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| **or-logo-stacked** | | **Institutional Review Board**  **Human Research Protections**  **Reviewer’s Checklist – New Study Exempt Research** |
| **HS#:** **{protocol\_no}** | **APP#:** {ELECTRONIC\_APP\_NUM} | |
| **Lead Researcher:** {lr\_name} | | |
| **Title:** {project\_title} | | |

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| **HRP ADMINISTRATIVE CHECKLIST** | | | **COMMENTS** |
| Required Signatures Received | YES | NO | Waiting for Signatures |
| Consent Document(s) Received | YES | NO | \_\_\_ Consent(s)  \_\_\_ Assent(s)  \_\_\_ Study Info Sheet(s)  Informed Consent Not Required – No Subject Contact  Documented Informed Consent Not Required  Appendix G: Use of Deception |
| Special Population(s) Identified | YES | NO | Appendix B: Pregnant Women / Neonates  Appendix D: Children  Appendix E: Cognitively Impaired / Medically Incapacitated  American Indian or Alaska Native Tribes |
| Recruitment Material Received | YES | NO |  |
| Data Collection Instrument Received | YES | NO |  |
| Source of Funding Identified | YES | NO | Specify: |
| Permission Letters / Off-Site Research Agreement Received | YES | NO | Specify:  Appendix A: Non-UCI Site  Appendix H: International Research  Appendix I: Field Work |
| PHI Accessed, Created or Disclosed | YES | NO | Appendix T: Total Waiver of HIPAA Authorization |
| Referred to COIOC | YES | NO | Specify: |
| Other Ancillary Committee Clearances Received | YES | NO | PRMC Approval/Exemption  hSCRO Approval |
| All Appendices Received | YES | NO | Appendix M: Storage of Data/Specimens for Future Research  Appendix N: Genetic Testing |

##### HRP ADMINISTRATIVE COMMENTS

**\*\*If you have any questions or would like assistance with this review, please feel free to contact me at (949) 824-XXXX or at XXXX@uci.edu. Thanks – XXXX**

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| **ADMINISTRATIVE QUESTIONS AND NOTES FOR THE IRB** |

**Notes for the IRB:**

**Questions for the IRB:**

1. **Question X:**?





**(Please comment as necessary):**

1. **Appendix X:** Please review Appendix X. Does the IRB agree with the information as presented?







1. **Administrative Comments:** Does the IRB agree with the Administrative Comments for the LR?





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| **ADMINISTRATIVE COMMENTS FOR THE LEAD RESEARCHER (LR)** |

**UCI IRB**

**REVIEWER’S CHECKLIST**

**REVIEWERS:**

1. Please specify whether you have a conflict of interest that would require you to be recused for the review of this protocol. If you do have a conflict, please contact HRP staff ASAP to arrange for reassigning this protocol.





1. Please review and specify if the research meets UCI’s Ethical Criteria outlined below by checking the corresponding box. Please document each concern you would like to be communicated to the LR in the corresponding comments box or in the open space below.

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| **CRITERIA FOR EXEMPT REGISTRATION** | |
| **BACKGROUND AND RESEARCH DESIGN** | **RISK/BENEFIT ANALYSIS** |
| * Statement of purpose/hypothesis is adequate * Study personnel appear appropriate/qualified | * Risks are relatively non-existent * Potential direct benefit to subjects or societal benefit included * Acceptable risk/benefit relationship |
|  |  |
| Comments: | Comments: |
| **SUBJECT RECRUITMENT** | **SUBJECT PROTECTION** |
| * Selection of subjects is appropriate (inclusion/exclusion criteria) * Selection of subjects is equitable * Recruitment procedures are proper (undue influence or   coercion is minimized, compensation is not coercive,  recruitment materials are appropriate) | * Provisions to protect subject privacy are adequate * Provisions to maintain confidentiality are appropriate * Addt’l Protections for Vulnerable Populations are addressed |
|  |  |
| Comments: | Comments: |
| **INFORMED CONSENT PROCESS** | **OTHER CONSIDERATIONS** |
| Is the informed consent process appropriate\*?  **\*If an informed consent process is appropriate,** the researcher will disclose:   * Name and contact information for the researcher * Activity involves research * Participation is voluntary * Description of the procedures * Estimate of the length of time the participation may last * Description of risks * Description of benefits * Description of provisions to maintain privacy and confidentiality | * Study meets the definition of human subjects research * Research does not involve prisoners as subjects except for research aimed at involving a broader population that only incidentally includes prisoners * Research aligns with Tribal Law when including American Indian or Alaska Native tribes * Research is not regulated by FDA (no drugs; not a clinical investigation of a medical device) * Research is not supported by Department of Justice (DOJ) |
|  |  |
| Rationale/Comments: | Comments: |

1. **Risk Assessment:**



If Virtually No Risk*, indicate all corresponding Category(ies)*:

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| [**Category 1**](https://www.federalregister.gov/d/2017-01058/p-1373)**: Education (the following criteria must be met)** | |
|  | Research, conducted in established or commonly accepted educational settings and 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 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. |
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| [**Category 2**](https://www.federalregister.gov/d/2017-01058/p-1374)**: Interactions (the following criteria must be met)** | |
|  | 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) **[[1]](#footnote-2)** |
|  | One of the following criteria must be met:  2i) 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,  2ii) 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  2iii) 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**  **[Note: For Category 2iii, any disclosure of the human subjects' responses outside the research *would* reasonably\* place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation]**  **Limited IRB Review:** There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The IRB has determined that all considerations below have been adequately addressed to assure appropriate protections:   * The nature of the identifiers associated with the data * The security controls in place:   + Physical safeguards for paper records   + Technical safeguards for electronic records   + Secure sharing or transfer of data outside the institution, if applicable * The potential risk for harm that would occur if the security of the data was compromised   \**Reasonably defined as with fair and sound judgment; a standard used by an ordinary, rational person under similar circumstances.* |
|  | |
| [**Category 3**](https://www.federalregister.gov/d/2017-01058/p-1378)**i: Behavioral Interventions (the following criteria must be met)** | |
|  | The research involves 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 |
|  | The 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. |
|  | One of the following criteria must be met:  3iA)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  3iB) 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  3iC) 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**  **[Note: For Category 3iC, any disclosure of the human subjects' responses outside the research *would* reasonably\* place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation]**  **Limited IRB Review:** There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The IRB has determined that all considerations below have been adequately addressed to assure appropriate protections:   * The nature of the identifiers associated with the data * The security controls in place:   + Physical safeguards for paper records   + Technical safeguards for electronic records   + Secure sharing or transfer of data outside the institution, if applicable * The potential risk for harm that would occur if the security of the data was compromised   \**Reasonably defined as with fair and sound judgment; a standard used by an ordinary, rational person under similar circumstances.* |
|  | One of the following criteria must be met:  The research does **NOT** involving deceiving the subjects regarding the nature or purpose of the research  The subject will be informed that he/she will be unaware of or misled regarding the nature or purpose of the research and will authorize the deception through a prospective agreement to participate |
|  | |
| [**Category 4**](https://www.federalregister.gov/d/2017-01058/p-1384)**: Secondary Research Without Consent (the following criteria must be met)** | |
|  | The research involves secondary use of identifiable private information or identifiable biospecimens |
|  | One of the following must be met:  4i) The identifiable private information or identifiable biospecimens are publicly available  4ii) 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  4iii) 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 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)  **[Note: Category 4iii is allowable when a UCI healthcare workforce member uses identifiable health information for research purposes and the information obtained for research will not be disclosed outside of the covered entity (i.e., not outside of UCI Health). IMPORTANT! Disclosure beyond UCI Health for research purposes does not meet category 4iii and the project should be submitted as Expedited Category 5.]**    4iv) 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**](https://www.federalregister.gov/d/2017-01058/p-1389)**: Federal Demonstration Projects (the following criteria must be met)** | |
|  | The research or demonstration project is 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 |
|  | The program under study delivers a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act) |
|  | The research or demonstration project is conducted pursuant to specific federal statutory authority |
|  | There is no statutory requirement that the project be reviewed by an IRB |
|  | The research involves no significant physical invasions or intrusions upon the privacy of participants |
|  | |
| [**Category 6**](https://www.federalregister.gov/d/2017-01058/p-1392)**: Taste and Food (the following criteria must be met)** | |
|  | The research involves taste and food quality evaluation and consumer acceptance studies where wholesome foods without additives are consumed, or 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 |
|  | |
| [**Category 8**](https://www.federalregister.gov/d/2017-01058/p-1396)**: Use of Data for Secondary Research with Broad Consent (one or more of the following criteria must be met)** | |
|  | Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the 2018 Exempt Category #7 criteria |
|  | The research to be conducted is within the scope of the broad consent |
|  | **Limited IRB Review:** There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. The IRB has determined that all considerations below have been adequately addressed to assure appropriate protections:   * The nature of the identifiers associated with the data * The security controls in place:   + Physical safeguards for paper records   + Technical safeguards for electronic records   + Secure sharing or transfer of data outside the institution, if applicable * The potential risk for harm that would occur if the security of the data was compromised |
|  | The investigator does not include returning individual research results to subjects as part of the study plan **[[2]](#footnote-3)** |
|  | One of the following criteria must be met:  Consent was documented in writing  Written documentation of consent was waived |
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If [Minimal](http://www.rgs.uci.edu/ora/rp/hrpp/levelsofreview.htm#Expedited) Risk*, indicate all corresponding Category(ies)*:



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| --- |
| **Please provide a rationale for any change in the risk assessment (e.g., from Exempt to Expedited or Full Committee).** |
|  |

1. **IRB Recommendation:**

 

 

1. **Reviewer Comments:**

**Reviewer’s Signature** **Date**

Note: The information provided on this form may be preliminary and may not necessarily reflect the discussion and final decision and/or recommendation of the Committee.

1. [Subpart D applicable only when involving educational tests or the observation of public behavior when the investigator(s) do NOT participate in the activities being observed.](https://www.federalregister.gov/d/2017-01058/p-1370) [↑](#footnote-ref-2)
2. [This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.](https://www.federalregister.gov/d/2017-01058/p-1399) [↑](#footnote-ref-3)