SAMFORD UNIVERSITY
INSTITUTIONAL REVIEW BOARD

Request for Exempt Review
Waiver of Informed Consent

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.

Name of Principal Investigator(s):

Project Title:

Check all descriptors that best apply to this proposed research project. To be eligible for Exempt Review, ONLY boxes in the LEFT column may be checked. If any boxes in the right column are checked, an Expedited Review may be necessary, including a separate informed consent form.

DATA COLLECTION METHOD

- ☐ Surveys/Questionnaires
- ☐ Educational tests (cognitive, diagnostic, aptitude)
- ☐ Public archival data

PARTICIPANT INFORMATION

- ☐ Individuals 19 years and older
- ☐ General population

FACTORS OF PARTICIPATION

- ☐ Voluntary
- ☐ Confidentiality
- ☐ Anonymity

DATA COLLECTION METHOD

- ☐ Private records/files
- ☐ Interview/Observation
- ☐ Audio or video recording
- ☐ Physical procedure (body measurements, venipuncture, etc.)

PARTICIPANT INFORMATION

- ☐ Individuals younger than 18 years
- ☐ Vulnerable population (mentally or physically challenged; prisoners; elderly; pregnant women; fetuses; non-English speakers)

FACTORS OF PARTICIPATION

- ☐ Involuntary
- ☐ Social, physical, or psychological risk
- ☐ Potential for more than minimal risk*

***Minimal Risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life during the performance of routine physical or psychological examinations or tests.

CATEGORIES OF EXEMPTION

Involvement of human subject research in the following categories may qualify for Exempt Review and may not require signed informed consent. Only the IRB may determine which activities qualify for an Exempt Review. From the six categories presented below, check "Yes" for the categories you believe describe your proposed research and "No" for all others. If none of the categories apply, your research may not qualify for Exempt Review, indicating you may need to have signed informed consent from participants.

INFORMED CONSENT: If your research project **will not** qualify for Exempt Review, based on one or more of the following categories, you must develop an **Informed Consent Form** (see IRB website) and attach it as a separate file with your completed application. Contact the IRB Chair if you have questions.

YOU MUST CHECK "YES" OR "NO" FOR EACH OF THE FOLLOWING:

☐ Yes ☐ No 1. EVALUATION/COMPARISON OF INSTRUCTIONAL STRATEGIES/CURRICULA

Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. The exemption category cannot be used for FDA regulated research.
If "Yes," briefly describe the educational setting in which the research will be conducted and the type of normal educational practices involved.

☐ Yes ☐ No 2. EDUCATIONAL TESTS, SURVEYS, INTERVIEWS OR OBSERVATIONS

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation. This exemption category cannot be used for FDA regulated research.

NOTE: When the research involves children as subjects, this exemption must be limited to educational tests (cognitive, diagnostic, aptitude, achievement) and observation of public behavior when the investigators do not participate in the activities being observed. Research that uses survey procedures, interview procedures, or observation of public behavior when the investigators participate in the activities being observed cannot be granted an exemption.

☐ Yes ☐ No 3. PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under the previous paragraph if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter. This exemption category cannot be used for FDA regulated research.

☐ Yes ☐ No 4. COLLECTION OR STUDY OF EXISTING DATA

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. This exemption category cannot be used for FDA regulated research.

NOTE: To qualify for this exemption, the data, documents, records, or specimens must be in existence before the project begins. Additionally, under this exemption, an investigator (with proper authorization) may inspect identifiable records, but may only record information in a non-identifiable manner.

☐ Yes ☐ No 5. RESEARCH & DEMONSTRATION PROJECTS

Research and demonstration projects that are conducted by or subject to approval of federal departmental or agency heads (such as the Secretary of HHS), and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those program; (iii) possible changes in or alternatives to those programs or procedures; (iv) possible changes in methods or levels of payment for benefits or services under those programs. This exemption category cannot be used for FDA regulated research.

Proof of approval by department/agency head is attached. ☐ Yes ☐ No

NOTE: This exception applies to federally funded projects only and requires authorization or concurrence from the funding agency. Additionally, specific criteria must be satisfied to invoke this exception. Also, this exemption category does not apply if there is a statutory requirement that this project be reviewed by an IRB or if the research involves physical invasion or intrusion upon the privacy of subjects.

☐ Yes ☐ No 6. FOOD QUALITY EVALUATION & CONSUMER ACCEPTANCE STUDIES

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome food, without additives, is consumed; or (ii) 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 EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.