Southwest Tennessee Community College Institutional Review Board (STC IRB)

Checklist to Determine If Research May Be Declared Exempt from IRB Review

Principal Investigator:

INFORMATION ONLY

Project Title:

If the ONLY involvement of human subjects will be in one or more of the following categories AND all the answers in one or more categories is 'True', the research may be eligible for exemption. However, the research must be declared exempt by the STCC IRB on the basis of the following answers, and responses on the IRB submission form.

Checklist Statements	True	Not True	Regulation
[ ] Category 1 **For Educational Settings:**			
1 The research will only be conducted in established or commonly-accepted educational settings including but not limited to schools and colleges. (May include other sites where educational activities regularly occur.)	[ ]	[ ]	45 CFR 46.104
2 The research will involve only normal educational 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 that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.	[ ]	[ ]	45 CFR 46.104
3 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	[ ]	[ ]	45 CFR 46.303
4 The research is not subject to FDA regulations.	[ ]	[ ]	
[ ] Category 2 **For Educational Tests, Surveys, Interviews, Public Behavior Observation:**			
5 The research will involve only the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior. (including visual or auditory recording).	[ ]	[ ]	45 CFR 46.104
Address statement 6 only if the research will involve children as participants. If children will NOT participate, check N/A and continue with statement 7. 6 The procedures will be limited to the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observation of public behavior where the investigator will NOT participate in the activities being observed.	[ ] **[ ] N/A**	[ ]	45 CFR 46.401
7 The information obtained from educational tests, survey procedures, interview procedures or observation of public behavior will be recorded in such a manner that human subjects CANNOT be identified, directly or through identifiers linked to the subjects.	[ ]	[ ]	45 CFR 46.104
8 Any disclosure of the human subjects' responses outside the research could NOT reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.	[ ]	[ ]	45 CFR 46.104
9 The research will <u>not</u> involve individuals as participants who are known to be prisoners.	[ ]	[ ]	45 CFR 46.303
10 The research is not subject to FDA regulations.	[ ]	[ ]	

Checklist Statements	True	Not True	Regulation
[ ] Category 3 For benign behavioral interventions in conjunction with the collection of information from an adult subject:			
11 Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection	[ ]	[ ]	45 CFR 46.104
12 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	[ ]	[ ]	45 CFR 46.104
13 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	[ ]	[ ]	45 CFR 46.104
14 The research will not involve individuals as participants who are known to be prisoners.	[ ]	[ ]	45 CFR 46.303
15 The research is not subject to FDA regulations.	[ ]	[ ]	
[ ] Category 4 **Secondary Research:**			
16 Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens.	[ ]	[ ]	45 CFR 46.104
17 The research will not involve individuals as participants who are known to be prisoners.	[ ]	[ ]	45 CFR 46.303
18 The research is not subject to FDA regulations.	[ ]	[ ]	
19 The identifiable private information or identifiable biospecimens are publicly available.	[ ]	[ ]	45 CFR 46.104
20 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.	[ ]	[ ]	45 CFR 46.104
21 The research involves only information collection and analysis involving the investigator's use of identifiable health information for the purposes of "health care operations" or "research" or for "public health activities and purposes".	[ ]	[ ]	45 CFR 160 45 CFR 164.501 45 CFR 164.512
[ ] Category 5 **Secondary Research Requiring Broad Consent**			
22 Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use.	[ ]	[ ]	45 CFR 46.104
23 Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained.	[ ]	[ ]	45 CFR 46.104
24 Documentation of informed consent or waiver of documentation of consent was obtained.	[ ]	[ ]	45 CFR 46.104

Checklist Statements	True	Not True	Regulation
[ ] Category 6 **Research and demonstration projects that are conducted or supported by a Federal department or agency:**			
25 Designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs,	[ ]	[ ]	45 CFR 46.104

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			
26 Projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision.	[ ]	[ ]	45 CFR 46.104
[ ] Category 7 **For Taste and Food Quality and Consumer Acceptance Studies:**			
27 The research involves only a taste and food quality evaluation or a food consumer acceptance study in which (i) wholesome foods without additives will be consumed **OR** (ii) food will be consumed that contains a food ingredient, agricultural chemical or environmental contaminant that is at or below the level found to be safe by the Food and Drug Administration or is approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.	[ ]	[ ]	45 CFR 46.104
28 The research will not involve individuals as participants who are known to be prisoners.	[ ]	[ ]	45 CFR 46.303
[ ] Emergency Use of an Unapproved Test Article (i.e., a drug, device or biologic that is not FDA-approved)			
29 ***The activity involves emergency use of an investigational drug, device or biologic. Such an activity is not exempt from IRB review. However, this emergency use may occur prior to IRB review and approval (see Category A or B in the Emergency Use Policy for details.) Note that such an emergency use must be reported to the STCC IRB within five business days.***	[ ]	[ ]	21 CFR 56.104
30 The activity does not meet the DHHS definition of "research."	[ ]	[ ]	45 CFR 46.102
[ ] Criteria that must be met for the research to be determined to be consistent with STCC ethical standards			
31 The research holds out no more than minimal risk to subjects.	[ ]	[ ]	
32 Selection of subjects is equitable.	[ ]	[ ]	
33 If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data.	[ ]	[ ]	
34 If there are interactions with subjects: There will be a consent process (and maybe some type of documentation) that will disclose such information as: ♦ That the activities involve research. ♦ The procedures to be performed. ♦ That participation is voluntary. ♦ Name and contact information for the investigator.	[ ]	[ ]	
35 There are adequate provisions to maintain the privacy interests of subjects.	[ ]	[ ]	

FOR THE IRB REVIEWER ONLY:

Is the activity exempt? YES [ ] NO [ ]

Does the research meet the **STCC** standards of ethical conduct? YES [ ] NO [ ]

Which exemption category or categories apply to the activity? _____

Signature of IRB Reviewer:

_____

Printed Name: Date: