**APPENDIX 1**

**OKLAHOMA CHRISTIAN UNIVERSITY**

**APPLICATION FOR EXEMPT RESEARCH**

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| Responsible Project Investigator (RPI) The RPI must be a member of OC faculty or staff who will serve as the project supervisor and be held accountable for all aspects of the project. Students cannot be listed as RPIs. | | | | | | |
| **First Name:** | | **Middle Initial:** | | | | **Last Name:** |
| **Telephone:** | | **Fax Number:** | | | | **E-mail:** |
| **Office Address:** | | | | | | |
| **City:** | **State:** | | | **Zip:** | | |
| **Department:** | | | **College:** | | | |
| **Complete Title of Research Project:** | | | | | **Code Name (One word):** | |
| Investigators Individuals who are directly responsible for any of the following: the project’s design, implementation, consent process, data collection, and data analysis. If more investigators exist than lines provided, please attach a separate list. | | | | | | |
| **First Name:** | **Middle Initial:** | | | **Last Name:** | | |
| **Telephone:** | **Fax Number:** | | | **Email:** | | |
| **Office Address:** | | | | | | |
| **City:** | **State:** | | | **Zip:** | | |
| **Affiliation:** \_\_Faculty \_\_Graduate Student \_\_ Undergraduate Student  \_\_Staff \_\_Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **First Name:** | **Middle Initial:** | | | **Last Name:** | | |
| **Telephone:** | **Fax Number:** | | | **Email:** | | |
| **Office Address:** | | | | | | |
| **City:** | **State:** | | | **Zip:** | | |
| **Affiliation:** \_\_Faculty \_\_Graduate Student \_\_ Undergraduate Student  \_\_Staff \_\_Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| List additional investigators on attachment and check here: \_\_ | | | | | | |

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| Type of Research |
| **1. This study is being conducted as part of (check all that apply):**  \_ Faculty Research \_ Non-Thesis Graduate Student Research  \_ Doctoral Dissertation \_ Honors or Individual Problems Project  \_ Master’s Thesis \_ Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| Funding |
| **2. Is this research project externally funded or contracted for by an agency or institution which is independent of the university? Remember, if the project receives ANY federal support, then the project MUST be reviewed by the University’s Institutional Review Board (IRB).**  \_\_\_Yes **(If yes, indicate the granting or contracting agency and provide identifying information.)**  \_\_\_No  **Agency Name:**  **Mailing Address:**  **Point of Contact:**  **Telephone:** |
| Research Dates |
| **3a. Date you wish to start research (MM/DD/YY)** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_  **3b. Date you wish to end research (MM/DD/YY)** \_\_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ |
| Human Subjects Review |
| **4. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research participants?**  \_\_\_Yes  \_\_\_No  **4a. If yes, is OC conducting the primary review?**  \_\_Yes  \_\_No (If no go to 4b)  **4b. Who is conducting the primary review?** |
|  |
| **5. Attach a description of the following items:**  \_\_Description of the Proposed Study  \_\_Research Protocol  \_\_References  \_\_Any Letters, Flyers, Questionnaires, etc. which will be distributed to the study subjects or other study participants  \_\_If the research is part of a research proposal submitted for federal, state or external funding, submit a copy of the FULL proposal.  Note: The description should be in sufficient detail to allow the Institutional Review Board to determine if the study can be classified as EXEMPT under Federal Regulations 45CFR§46.104 Exempt research. |
| **Exemption categories** |
| 1. **Identify which of the 8 federal exemption categories below applies to your research proposal and explain**   **why the proposed research meets the category. Federal law 45 CFR §46.104 identifies the following EXEMPT categories. Check all that apply and provide comments.**  SPECIAL NOTE: The exemptions at 45 CFR §46.104 do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR §46.104, for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. |
| \_\_\_\_(6.1) 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. This 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.  **Comments:** |
| \_\_\_\_(6.2) 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:  (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; (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 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).  **Comments:** |
| \_\_\_\_(6.3) (i) 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 and at least one of the following criteria is met:  (A) 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; (B) 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 (C) 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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)).  (ii) For the purpose of this provision, benign behavioral interventions are 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. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.  (iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.  **Comments:** |
| \_\_\_\_(6.4) 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:  (i) The identifiable private information or identifiable biospecimens are publicly available; (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; (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, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or (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, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.  **Comments:** |
| \_\_\_ (6.5) Does not apply to the university setting; do not use it |
| \_\_\_\_(6.6) Taste and food quality evaluation and consumer acceptance studies:  (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.  **Comments:** |
| \_\_\_\_(6.7)  Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by [§46.111(a)(8)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(8)).  **Comments:** |
| \_\_\_\_(6.8)  Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens 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 biospecimens was obtained in accordance with [§46.116(a)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(1)) through [(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(4)), [(a)(6)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(6)), and [(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(d)); (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with [§46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117); (iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(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)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.104(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.  **Comments:** |
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| **PLEASE NOTE:**   * 1. You may begin research when the Institutional Review Board gives notice of its approval.   2. You MUST inform the Institutional Review Board of ANY changes in method or procedure that may conceivably alter the exempt status of the project. |
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| **Responsible Project Investigator** (Must be original signature)  **Date** |