Institutional Review Board Checklist IRB Number

Name of Principal Investigator

Title of Project

Please address all checked items ☐ and other conditions below

Consent Form	
☐	Please print the consent form on Kent State University letterhead or type in equivalent of KSU letterhead at top of document/email/webpage.
☐	You have confused “Anonymous” and “Confidential.” Please change to the appropriate word. If the survey is anonymous (i.e., you do not know who the participants are) please use anonymous. If linking names and responses is “nearly impossible”, please use "confidential"
☐	Explain to participants how confidentiality will be protected.
☐	Please remove the statements about accidental injury and unforeseen risk.
☐	Add a statement indicating that participation in this project is voluntary.
☐	Tell participants that deciding to participate or not will not impact grades/class standing/relationship to the institution.
☐	Add a statement informing participants that they are free to withdraw at any time.
☐	Please spell out all the acronyms.
☐	Please add a statement detailing the purpose of this project.
☐	Please add a statement explaining the potential benefits of this project.
☐	Please add a statement explaining the anticipated risks of participation.
☐	Children participating in this study also need to give assent. Explain how you will seek this assent.
☐	Tell participants they may contact Kent State University IRB at 330.672.2704, with questions about participant rights.
☐	Provide contact information for the P.I. and project advisor regarding questions about the study.
IRB Application	
☐	Your application must be reviewed by a departmental reviewer before arriving in the Research Compliance Office. Please visit our website http://www.kent.edu/research regarding contact information for IRB departmental reviewers.
☐	Please include a copy of the instruments (list of questions, survey) to be used in this study.
☐	Please submit a copy of the recruiting letter or script that will be used in this study.
☐	Include information about how the subjects will be recruited for this study.
☐	Please indicate how you will limit participation to subjects that are at least 18 years of age.
Data Collection	
☐	Add a statement indicating that completion of the survey constitutes consent to participate.
☐	Please inform participants how much time participation in the research (e.g., survey, interview, focus group) will require.
External Approval	
☐	Please include documents that show IRB approval from other participating institution(s).
☐	Please provide documents that show approval from participating agencies, school districts, etc.

****OTHER CONDITIONS in Addition to any items checked above****

KENT STATE UNIVERSITY

Expedited (Level II) Review Checklist

An IRB may use the expedited review procedure to review initially proposed research involving no more than minimal risk to human subjects and using one or more of the procedures listed in one or more of the seven (7) categories listed below. Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by a convened IRB in accordance with the non-expedited procedure set forth in the regulations at 45 CFR 46.108(b) and 21 CFR 56.108(c). (Other Applicable regulations: 45 CFR 46.110 and 21 CFR 56.110.) *Please complete this checklist and send as an attachment via email to Researchcompliance@kent.edu along with the application that you reviewed and the associated documents (consent form, instruments, CITI training certificate, etc...)*

IRB Reviewer:	Date:
Principal Investigator:	
Title of Study: *Please abbreviate longer titles*	
1. Does the research involve the use of an investigational drug or medical device?	○ No ○ Yes
2. Does the research involve more than minimal risk to participants? *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 or during the performance of routine physical or psychological examinations or tests. (See Section 5 of the application)*	○ No ○ Yes
3. Does the research involve the use prisoners as the subjects of the research? *(See Section 4(d) of application)*	○ No ○ Yes
4. Could identification of the subjects and/or their responses reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing? (The answer is No if there are reasonable and appropriate protections implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.)	○ No ○ Yes
5. Does the research involve classified human subjects research? *Classified research is generally defined as research subject to a security classification established by a United States government agency.*	○ No ○ Yes
6. Are the requirements for informed consent (or for altering or waiving the requirement for informed consent) satisfied?	○ No ○ Yes
7. Choose one or more categories for which this research qualifies.	
☐ **Category 1**	**Drugs or devices which do not require an IND or IDE** *(See Section 3(g) and Appendices E & F of application)* Clinical studies of drugs and medical devices only when condition (a) **or** (b) is met. ○ a. Research on drugs for which an investigational new drug application (IND; 21CFR312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.) ○ b. Research on medical devices for which (i) an investigational devices exemption application (IDE; 21CFR812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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Expedited (Level II) Review Checklist

☐ **Category 2**	**Blood Samples** *(See Section 3 (g) of the application)* Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows: ◯ a. from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or ◯ b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
☐ **Category 3**	**Specimens (collected prospectively and by non-invasive means)** Prospective collection of biological specimens for research purposes by noninvasive means. *Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.*
☐ **Category 4**	**Data (collected through non-invasive, routine clinical procedures)** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. *Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications. Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.*
☐ **Category 5**	**Materials (collected retrospectively or prospectively, depending on circumstance)** Research involving materials (data, documents, records or specimens) that have been collected, or will be collected solely for non-research purposed (such as medical treatment diagnosis). *Some research in this category may be exempt from the HHS regulations for the protection of human subject [45 CFR 46.101 (b)(4)]. This listing refers only to research that is not exempt. Guidance from the HHS Office of Human Research Protections (OHRP) indicates that this category includes research involving materials (data, documents, records, or specimens) that (a) will be prospectively collected solely for non-research purposes such as medical treatment or diagnosis, or (b) have already been collected for either non-research or research purposes, provided the materials were not collected for the currently proposed research.*
☐ **Category 6**	**Voices, video, digital or image recordings** *(See Section 3 (g) of application)* Collection of data from voices, video, digital or image recordings made for research purposes.
☐ **Category 7**	**Individual or group characteristics or behavior; surveys, interviews, etc** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [45 CFR 46.101 (b) (2) and (b)(3)]. This listing refers only to research that is not exempt.)