Instructions: This form is used to establish whether your research can be determined to be “Human Research” that is exempt from IRB Review according to the federal regulations. To request a determination of exemption, please complete the protocol application and attach this form in Section 1.8 of the Basic Information Page of the online study submission. Also attach recruitment materials, study instruments, and, if a consent process is required, the HRP-254 Summary Explanation for Exempt Research. *The IRB Office will then make the final determination on whether the activity meets an exempt category under Health and Human Services regulations (HHS)45 CFR 46.101 (b).*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Investigator:** | |  | | |
| **Study Title:** | |  | | |
| **Co-Investigators(s) (if Applicable):** | |  | | |
| **Faculty Advisor (if Applicable):** | |  | | |
| **Section 1 – Justification of IRB Exemption**  **In order to be considered exempt, the research study MUST meet the following conditions:** | | | | |
| 1. **The research protocol involves NO more than minimal risk. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons. 45CFR46.303 (d).** | | | | |
|  | Yes, this research involves NO more than minimal risk. | | | |
|  | No, this research involves GREATER than minimal risk. **STOP, your submission does not qualify for an exemption determination. Discard this form and complete a Protocol using Form HRP-503 for submission to the IRB.** | | | |
| 1. **This study fits into at least one of the following 6 Exemption categories. Please indicate which of the following categories you think most clearly represents your research.** | | | | |
|  | 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. | | | |
|  | 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 be readily ascertained, directly or indirectly through identifiers linked to the subjects; OR  (ii) Any disclosure of 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 be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.  **Note: If your research includes surveys or interviews with minors, this study will not qualify for an exemption.**  If the research involves children and is conducted, funded, or subject to regulation by DHHS, Dept. of Defense (DOD), Dept. of Education (ED), Environmental Protection Agency (EPA), or Veterans Administration (VA), the procedures are limited to (1) the observation of public behavior when the investigator(s) do not participate in the activities being observed or (2) the use of educational tests and 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 indirectly through identifiers linked to the subjects; OR  ☐ (ii) Any disclosure of 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 achievement, or reputation. | | | |
|  | 3(i). Research involving benign behavioral interventions[[1]](#endnote-1) 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 indirectly, 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 be readily ascertained, directly or indirectly through identifiers linked to the subjects, AND there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. | | | |
|  | 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; 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  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 (HIPAA), 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  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 | | | |
|  | 5. Research and demonstration projects which 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 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[[2]](#endnote-2)  (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. | | | |
|  | 6.[[3]](#endnote-3) 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 Dept. of Agriculture. | | | |
| **Section 2 – Study Details**  **Complete each section** | | | | |
| **Protocol Synopsis/Summary:** | | |  | |
| **Objective/Background:** | | |  | |
| **Study Design:** | | |  | |
| **Study Instruments:** (List **all** materials the participant will view or hear. This list must match the document names attached in the Local Site Documents in the Huron IRB system)**:** | | |  | |
| **Maximum number of participants:** | | |  | |
| **Study Population:**  (check 🗹 all that apply) | | | UCF Students, Faculty or Staff  Children or Young Adults Under the age of 18  Adults over 65  Pregnant Women  Prisoners  Adults to Unable to Consent  Other (specify): | |
| **Recruitment Methods:**  (Unless the content is exactly the same for all versions, upload a copy of each type selected) | | | Flyer  Email  Social Media Post  Other (specify):  The content is the same for all methods | |
| **Languages Included:** | | | English  Other (specify):  Note, the IRB will request translated versions of the study materials after the English versions are approved. | |
| **Research Locations:**  (check 🗹 all that apply) | | | UCF Owned or Operated Locations(s) (specify all applicable locations):  Online  Amazon M-Turk  Sona  Qualtrics  Other (specify):  International (specify all applicable locations):  Multi-site (specify all No-UCF locations):  Other (specify): | |
| **Involves Deception:**  Note: 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. | | | No  Yes (Completion of HRP-509 – Debriefing Statement is required)  If Yes, describe the nature of the deception: | |
| **Illegal activity/sensitive information (Drug use, underage alcohol use, rape, suicidal thoughts, etc.):** | | | No  Yes  If Yes, describe the nature of the sensitive information: | |
| **Compensation:** | | | No  Yes  If Yes, specify the form of compensation (check all that apply):  Course Credit (students) **(if offering course credit, “Alternate Assignment” below must also be selected)**  Alternate Assignment (students)  Monetary (cash/check/gift card)  Other (specify):  Lottery (Note: In general, due to Florida's strict state laws regarding lotteries and the appearance of coercion in research studies, the IRB does not allow lotteries unless the study is investigating the lottery process or psychological effects of lotteries as the purpose of the study. | |
| **Type of Interaction(s)to Take Place for Research Purposes:**  (check 🗹 all that apply) | | | Online survey  In-person/Face-to-Face  Voice Call  Voice/Video Call (i.e. Skype)  Voice Recordings  Video Recordings  Observation (describe the nature of the observation):  Other (specify): | |
| **Identifiable Data Collection:**  (check 🗹 all that apply and upload the study data collection sheet) | | | None  Name  Contact Information (email, phone number, address, etc.)  NID  Video Recording-- Face or other identifying personal attribute  Protected Health Information (PHI) (includes any of the 18 HIPAA identifiers associated with medical records, biological specimens, biometrics, data sets)  Biospecimens (describe):  Other (specify): | |
| **Data Retention:**  (check 🗹 all that apply for both the identifiable and de-identified sections, as applicable) | | | **If You are Collecting Identifiable Data:**  Identifiers deleted after transcription  Identifiers deleted after data analysis  Identifiers deleted at a specific timepoint (specify):  **De-Identified Data:**  De-identified data stored for a minimum of 5 years (per UCF policy)  De-identified data stored for a certain amount of time or specific timepoint (specify): | |
| **Section 3 – Ethical Considerations**  **Complete each section** | | | | |
| 1. **Describe how subject selection is equitable** (describe inclusion/exclusion criteria): | | |  | |
| 1. **This study involves the collection of identifiable data:** | | | No  Yes  If Yes, describe the provisions in place to protect the confidentiality of the data: | |
| 1. **There are interactions with participants** (including surveys): | | | No  Yes  **If Yes, question number 4 is required.** | |
| 1. **Informed Consent Process** (required for all studies involving subject interaction) | | | **Note: The Consent Process Must:**  Disclose that the activities involve research;  Disclose the procedures to be performed;  Disclose that participation is voluntary;  Disclose the name and contact information for the investigator.  Disclose what identifiable data will be collected and the confidentiality provisions in place to protect that data.  **Describe the informed consent process. This description should include information about how you are using the HRP-254 – Summary of Research Explanation and any other documents used to facilitate the consent process.** | |
| 1. **Subject Privacy** | | | **Describe the provisions to maintain privacy interests:** | |
| **Section 4 – Certification and Investigator Sign-Off** | | | | |
| Please be aware that the different activities listed under the categories for exemption do not automatically deem these activities as exempt from IRB review. Exempt determination does not designate that research is automatically excused from IRB submission or review, but rather are exempt only from certain federal regulations. The activities presented here only indicate that a significant portion of these types of research activities could be eligible for exemption procedures. In addition, this eligibilityalso depends on whether or not the specific circumstances surrounding the proposed research activities involves no more than minimal risk to the participants. **Decisions regarding eligibility for exemption will be made on a case-by-case basis by the IRB Office*.* The IRB Office may request additional documentation, including the full protocol (HRP-503 – Protocol Template), in order to make the appropriate determination.**  **By entering your initials below you certify that the information you have provided is complete and accurate. In addition, you acknowledge that any intended/proposed modifications to this research must first be submitted to the IRB as certain modifications may increase risk to participants or change the review category.** | | | | |
| **Investigator Initials** | | | | **Date** |
|  | | | |  |

1. 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. [↑](#endnote-ref-1)
2. 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. [↑](#endnote-ref-2)
3. Note that for FDA-regulated research exemption (6) is an exemption from IRB review in 21 CFR §56, but unlike DHHS regulations is not an exemption from FDA requirements for consent in 21 CFR §50. If an organization’s policy is to grant exemptions to FDA-regulated research in category (6), then additional criteria for such exemptions would be that consent will be obtained in accordance with 21 CFR §50.20 and §50.25, and the consent will be either be documented in writing in accordance with 21 CFR§50.27 or waived in accordance with 21 CFR §56.109(c)(1). [↑](#endnote-ref-3)