1.0 POLICY

1.1 Background.

1.1.1 Research that meets the categories set forth by the federal regulations [45 CFR §46.101(b); 45 CFR §46.301(a), 45 CFR §46.401 (b) (2), 21 CFR 56.104(d); 38 CFR §16.102(b)] may qualify for exemption from IRB review.

1.2 Policy Statement.

1.2.1 It is the policy of the University of Alabama that the IRB must review and approve all exemptions claimed for research conducted at the University of Alabama by employees or agents of the University.

1.2.2 The IRB chairs may make decisions about whether applications qualify for exempt status or may delegate that authority to the Director of Research Compliance (DRC).

NOTE: At UA this authority has been delegated to the DRC.

1.2.3 The criteria used to determine that participants are protected in exempt research include the following:

1.2.3.1 The research involves no more than minimal risk to participants. This includes consideration of the declared or undeclared potential for a conflict of interest by the PI or research staff.

1.2.3.2 Selection of participants is equitable;

1.2.3.3 If identifiable information is recorded, there are adequate provisions to maintain the confidentiality of the data;

1.2.3.4 If there are interactions with participants, there will be a consent process that discloses such information as the activity involves research, the procedures to be used, that participation is voluntary, and name and contact information for the investigator;

1.2.3.5 There are adequate provisions for maintaining the privacy of participants.

1.2.3.6 The research does not raise ethical questions, even if the criteria for exempt research are met. For example:

1.2.3.6.1 An investigator proposes to observe teens drinking in a public park and their decisions about who will drive the car. The investigator will not participate in the activities and the data will be anonymous. Although this technically meets the requirements for exemption, the study raises the ethical issue of
whether the investigator as an adult observer has an obligation to intervene in potentially life-threatening situations.

1.2.3.6.2 An investigator proposes to survey emergency medical records to determine how frequently a certain diagnosis is missed at the institution. This study raises the ethical question of putting all emergency room physicians at risk of identifying them with poor medical care practices.

1.2.4 The DRC shall inform the IRBs each month of applications that have been ruled exempt. IRB chairs and members have the right to question this ruling for specific proposals and to review the applications for themselves.

1.2.5 Exempt studies, like expedited and full-reviewed studies, are subject to routine monitoring and monitoring for cause.

1.2.6 Exempt studies, like expedited and full-reviewed studies, are approved for one year. If the study lasts longer, the principal investigator is responsible for applying for renewal.

1.2.7 **Research involving prisoners cannot be considered for exempt status.**

1.3 **Objective**

1.3.1 Compliance with this policy will assure protection of participants in research for which exempt status is requested and granted and UA compliance with federal regulations for exempt research.

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 Specialists, IRB members, principal investigators, and faculty supervisors of research.

2.0 **PROCEDURE**

2.1 The principal investigator should first assess whether the proposed research is human subjects research. FORM: Human Research Determination (DHHS and FDA) for Research Compliance Staff and IRB can assist with this determination. Consult with a Research Compliance Specialist if there are questions.

2.2 Consult FORM: Exemption Eligibility Checklist which lists the categories for exempt research and the circumstances under which exemptions are not possible and identify the category(ies) of exemption the research may meet. If the research appears to qualify for exempt status, request that it be considered for that in a cover letter or on the electronic protocol submission program. Consult with a Research Compliance Specialist if you have questions.
2.3 Prepare and submit a complete IRB application, including a description of any COI and its management. See GUIDANCE: IRB Application Guide.

2.3.1 If the proposed research is a secondary analysis of data from an approved data set, describe the purpose and background, the research question(s), the source and nature of the dataset, the variables to be used, and whether the data sought have been de-identified.

2.3.1.1 If the data set is not yet on the approved list, you may propose that it be considered for addition to the approved list of data sets. See POLICY: Use of Publicly Available Data Sets.

2.3.1.2 If the dataset is a personal dataset from another investigator, attach a letter from the original principal investigator giving you access to the data and describing if and how the data will be or have been de-identified.

2.3.1.3 If available, provide the URL for the database website.

2.4 Upon receipt of the application, a Research Compliance Specialist will verify completeness of the application and, if necessary, request missing or incomplete elements.

2.5 Once the application is complete, the Research Compliance Specialist will use FORM Exemption Eligibility Checklist and GUIDANCE: Issues When Conducting Exempt Review to determine whether the research meets criteria for exempt status and evaluate the application using the criteria listed in 1.2.3 of this policy for protection of human subjects in exempt research. The Specialist will indicate his/her preliminary decision on the FORM and send the application and the form to the Director of Research Compliance.

2.6 The Director of Research Compliance will make the final decision and either signs the Face Sheet of the application indicating approval or deny the application for exempt status and direct that the application receive expedited or full board review. (The IRB Chairs have designated the DRC to perform this function.)

2.7 On receipt of the Director of Research Compliance’s decision, the Research Compliance Specialist will send the appropriate notification letter to the investigator, referencing the category(ies) under which an exemption is granted if that is the case. If the study is approved, a copy of the signed Face Sheet and, if used, the stamped consent document or approved information sheet will be sent also.

2.8 Every effort will be made to notify the investigator of the decision within ten working days of receipt of the application.

2.9 Investigators have 60 days in which to respond to the reviewer’s requests for more information, revision, or resubmission. If there is no response within 60 days, the application will be administratively withdrawn.

2.10 If any circumstances arise that may or do change the study’s suitability for exempt status, the investigator must report this immediately to the Director of Research Compliance.
Compliance and submit a new application requesting either expedited or full board review.

2.11 If the study is completed in less than one year, the investigator closes the study using FORM: IRB Renewal Application. If the study lasts longer than one year, the investigator must an application for IRB continuing renewal on that form.

2.12 In the event that a reportable event occurs in a study approved as exempt, POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events will be followed.

2.13 If monitoring for cause becomes necessary, this activity will be conducted according to POLICY: Monitoring of Approved Research for Cause: Suspension and Termination and/or POLICY: Allegations and Findings of Noncompliance.

3.0 REFERENCES

3.1 45 CFR 46.101(b)

3.2 45 CFR §46.46.301(a)

3.3 45 CFR §46.46.401 (b) (1-6)

3.4 21 CFR 56.104(c-d)

3.5 OHRP Guidance at 45 CFR 46.101(b)(5): Exemption for Research and Demonstration Projects on Public Benefit and Service Programs


3.7 38 CFR 16.102(b)

4.0 RELATED SECTIONS

4.1 FORM: Human Research Determination (DHHS and FDA)

4.2 FORM: Exemption Eligibility Checklist

4.3 GUIDANCE: IRB Application Guide

4.4 POLICY: Research Using Publicly Available Datasets

4.5 GUIDANCE: General Responsibilities of Investigators
4.6 POLICY: Reportable Events: Protocol Deviations, Unanticipated Problems, and Adverse Events

4.7 POLICY: Monitoring of Approved Research for Cause: Suspension and Termination

4.8 POLICY: Allegations and Findings of Noncompliance.