**TU IRB EXEMPT CHECKLIST FOR INVESTIGATORS**

**Principle Investigator :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Faculty Mentor** (If PI is a TU student): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Protocol Title :\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

1. **IS THE ACTIVITY “RESEARCH”?**

Is the activity a systematic investigation, including research development and testing? **YES**[ ]   **NO**[ ]

Is the activity designed or intended to develop or contribute to generalizable knowledge? **YES**[ ]   **NO**[ ]

**If you answered NO to one or both of questions, the activity is NOT “research”.**

**\*YOU CAN STOP THIS CHECKLIST, THIS CANNOT BE “HUMAN SUBJECTS RESEARCH”.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **DOES THE ACTIVITY INVOLVE HUMAN SUBJECTS?**

Is the information being collected for the study personally about the individual **YES**[ ]   **NO**[ ]

they are collecting it from?

Does the investigator conducting research: (i) Obtain information or biospecimens **YES**[ ]   **NO**[ ]

through intervention or interaction with the individual, and use, study or analyze

the information or biospecimens?; or (ii) Obtain, use, study, analyze, or generate

identifiable private information or identifiable biospecimens?

**If you answered NO to one or both of questions, the activity is NOT “human subjects”.**

**\*YOU CAN STOP THIS CHECKLIST, THIS CANNOT BE “HUMAN SUBJECTS RESEARCH”.**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**If you answered YES to BOTH questions in both sections above, the activity is, “HUMAN SUBJECTS RESEARCH”. (CONTINUE WITH THIS EXEMPT CHECKLIST)**

1. **DO THE ACTIVITIES INVOLVE NO RISK OR NO MORE THAN YES**[ ]   **NO**[ ]

**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 of the general population or

during the performance of routine physical or psychological examinations

or tests.

1. **IS THE SELECTION OF SUBJECTS EQUITABLE? YES**[ ]   **NO**[ ]

**\***Fairly sharing benefits and burdens of research participation

(Possibility of harm, inconveniences)

1. **ARE THERE ADEQUATE PROVISIONS TO PROTECT THE YES**[ ]   **NO**[ ]

**CONFIDENTIALITY OF DATA?**

1. **ARE THERE ADEQUATE PROVISIONS TO PROTECT SUBJECTS’ PRIVACY? YES**[ ]   **NO**[ ]
2. **IF THERE IS INTERACTION WITH SUBJECTS, THE CONSENT PROCESS YES**[ ]   **NO**[ ]  **N/A**[ ]

**WILL DISCLOSE (as appropriate):**

* A statement that the activities involve research;
* The purpose of the research;
* A description of the procedures to be performed and duration;
* A statement that the participation is voluntary;
* A statement about risks and confidentiality/privacy; and
* The name and contact information for the PI and TU IRB.
1. **IS AN EXEMPTION PROHIBITED?**

Are prisoners involved in the project? **YES**[ ]   **NO**[ ]

Are minors involved in the project? (Exempt **YES**[ ]   **NO**[ ]

Category (d) 2 does not apply to research involving minors

unless research involves observations of public behavior and

the researcher does not participate in activities being observed).

Are you specifically recruiting Native Americans or recruiting or **YES**[ ]   **NO**[ ]

Conducting research on tribal lands?

Does the research involve an investigational new drug or medical **YES**[ ]   **NO**[ ]

device?

Is there deception or is the information about the project not fully **YES**[ ]   **NO**[ ]

explained to participants (Without at least a broad statement that

not all the information would be fully explained to them until after their

participation is over)?

\*Exemption is not applicable unless the subject authorizes the deception.

(For the purpose of this provision, authorized deception would be prospective

agreement by the subject to participate in research where the subject is

informed that they will be unaware of or misled regarding the nature or

purposes of the research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **EXEMPT DETERMINATIONS (**The **only** involvement of human subjects will be in one or more of the following categories.) **CHECK ALL THAT APPLY:**

[ ]  **Exempt Category** **(§ ll.104(d)(1))**

Research conducted in established/commonly accepted educational settings that specifically involves normal educational practices, so long as the research is not likely to adversely affect students’ opportunity to learn required educational content or the assessment of educators who provide instruction. Includes most research on regular and special education instructional strategies, and research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Exempt Category** **(§ll.104(d)(2))**

Research That Includes Only 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 Three Criteria Is Met:

**CHECK ALL THAT APPLY:**

[ ]  **(i)** The information obtained is recorded by the investigator in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects;

[ ]  **(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**

[ ]  **(iii)** The information obtained is recorded by the investigator in such a manner that the identity of 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 § ll.111(a)(7) (which relate to there being adequate provisions for protecting privacy and maintaining confidentiality).

\*\*IF CHECKED, A LIMITED REVIEW IS REQUIRED by the TU IRB Chair/Chair designate

[ ]  **Exempt Category** **(§ll.104(d)(3)(i)**

Benign Behavioral Interventions Research **§ll.104(d)(3)(i)**

**CHECK ALL THAT APPLY:**

[ ]  (A) Information obtained is recorded by the investigator in such a manner that the identity of the subjects cannot readily be ascertained directly or through identifiers linked to the subjects; **or**

[ ]  (B) Any disclosure of responses outside the research would not reasonably place subjects at risk of criminal/civil liability or damaging to the subjects’ financial standing, employability, educational advancement, or reputation; **or**

[ ]  (C) Information obtained is recorded by the investigator in such a manner that the identity of the subjects can readily be ascertained, directly or through identifiers linked to the subject, **and** **an IRB conducts a limited IRB review** to make the determination required by § ll.111(a)(7).

\*\*IF CHECKED, A LIMITED REVIEW IS REQUIRED by the TU IRB Chair/Chair designate

**§ll.104 (d)(3)(ii)** the term ‘‘**benign interventions**,’’ the word ‘‘**behavioral**’’ has been inserted to modify the type of intervention which may be included. The intent of this change is to exclude the use of medical interventions (including medical tests, procedures and devices)

For the purpose of this provision, the exemption describes **benign behavioral interventions** as brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

**§ll.104 (d)(3)(iii) Deception:** If the research involves deceiving subjects about the nature/purposes of the research, this exemption would not be applicable unless the subject authorizes the deception. \*For the purpose of this provision, authorized deception would be prospective agreement by the subject to participate in research where the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Exempt Category** **(§ ll.104(d)(4))**

Secondary Research uses of identifiable private information or identifiable bio-specimens when consent is not required, if at least **one** of the following criteria is met:

**CHECK ALL THAT APPLY:**

[ ]  (i) The identifiable private information or identifiable bio-specimens are publicly available; **or**

[ ]  (ii) The information is recorded by the investigator in such a way that the identity of subjects cannot readily be ascertained, and the investigator does not try to contact subjects or re-identify subjects; **or**

[ ]  (iii) The secondary research activity is regulated under HIPAA; **or**

[ ]  (iv)The secondary research activity is conducted by or on behalf of a federal entity and involves the use of federally generated non-research information provided that the original collection was subject to specific federal privacy protections and continues to be protected.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Exempt Category** **(§ ll.104(d)(5))**

Research and Demonstration Projects Conducted or Supported by a Federal Department or Agency

­­­­­­­­­­­­­­­­­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Exempt Category** **(§ ll.104(d)(6))**

Taste and Food Quality Evaluation and Consumer Acceptance Studies

**CHECK ALL THAT APPLY:**

[ ]  (i) If wholesome foods without additives are 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ]  **Exempt Category** **(§ll.104(d)(7)**

Exemption for the **Storage or Maintenance** for Secondary Use of Identifiable Private Information or Identifiable Bio-specimens for Which Broad Consent is Required:

Storage or maintenance of identifiable private information or identifiable bio-specimens for potential secondary research use if an **IRB conducts a limited IRB review** and makes the determinations required by §ll.111(a)(8).

\*\*IF CHECKED, A LIMITED REVIEW IS REQUIRED by the TU IRB Chair/Chair designate

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

[ ]  **Exempt Category** **(§ll.104(d)(8)**

Exemption for Research Involving the **Use** of Identifiable Private Information or Identifiable Bio-specimens for Which Broad Consent is Required:

Research involving the use of identifiable private information or identifiable bio-specimens for secondary research use, if the following criteria are met:

 (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable bio-specimens was obtained in accordance with §ll.116(a)(1) through (4), (a)(6), and (d);(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §ll.117;

(iii) **An IRB conducts a limited IRB review** and makes the determination required by §ll.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; **and**

(iv) The investigator does not include returning individual research results to subjects as

part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

\*\*IF CHECKED, A LIMITED REVIEW IS REQUIRED by the TU IRB Chair/Chair designate

**I have made a preliminary determination that my proposed research study, as described, qualifies for Exemption and that my protocol meets the ethical standard for research conducted at The University of Tulsa. Specifically, the three key ethical principles of the Belmont Report: Respect for Persons, Beneficence, and Justice are adhered to.**

**Signature of Principle Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of Faculty Mentor (If PI is a TU student): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_**