POLICY # RESEARCH USING A LIMITED DATA SET

1.0 POLICY

1.1 Background.

1.1.1 Privacy Regulations (45 CFR 164.512) issued under the Health Insurance Portability and Accountability Act, better known as "HIPAA" ,allow access for research purposes to health information that includes a limited number of identifiers. This "limited data set" of information may be disclosed to an outside party without a patient's authorization if certain conditions are met.

1.1.1.1 A **Limited Data Set** is protected health information (PHI) containing such information as dates of admission, discharge, or other services; dates of birth or death; age of participant (including those over 90 years of age); full five digit ZIP code and any other geographic subdivision such as county, city, precinct, and equivalent geocode (except street address) that may be used for research, public health, or health care operations. No direct identifiers, such as names, full postal address, record numbers, electronic addresses, biometric data (finger or voice prints) or photographic images may be used, nor may it include any information that identifies persons' relatives, employers, or household members. No links for re-identifying the data at a later time are allowed.

1.1.2 Because a limited data set is still protected health information, the Privacy Regulations contemplate that the privacy of individuals will be protected by requiring covered entities to enter into data use agreements with recipients of limited data sets.

1.1.3 This policy deals only with limited use data sets. For other kinds of data use, see POLICY: Research Using Publicly Available Data Sets and POLICY: Research Using Restricted Data Sets

1.1.4 *NOTE: Limited data sets and HIPAA may interact with other laws such as FERPA. Investigators are responsible for satisfying all legal requirements in their use of data. See HHS/ED Joint Guidance on Application of Student Health Records to FERPA and HIPAA (11/25/08).*

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that the use of a limited data set shall be in full accordance with regulations at Human Health Services 45 CFR § 46. A researcher with IRB approval and a data use agreement between the holder of the individual health information, the "covered entity", and the recipient can use and

disclose protected health information that contains a limited data set without a HIPAA authorization or a waiver of consent granted by the IRB.

1.2.2 Investigators requesting use of a limited data set shall prepare an agreement governing use of the data set that meets standards specified in the Privacy Regulation and submit it in the IRB application.

1.2.3 As this type of data does not allow direct or indirect links to the subjects, it may be suitable for use in studies that the IRB finds are exempt from IRB review under the Common Rule for Research.

1.3 Objective

1.3.1 Implementation of this policy assures protection of the privacy of research participants and UA compliance with the Privacy Rule (HIPAA).

1.4 Responsibility

1.4.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include principal investigators, covered entities, the Office for Research Compliance, and the University Privacy Officer.

2.0 PROCEDURE

2.1 To determine if a request meets the requirement for a limited data set, investigators must address the following series of questions within their application:

2.1.1 What PHI will be accessed? Please note the standard is that only the minimum necessary information to prepare for the research project should be accessed.

2.1.2 In addition to the principal investigator which individuals or class of individuals will use or receive the PHI for the purposes described above?

2.1.3 Do you agree that the <u>data being requested does not include any of the following</u> for the individual, the individual's relatives, employers and household members? (Answer YES or NO)

2.1.3.1 Names

2.1.3.2 Postal address information other than town/city/state

2.1.3.3 Telephone number

2.1.3.4 FAX number

2.1.3.5 E-mail address

2.1.3.6 Social security number

2.1.3.7 Medical record number

2.1.3.8 Health plan number

2.1.3.9 Account numbers

2.1.3.10 Certificate or license numbers

2.1.3.11 Vehicle identification/serial numbers, including license plate numbers

2.1.3.12 Device identification/serial numbers

2.1.3.13 Universal resource locators (URLs)

2.1.3.14 Internet protocol addresses

2.1.3.15 Biometric identifiers, including finger and voice prints

2.1.3.16 Full face photographs and comparable images

2.2 Investigators prepare and submit a signed data use agreement between the investigator and the covered entity with the IRB application. According to the Privacy Regulation, a data use agreement must:

2.2.1 Establish the permitted uses or disclosures of the information by the recipient;

2.2.2 Establish who is permitted to use or receive the limited data set;

2.2.3 Provide that the recipient will not use or further disclose the information other than as permitted by the agreement or required by law;

2.2.4 Provide that the recipient will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the agreement;

2.2.5 Provide that the recipient will report to the covered entity any impermissible use or disclosure of which it becomes aware;

2.2.6 Require that the recipient ensure that any agents to whom it provides the limited data set agree to the same restrictions and conditions;

2.2.7 Provide that the recipient not identify the information or contact the individuals; and

2.2.8 Provide that if the attempts to cure a breach or end a violation are unsuccessful, disclosure of the limited data set to the recipient will be terminated and the problem will be reported to the Research Compliance Officer;

2.2.9 Be signed by both the investigator and the covered entity.

2.3 The investigator requests EXEMPT status (if desired) and submits the application to the IRB.

2.4 Upon receipt of the IRB application, the Director of Research Compliance determines whether the application qualifies as exempt.

2.4.1 If EXEMPT, the application is processed in accordance with POLICY: Review for Exemption.

2.4.2 If not exempt, the application will be referred for expedited or full board review and processed in accordance with those policies.

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 1966 (HIPAA).

4.0 RELATED SECTIONS

4.1 POLICY: Research Using Publicly Available Data Sets

4.2 POLICY: Research Using Restricted Access Data Sets

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

4.4 GUIDANCE: IRB Application Guide