Samford University
Institutional Review Board

Request for Exempt Review
Waiver of Informed Consent

Name of Principal Investigator(s):

Project Title:

Please complete this form if you are requesting Exempt Review. This type of review allows for waiver of signed informed consent. **NOTE: Only the IRB may determine which activities qualify for Exempt Review.** This form should be sent by the faculty member/advisor, with the application, to IRB@samford.edu.

Involvement of human subject research in the following categories may qualify for Exempt Determination. Only the IRB may determine which activities qualify for an Exempt Review. From the 8 categories presented below, check "Yes" for the category you believe describes your proposed research and "No" for all others. If you cannot check ñYesòfor any of these categories, your research may not qualify for Exemption, indicating you will require IRB Review.

Exemption Categories

◯ Yes ◯ No 1. Research, **conducted in established or commonly accepted educational settings,** that specifically involves **normal educational practices** that are **not likely to adversely impact students' opportunity** to learn required educational content **or the assessment of educators** who provide instruction.

2. **Research that only includes** interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **if at least one of the following criteria is met**:

◯ Yes ◯ No i. The information obtained is recorded by the investigator in such a manner that **the identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;

◯ Yes ◯ No ii. Any **disclosure of the human subjects' responses** outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

◯ Yes ◯ No iii. The information obtained is recorded by the investigator in such a manner that the identity of **the human subjects can readily be ascertained**, directly or through identifiers linked to the subjects, **and an IRB conducts a limited IRB review** to make the determination required by §46.111(a)(7).

Application of Exemption 2(i) and 2(ii) is limited for research involving children. Exemption 2(iii) may not be applied to research involving children.

3. **Research involving benign behavioral interventions in conjunction with the collection of information from an adult subjects through verbal or written responses** or audiovisual recording **if the subject prospectively agrees** to the intervention and information collection and **at least one of the following criteria is met**:

Yes No i. The information obtained is recorded by the investigator in such a manner that **the identity of the human subjects cannot readily be ascertained**, directly or through identifiers linked to the subjects;

Yes No ii. Any **disclosure of the human subjects' responses** outside the research **would not reasonably place the subjects at risk** of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation;

Yes No iii. The information obtained is recorded by the investigator in such a manner that **the identity of the human subjects can readily be ascertained**, directly or through identifiers linked to the subjects, and **an IRB conducts a limited IRB review** to make the determination required by §46.111(a)(7).

4. **Secondary research for which consent is not required**: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

Yes No i. The identifiable private information or identifiable biospecimens are **publicly available**;

Yes No ii. Information, which may include information about biospecimens, is **recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained** directly or through identifiers linked to the subjects, the **investigator does not contact the subjects, and the investigator will not re-identify subjects**;

Yes No iii. The research involves **only information collection and analysis** involving the investigator's **use of identifiable health information** when that use is **regulated under 45 CFR parts 160 and 164, subparts A and E [HIPAA]**; or

Yes No iv. The research **is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities,...**

Yes No 5. Research and demonstration projects that are **conducted or supported by a Federal department or agency**,... and that are designed to study, evaluate, or otherwise examine: Public benefit or service programs; or procedures for obtaining benefits or services under those programs; or possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs...

Yes No 6. Taste and food quality evaluation and consumer acceptance studies,
1. if wholesome foods without additives are consumed, or
2. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Samford does not implement federal exemptions 7 and 8.