1.0 POLICY

1.1 Background.

1.1.1 Investigators from many disciplines (medicine, social work, education, political science, business, to name a few) conduct research using records, chart reviews, and case studies/reports or case reports.

1.1.2 Research studies involving the retrospective review, collection and analysis of information from medical or other records are descriptive studies that ordinarily seek to evaluate relationships between one or more biomedical, educational, social, vocational or other treatments and life circumstances and one or more outcome measures in patients or other people. Data may include a wide range of information from the record (raw data on a range of tests or assessments, results of tests, caregiver notes, responses to medical or other treatments and interventions, consultant reports, employment histories, etc.). Because this is research, University IRB oversight is required, in accordance with the Federal Policy regulations (45 CFR Part 46) governing human subject protections. Further, because the research involves medical records, compliance with the HIPAA Privacy Rule (46 CFR Part 160; Part 164 (subparts A, E)) is required.

1.1.3 The IRB recognizes that some record/chart reviews and case studies/reports and case reports are done purely for educational or scholarly purposes and do not meet requirements for research. Circumstances that distinguish between educational/scholarly purposes and research are described in this policy.

1.1.4 Whether or not medical record/chart reviews and case studies/reports and case reports are judged to be research, they may involve use of private information and possible compliance with the HIPAA privacy rule. Record reviews and case studies/reports and reports in non-medical fields may involve compliance with various other laws such as those governing student or employee privacy.

1.2 Definitions

1.2.1 **Research** is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

1.2.2 **Human subject** (DHHS) is a living individual about whom an investigator (whether professional or student) conducting research obtains (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual, and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information in order for obtaining the information to constitute research with human subjects.

Human subject (FDA) is “an individual who is or becomes a participant in research, either as a recipient of the test article [drug, device, or biological] or as a control. A subject may be either a healthy human or a patient. For device research, a subject is also an individual on whose specimen a device is used.

Case study and case report (hereafter referred to as “case study/report”) are synonymous and refer to the written or oral description of one person’s history, treatment, education, activities, or functioning within his/her setting (medical or otherwise). Cases may be chosen as typical or unusual, but may not involve research intent, an innovative treatment, or be used to satisfy a research requirement.

1.3 Policy Statement.

1.3.1 It is the policy of the University of Alabama that the IRB will review all human participant research prior to the investigator’s collection of data from medical or other records, charts, and case studies/reports. The IRB shall give consideration to the protection of the privacy of the participants, purpose of the research, and the investigator’s ability to meet the objectives of the study.

1.4 Records and Chart Reviews

1.4.1 The IRB shall review all requests for access to medical and other records and chart reviews for research. Inappropriate use of private, confidential information can result in harm to a human research participant.

1.4.2 Investigators performing record and chart reviews may not perform any follow-up activities related to persons whose records were used, such as notifying physicians or other professionals of a trend or proposing local changes in the standard of care or practice.

1.5 Potentially Exempt Research Activities

1.5.1 Research utilizing information available in public documents in the United States (i.e. court records, police records, etc.), is not “human subject research” if the activity
does not involve the collection of private identifiable information. Since “private information” is defined as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public,” most research utilizing information available in public documents in the United States is not “human subject research”.

1.5.2 Human subject research that involves the collection of existing public information is not FDA-regulated, and may be exempt, regardless of whether the information is recorded in such a way that participants can be identified directly or through linkage. All use of public documents from another country is subject to the relative laws and regulations of that country and the investigator is responsible to assure compliance with those laws and regulations.

1.5.3 Human subjects research that involves the collection of retrospective data (records that exist prior to the start of the research project) from medical records can be exempt if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

1.5.4 Research that involves collection of data from medical records of patients no longer living is exempt, provided that a related living being is not put at risk (as in some types of infectious disease or genetics research).

1.6 Non-Exempt Research Activities

1.6.1 Research involving the study of medical records is not exempt if the investigator records the data in such a manner that participants can be identified either directly or through identifiers linked to the participant or if the study involves prospective collection of records.

1.6.2 If participant identifiers must be temporarily maintained in order to permit the investigator to identify additional records for inclusion in the study, informed consent/authorization is required unless the IRB grants a waiver of informed consent in accordance with the following specific requirements of HIPAA and 45 CFR § 46.116(d):

1) Only the minimum amount of participant identifier data is recorded.

2) The use or disclosure of Protected Health Information or data, which is not Protected Health Information, involves no more that minimal risk.

3) The alteration or waiver of informed consent will not adversely affect the rights and welfare of the participants.

4) The research cannot be practicably be carried out without the alteration or waiver.

5) There must be an adequate plan to protect participant identifiers from improper use and disclosure.
6) There must be an adequate plan to destroy the identifiers associated with Protected Health Information at the earliest opportunity, unless there is a health or research justification for retaining the identifiers or retention is required by law.

7) Whenever appropriate, the participants will be provided with additional pertinent information after participation.

8) If identifiers are recorded for the purpose of selecting a prospective participant population and the investigator intends to subsequently solicit informed consent to participate in a perspective study, specific guidelines must be followed regarding initial contact with potential participants. Contact with potential participants should originate with an individual who has the appropriate professional relationship with the potential participant (e.g., primary care physician, counselor, teacher, etc). If investigators do not have such a relationship, they should obtain assistance from someone who does. Once the appropriate professional has originated the contact, negotiation for informed consent can begin as with any other research protocol.

1.7 Case Studies/Reports

1.7.1 A clinical case study/report on a single patient/person without any research intent or change in standard practice is not research and does not require IRB review.

1.7.1.1 Although a case study/report involves a human subject by definition and may contribute to generalizable knowledge by presentation or publication, a case report does not meet the definition of a systematic investigation and thus does not meet the definition of research. A case study/report simply describes the course of medical or other treatment; a person’s activities or progress in relation to life circumstances; a unique outcome, or a unique case.

1.7.1.2 The statement that a single case study/report is not research and does not require IRB means that that nothing was done to the person with prior “research” intent. No review is needed, even if the case report is presented or published, or used to fulfill a requirement for scholarly activity.

1.7.1.3 Conversely, if anything was done in the course of care with a research intent (for example, a physician tests a non-standard use of a drug), the case study/report becomes research.

1.7.1.4 If more than one human subject is included in the project, it becomes a case series, is considered research, and requires IRB review.

1.7.1.5 Since a case study/report is not considered research, it should not be called research or used to fulfill a “research” requirement. Programs may consider a case study/report a scholarly activity and use them to fulfill a scholarly activity requirement. If a program or investigator calls a case report “research” or uses it to fulfill a “research” requirement, it requires IRB approval.
1.7.1.6 In most cases, regardless of whether IRB review is required, HIPAA authorization from the subject will be required. If the subject is deceased, and no information is obtained from living subjects (e.g. relatives) HIPAA authorization is not required. In rare cases a waiver of HIPAA authorization may be applied for.

1.8 Objective

1.8.1 Adherence to this policy will ensure protection of the privacy of research participants or other individuals being

1.9 Responsibility.

1.9.1 The Vice President for Research is ultimately responsible for this policy. Enabling parties include the Director of Research Compliance, Research Compliance Specialists, the IRB, investigators, and faculty supervising student research or faculty supervising scholarly activities that involve records, charts, and case studies/reports.

2.0 PROCEDURE

2.1 If there is any question of whether a study using medical or other records or case studies/reports/reports is research, the investigator should contact the Research Compliance Specialist or the Director of Research Compliance for a determination in accordance with POLICY: Review for Exemption.

2.2 If the study is judged to be research, the investigator prepares and submits an application appropriate to the level of review being requested. Research using records, charts, or case studies/reports/reports may be eligible for exempt, expedited, or full board review. The application should also demonstrate compliance with any applicable legislation such as HIPAA, FERPA or No Child Left Behind.

2.3 The IRB will conduct the appropriate level of review, paying special attention to protection of participants’ privacy and confidentiality, and notify the investigator of the decision.

2.4 As with any other study, investigators must report any reportable events (particularly breaches of confidentiality) to the IRB.

3.0 REFERENCES

3.1 45 CFR 46

3.2 45 CFR 160

3.3 46 CFR 164 (subparts A and E)
4.0 RELATED SECTIONS

4.1 POLICY: Protection of Human Research Participants' Privacy and Confidentiality
4.2 POLICY: Review for Exemption
4.3 UA and HIPAA http://hipaa.ua.edu
4.4 HIPAA regulation: http://www.hhs.gov/ocr/hipaa/
4.5 GUIDANCE: Reportable Events