Restricted Data Set

2.2.1 The Office for Research Compliance may recommend that the application receive exempt, expedited, or full board review, depending on the nature of the data and the risks to participant confidentiality.

2.2.2 The IRB reviews the application and data transfer agreement at the requested level, giving special attention to the application elements requested in 2.1.

2.2.3 The Research Compliance Specialist notifies the investigator of the IRB’s decision.

2.3 Contract approval

2.3.1 Any contract entered into on behalf of The University of Alabama, such as a data licensing agreement, must be approved by The University of Alabama’s contracting authority, The Office for Research.

2.3.2 A copy of the contract as approved by the Office for Research will be placed in the study file.

3.0 REFERENCES

3.1 45 CFR 164.512 Medical Privacy: National Standards to Protect the Privacy of Health Information. The Health Information and Portability and Accountability Act of 1996 (HIPAA).

4.0 RELATED SECTIONS

4.1 POLICY: Research Using Publicly Available Data Sets

4.2 POLICY: Research Using Limited Data Sets

4.3 POLICY: Protection of Human Research Participants’ Privacy and Confidentiality

4.4 GUIDANCE: IRB Application Guide

4.5 GUIDANCE: The Meaning of Anonymous, Confidential, and De-Identified and Implications for Data Sharing or Re-use