**INSTRUCTIONS**

In order to qualify for exemption, **all** human subject research activities and procedures in the study must:

* Fall into one or more of the exemption categories
* NOT involve prisoners\* or their existing data and/or specimens UNLESS the research is aimed at involving a broader subject population that only incidentally includes prisoners.
* NOT be regulated by the FDA (with the exception of category #6)
* NOT be submitted to the FDA for marketing approval
* NOT intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit

\***Prisoner** means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing. [45 CFR 46.303(c)]

Checklist of Submission Requirements for Exempt Review:

Exempt Application Form

Protocol or Research Plan

If consent will be obtained, Consent/Assent/Parent Permission forms, letters, or scripts for verbal consent

Recruitment materials (including, but not limited to, flyers, emails, and social media posts)

Any study materials that will be given to or seen by participants (questionnaires, surveys, web pages, instructions, interview questions, etc.)

All “key personnel” must have completed required Baylor IRB CITI training.

**Use lay language and spell out acronyms. Do not cut and paste from or refer the reviewer to a grant or abstract.**

**Study activities may not be implemented until the investigator receives final written notification from OVPR that the exemption has been granted.**

**You may reference the OHRP Decision Charts to help you determine whether your research may be exempt:** [**http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html**](http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html)

**If you have any questions, please contact of Research Compliance at:**

[**IRB@Baylor.edu**](mailto:IRB@Baylor.edu)

**T: 254-710-3708**

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| **STUDY TITLE** |  |

**PRINCIPAL INVESTIGATOR (must be Baylor University faculty, staff, or student)**

|  |  |  |  |
| --- | --- | --- | --- |
| **1.** | Name: | | Degree(s): |
| Department: | | Phone: |
| Campus Address: | | Email: |
| Faculty  Staff  Student | | |
|  | | | |
| **2.** | **If student:** | | |
| Undergraduate student | Graduate or Professional Student  (degree program): | |
| Faculty Advisor: | | |
| Email: | | |
| Phone: | | |

**RESEARCH PERSONNEL (other than the PI)**

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| **INSTRUCTIONS:** All Baylor and non-Baylor “**key personnel**” must be identified and listed. ***Key personnel*** are defined as individuals who participate in the design, conduct (including data analysis), or reporting of human subjects research. At a minimum, include individuals who recruit participants, obtain consent, interact with participants, or who collect and/or analyze identifiable study data. If the individual for an anticipated position is unknown at this time, a “Change in IRB-Approved Research” must be submitted and approved prior to that individual becoming involved in the research. ***\*Attach a separate sheet if you need more space for additional personnel.*** | | | |
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| **3.** | **Name & Degree(s)** | **Role** | **Study Responsibilities** |
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| BU  Other Institution: | | |
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| BU  Other Institution: | | |
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| BU  Other Institution: | | |

**FUNDING**

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| **4.** | Indicate the type of funding for this research: | |
|  | No external or internal funding. |
|  | Internal funding.  Approved  Pending  List source(s): |
|  | External funding.  Approved  Pending  List source(s) (no initials or acronyms):  \*For Department of Defense research, submit **SUPPLEMENT: DEPARTMENT OF DEFENSE (F-06)\***  Is Baylor the primary awardee?  Yes  No. If no, identify primary awardee:  Has this proposal been submitted to the BU Office of Sponsored Programs?  Yes  No |
|  | Intend to submit for funding. From whom?  Date of submission: |

**STUDY LOCATION**

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| **5.** | Will the research be conducted at a physical location in the U.S. external to Baylor University? | | | Yes  No |
| **If yes,** provide the following: ***\*Attach a separate sheet if more than 2 external sites.*** | | | |
| **Name of Site** | **City/State** | **Does this site have its own IRB?** | |
|  |  | Yes – must attach IRB approval or waiver  No – must attach letter of support  **Note**: IRB or support letters must be dated and should be on the site’s letterhead | |
|  |  | Yes – must attach IRB approval or waiver  No – must attach letter of support  **Note**: IRB or support letters must be dated and on the site’s letterhead | |
|  | | | | |
| **6**. | Will any part of this research be conducted outside of the United States? | | | Yes  No |
| **If yes,** complete **SUPPLEMENT: INTERNATIONAL RESEARCH (F-03)** | | | |

**EXEMPT CATEGORIES**

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| There are **eight (8)** exemption categories. **ALL** research activities and/or procedures involving human subjects must fall within one or more of the categories to be exempt.  OVPR is ultimately responsible for deciding if research qualifies for exemption; however, investigators are asked to make an initial determination of the appropriate exemption category. **Select the appropriate category or categories that apply to the research activities/procedures and answer the questions that are included within that category.** | |
|  | **Category 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.   * Explain why the setting is considered an “established or commonly accepted education setting”: * Explain why this research involves “normal educational practices”: * Is this research likely to adversely impact students’ opportunity to learn required educational content?  Yes\*  No \*If YES, this exemption does not apply. * Is this research likely to adversely impact the assessment of educators who provide instruction?  Yes\*  No \*If YES, this exemption does not apply. |
|  | |
|  | **Category 2**  Research that only includes interactions involving the use of 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 **(please check one):**  (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; **OR**  (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 45 CFR 46.111(a)(7).   * Indicate which research activities are taking place:   educational tests (cognitive, diagnostic, aptitude, achievement)  survey procedures  interview procedures  observation of public behavior   * Does this research involve children?  Yes\*  No   \*If yes, exemption under category 2(i) & (ii) is limited to educational tests and the observation of public behavior where the investigator(s) will NOT participate in the activities being observed. Category 2(iii) may not be applied to research with children. |
|  | |
|  | **Category 3**  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 **(please check one)**:  (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; **OR**  (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 45 CFR 46.111(a)(7).  \*For the purpose of this exemption, **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.  Will this research involve deceiving the subjects regarding the nature or purposes of the research? (This includes “incomplete disclosure.”)  Yes\*  No  \*If yes, the subject **MUST** authorize the deception through 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. This information is normally contained in the consent form.  **NOTE**: Research involving children is not eligible for this exemption. |
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|  | **Category 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 **(please check one)**:  (i) The identifiable private information or identifiable biospecimens are publicly available (*Publicly available* means that the general public could obtain the data or specimens. If access is limited to research, data/specimens are not considered publicly available.); **OR**  (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; **OR**  (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 Privacy Rule), 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. |
|  | |
|  | **Category 5**  Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.  (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website 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. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.   * Provide the web address where this research project is listed. If no website, provide information on how the federal department/agency publishes this information: |
|  | |
|  | **Category 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.   * Does this research involve a taste and food quality evaluation and/or consumer acceptance studies?  Yes  No * Indicate the activity taking place:   Only wholesome foods without additives will be consumed.  The food consumed will contain a food ingredient that is at or below the level found to be safe and is for a use found to be safe.  A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level found to be safe by the FDA.  A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the EPA.  A food will be consumed that contains an agricultural chemical or environmental contaminant that is at or below the level approved by the Food Safety and Inspection Service of the Department of Agriculture. |
|  | **Category 7**  **NOT IN USE AT BAYLOR**  Contact the Office of Research Compliance for more information. |
|  | **Category 8**  **NOT IN USE AT BAYLOR**  Contact the Office of Research Compliance for more information. |

**RECRUITMENT**

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| **7.** | Identify the age group to include all subjects: | | | |
| Proposed number of subjects: | | | |
|  | | | | |
| **8.** | Will subjects from the following “vulnerable” categories be targeted for recruitment? (Check all that apply.) | | | |
|  | Minors (as defined by the location where the research will occur) | | |
|  | Non-English speaking. List the language(s): | | |
|  | Adults who are unable to consent for themselves | | |
|  | Other individuals that may be susceptible to undue influence/coercion. Describe: | | |
|  | | | | |
| **9.** | How do you plan to recruit subjects?  **NOTICE**:   * All recruitment materials must be submitted for IRB review prior to use. * Materials must be in their final format, including all images, colors, etc. (i.e., how they will be seen by potential subjects). * If eligibility screening over the phone will take place, a script must be submitted. * Placeholders for contact information that is unknown at the time of submission are allowable. | | | |
|  | Print Materials (flyer, brochure, letter, newspaper ad, etc.) |  | From a database of individuals who have given prior permission to be contacted for research. |
|  | Online/Mobile/Social Media (website, web posting, Facebook, Twitter, etc.) |  | Personal Contact |
|  | Email or text |  | Referrals, from whom? |
|  | Radio or TV ad\* |  | Other: |
| \*For radio and TV ads, scripts should be submitted with the recording. To avoid unnecessary production costs, pre-approval of scripts is highly recommended. | | | |

**CONSENT**

**Note**: Regulations do not require that consent be obtained for exempt studies. However, the ethical principle of Respect for Persons requires that individuals should be provided with the opportunity to choose what they will or won’t do. Additionally, the voluntariness of participation must be preserved. Therefore, Baylor IRB encourages obtaining some type of indication of consent (verbal, electronic, or written) when it is practicable.

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| **10.** | Check all that apply to your research: | | | | |
|  | Written consent from adult subjects  (or LAR\*) |  | Verbal or Online consent from adult subjects | |
|  | Written permission from parents/guardians of minor subjects |  | Verbal or Online permission from parents/guardians of minor subjects | |
|  | Written assent from minor subjects |  | Verbal or Online assent from minor subjects | |
|  | Consent/Assent will not be obtained because it is impracticable.  Explain: |  | Consent/Assent will not be obtained for reasons other than impracticability.  Explain: | |
| \*LAR = Legally Authorized Representative. This is an individual that consents on behalf of another adult who does not have the legal capacity to consent to research. | | | | |
|  | | | | | |
| **11.** | Will the research involve incomplete disclosure/deception to subjects?  (i.e., some features of the research will not be revealed to subjects until after the research is concluded). | | | | Yes  No |
| **If yes**, answer the following:  1. Explain how the incomplete disclosure is truly necessary to accomplish the goals of the research:    2. Are there undisclosed risks to subjects that are more than minimal?  Yes  No  3. Participants should prospectively agree to incomplete disclosure/deception. Will the consent process contain notice that incomplete disclosure/deception is involved?  Yes  No  If no, explain why not:  4. Describe an adequate plan for debriefing subjects, when appropriate: | | | | |

**SUBJECT INCENTIVES & COSTS**

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| An incentive is anything of value that will be offered in order to motivate or encourage an individual to participate in the research. This could be money, gift cards, t-shirts, tickets, course or extra credit, etc. | | |
|  | | |
| **12.** | Will subjects be paid or offered a monetary incentive?  **If yes**, indicate total possible amount: | Yes  No |
|  | | |
| **13.** | Will subjects be given any tangible gifts (e.g., t-shirt, mug, tote bag) or services without charge?  **If yes**, describe and provide the value of any gifts or services: | Yes  No |
|  | | |
| **14.** | Will subjects receive extra credit or course credit?  **If yes**, an equivalent alternative to research participation must be provided. Describe: | Yes  No |
|  | | |
| **15.** | Will all subjects receive the same payment, gift, or other incentive?  **If no**, describe the incentive plan and explain why it is appropriate for this research: | Yes  No  N/A |
|  | | |
| **16.** | Are there any costs to subjects (or his/her insurance) as a result of participating in this study?  **If yes**, describe the costs: | Yes  No |
|  | | |
| **17.** | Will subjects be reimbursed for any expenses?  **If yes**, describe: | Yes  No |

**PRIVACY/CONFIDENTIALITY**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **18.** | Check the identifiers that will be collected **at any point in the research**, even if they will be destroyed at a later time.  No identifiers will be collected or recorded. | | | | | |
|  | | Names or initials |  | Telephone or fax numbers | |
|  | | Any geographical subdivision smaller than a state, including street address, city, county, precinct, and zip code |  | Any element of a date (except the year) that is directly related to the individual (e.g., birth date, diagnosis date, admission date, etc.) | |
|  | | E-mail addresses |  | URLs or IP address numbers | |
|  | | Any identifying number (e.g., BearID, medical record, social security or national ID, health insurance, account, certificate/license, vehicle identifiers and serial numbers, license plates, driver’s license) |  | Full face or other identifying video/photographic images (e.g., tattoos, scars) | |
|  | | Digital or online identities (e.g., avatars, personas, screen names, etc.) |  | Biometric identifiers (e.g., fingerprints, voiceprints, dental x-rays, retinal scans, handwriting, etc.) | |
|  | | Genetic information |  | Any other unique identifying number, characteristic, or code | |
| **If any of the above boxes are checked**, how long will the identifiers be kept? | | | | | |
|  | | | | | | |
| **19.** | Does this study involve collection of information from student school/university records? (If yes, FERPA requirements may apply.) | | | | | Yes  No |
|  | | | | | | |
| **20.** | Will a coding system\* be used?  \*For privacy purposes, **coding system means** a random unique ID is assigned to each subject’s data and a separate document (key) is maintained that links the subject to the ID number. | | | | | Yes  No |
| **If yes**, who will have access to the key?  How long will the key be kept? | | | | | |
|  | | | | | | |
| **21.** | | Is this research being conducted at a location outside of BU that is a HIPAA covered entity (such as a health care clinic or hospital)? | | | | Yes  No |
| **If yes,** identify the location: | | | | |
| **If yes,** please note that no protected health information (PHI) should be brought onto Baylor campus or saved on any Baylor system unless certain conditions are met.  **Check the appropriate box:**  All data that I receive from a HIPAA covered entity will be DE-IDENTIFIED prior to coming into my possession and/or being transferred to any Baylor system.  This research requires identifiable protected health information to be conducted. I will work with the Office of Research Compliance to make sure appropriate conditions are met. | | | | |

**ADDITIONAL RESEARCH INFORMATION**

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| --- | --- | --- |
| **22.** | Is this research being transferred from another institution (e.g., new faculty member bringing currently active research to BU)? | Yes  No |
| **If yes,** submit a copy of the other IRB’s exemption determination or approval letter and, if applicable, the most recent continuing review approval. More information may be requested. | |
|  | | |
| **23.** | **EXPORT CONTROLS**  As a Principal Investigator, researcher, or faculty member, you are responsible for being aware of and complying with any United States export control laws and regulations that may apply to your project. You are specifically responsible for determining if the research you are performing, the information you are developing, receiving or disseminating, the technology you are developing, receiving or disseminating, or the presence of any individual who is involved in your project is controlled by export controls laws and regulations or how they may apply to your project. Export Compliance is here to assist you in this determination and should be used as a resource.\*  Click here to affirm that you are aware of the above responsibility.  **\***Contact Export Compliance at (254) 710-6613 or via email at [export@Baylor.edu](mailto:export@Baylor.edu) . Additional information available at: <http://www.baylor.edu/export/> | |

**Principal Investigator Attestation**

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| By submitting this form electronically through IRBNet, you (the Principal Investigator or designee) are certifying the following: (check to indicate that you have read each one)  The information contained in this report is true, complete, and accurate to the best of your knowledge;  The research will be conducted in accordance with applicable laws, regulations, and Baylor University policies and procedures;  Research records will be kept for at least 3 years after completion of the research (a longer period may be required by the sponsor, funding agency, or other institutional policy)  You are aware, as the Principal Investigator, you are ultimately responsible for the conduct of this research and the individuals to whom you delegate research responsibilities. |