**Section 1: Submission information**

|  |  |  |  |
| --- | --- | --- | --- |
| EDO Log #: | Local Study #: | | Date Received: **Click here** |
| PI: | PI Email: | | PI Phone: |
| Title: | | | |
| Lead Site: | | Other Site: | |
| List any supporting documents: | | | |

**Section 2: Is this activity “Research” in accordance with 32 CFR 219.102(l)?**

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

The following activities are deemed not to be research:

1) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

2) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an events or crisis that threatens public health (including natural or man-made disasters).

3) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Is the activity “Research”? Click to select If yes, then continue to Section 3, if no, then stop.

**Section 3: Does this research activity involve “Human Subjects” in accordance with 32 CFR 219.102(e)(1)?**

Human Subject means a living individual about whom an investigator (whether professional or student) conducting research: i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or ii) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.

Does the activity involve “Human Subjects”? Click to select If “yes”, then continue to Section 4

If no, then stop.

**Section 4: Exemption Category review conducted (32 CFR 219.104(d)(1)-(8))**

Category 1: [Proceed to Section 5](#Exemption_1)  Category 5: [Proceed to Section 9](#Exemption_5)

Category 2: [Proceed to Section 6](#Exemption_2)  Category 6: [Proceed to Section 10](#Exemption_6)

Category 3: [Proceed to Section 7](#Exemption_3)  Category 7: [Proceed to Section 11](#Exemption_7)

Category 4: [Proceed to Section 8](#Exemption_4)  Category 8: [Proceed to Section 12](#Exemption_8)

**Section 5: Category 1 Exemption**

*(Instructions: To use Category 1 Exemption, the first 3 questions must be answered “yes”, question 4 can be either “yes” or “no” but if “yes” then provide explanation, and question 5 must be answered “no”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Will be conducted in an established or commonly accepted educational setting? (*32 CFR 219.104(d)(1)*) |  |  |  |
| 1. Involves normal educational practices?   (*32 CFR 219.104(d)(1)*) |  |  |  |
| 1. Unlikely to adversely impact students’ opportunity to learn required educational content?   (*32 CFR 219.104(d)(1)*) |  |  |  |
| 1. Involves an assessment of educators who provide instruction? (*32 CFR 219.104(d)(1)*) |  |  |  |
| 1. Will be used in employment decisions that could adversely impact instructor(s) being evaluated?  (*32 CFR 219.104(d)(1)*) |  |  |  |

**Section 6: Category 2 Exemption**

*(Instructions: To use Category 2 Exemption, the first 2 questions must be answered “yes” and one of the questions in the blue set (questions 3-5) must be answered “yes”; question 2.a can be either “yes” or “no” but if “yes” then provide explanation; 2b must be answered “no”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Activity involves ONLY *interactions* – No *interventions*? (*32 CFR 219.104(d)(2)*) |  |  |  |
| 1. Involve either educational tests, survey procedures, interview procedures or observation of public behavior?   (*32 CFR 219.104(d)(2)*) |  |  |  |
| 1. If educational tests or observations of public behavior are used, then are children subjects?   (*32 CFR 219.104(b)(3)*) |  |  |  |
| 1. If yes to a) above, then is the investigator participating in the activities being observed?   (*32 CFR 219.104(b)(3)*) |  |  |  |
| 1. Information recorded in de-identified manner?   (*32 CFR 219.104(d)(2)(i)*) |  |  |  |
| 1. Disclosure 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? (*32 CFR 219.104(d)(2)(ii)*) |  |  |  |
| 1. If information will be recorded in an identifiable manner, then limited IRB review completed?   (*32 CFR 219.104(d)(2)(iii)*) |  |  |  |
| ***Limited IRB Review Criteria (If allowed by the Institution)*** | | | |
| 1. When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data? (*32 CFR 219.111(a)(7)*) |  |  |  |
| 1. Have data been partially de-identified, such as that required for a Limited Data Set as defined by HIPAA? |  |  |  |
| * 1. Is there increased risk to subjects if fully re-identified? |  |  |  |
| 1. Will information be used in a manner that substantially increases risk of harm if disclosed and linked to subjects? |  |  |  |
| 1. Will information be shared beyond the study team in an identifiable manner? |  |  |  |
| 1. Are adequate physical security controls described (locks, facility security system, security cameras or guards, *etc*.)? |  |  |  |
| 1. Is recruitment free of undue command influence/coercion?   (*DoDI 3216.02 Enclosure 3, paragraph 7.e.(1)(c)*) |  |  |  |

*Limited IRB reviews shall only be conducted by an IRB, either through expedited review procedures by the IRB Chair or an experienced IRB member, or by a convened board. Each limited IRB review decision must be reported at the IRB meeting and listed on the IRB minutes.*

**Section 7: Category 3 Exemption**

*(Instructions: To use Category 3 Exemption, the first 5 questions must be answered “yes”, question 6 can be either “yes” or “no” but if “yes” then provide explanation, questions 6a, and 7 must be answered “yes”, and one of questions in blue set (questions 8-10) must be answered “yes”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Includes ONLY adult subjects (servicemembers are adults)? (*32 CFR 219.104(d)(3)(i)*) |  |  |  |
| 1. Involves behavioral interventions with information collection from verbal or written responses or audiovisual recordings that are “benign”1 as defined in the regulatory text? (*32 CFR 219.104(d)(3)(ii)*) |  |  |  |
| 1. All subjects are capable of and “prospectively agree to the intervention and information collection”?   (*32 CFR 219.104(d)(3)(i)*) |  |  |  |
| 1. There are NO medical or clinical interventions?   (*32 CFR 219.104(d)(3)(ii)*) |  |  |  |
| 1. There are NO data obtained using physical or physiological monitors, sensors or devices?   (*32 CFR 219.104(d)(3)(ii)*) |  |  |  |
| 1. Includes deception regarding the nature or purpose of the research? (*32 CFR 219.104(d)(3)(iii)*) |  |  |  |
| 1. Do subjects “prospectively agree” to deception?   (*32 CFR 219.104(d)(3)(iii)*) |  |  |  |
| 1. Information recorded in de-identified manner?   (*32 CFR 219.104(d)(3)(i)(A)*) |  |  |  |
| 1. 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 subjects’ financial standing, employability, educational advancement, or reputation?   (*32 CFR 219.104(d)(3)(i)(B)*) |  |  |  |
| 1. If *identifiable*, then limited IRB review completed?   (*32 CFR 219.104(d)(3)(i)(C)*) |  |  |  |
| ***Limited IRB Review Criteria (If allowed by the Institution)*** | | | |
| * 1. When appropriate, are there adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data? (*32 CFR 219.111(a)(7)*) |  |  |  |
| * 1. Have data been partially de-identified, such as that required for a Limited Data Set as defined by HIPAA? |  |  |  |
| * + 1. Is there increased risk to subjects if fully re-identified? |  |  |  |
| * 1. Will information be used in a manner that substantially increases risk of harm if disclosed and linked to subjects? |  |  |  |
| * 1. Will information be shared beyond the study team in an identifiable manner? |  |  |  |
| * 1. Are adequate physical security controls described (locks, facility security system, security cameras or guards, *etc*.)? |  |  |  |
| * 1. Is recruitment free of undue command influence/coercion?   (*32 CFR 219.111(b)* and *DoDI 3216.02 Enclosure 3, paragraph 7.e.(1)(c)*) |  |  |  |

*Limited IRB reviews shall only be conducted by an IRB, either through expedited review procedures by the IRB Chair or an experienced IRB member, or by a convened board. Each limited IRB review decision must be reported at the IRB meeting and listed on the IRB minutes.*

*1Benign 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. Examples 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.*

**Section 8: Category 4 Exemption**

*(Instructions: To use Category 4 Exemption, the first question must be answered “yes”, questions 2 and 3 may be answered “yes” or “no” depending upon research. and one of the four questions in the blue set (questions 4-7) must be answered “yes”; if question 6 is answered “yes” then 6a must be “yes” and 6b can be either “yes” or “no”; if question 7 is answered “yes” then 7a and 7b must be answered “yes”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Involves only *secondary research* for which consent is not required? (*32 CFR 219.104(d)(4)*) |  |  |  |
| 1. *Identifiable private information* will be used?   (*32 CFR 219.104(d)(4)*) |  |  |  |
| 1. *Identifiable biospecimens* will be used?   (*32 CFR 219.104(d)(4)*) |  |  |  |
| 1. *Identifiable private information* or *identifiable biospecimens* are publicly available?   (*32 CFR 219.104(d)(4)(i)*) |  |  |  |
| 1. Information, including information about biospecimens, is recorded in a de-identified manner, the investigator will not contact the subjects and the investigator will not re-identify the subjects? (*32 CFR 219.104(d)(4)(ii)*) |  |  |  |
| 1. Only involves use of identifiable *health* information that is subject to HIPAA? (*32 CFR 219.104(d)(4)(iii)*) AND |  |  |  |
| * 1. If identifiable *health* information is being used, then a Data Sharing Agreement has been requested (application included as part of the protocol submission)? OR |  |  |  |
| * 1. If identifiable *health* information is being used, then a Data Sharing Agreement has been executed (DSA memo included as part of the protocol submission)? |  |  |  |
| 1. Conducted by/on behalf of the Federal government using Federal government-generated/collected information collected for non-research purposes?   (*32 CFR 219.104(d)(4)(iv)*) |  |  |  |
| 1. Identifiable private information will be generated through the proposed research? AND |  |  |  |
| 1. If yes to a) above, then is or will the information be stored on IT system subject to the Federal privacy standards cited in the regulatory text? |  |  |  |

**Section 9: Category 5 Exemption**

*(Instructions: To use Category 5 Exemption, questions 1 through 5 must be answered “yes”)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Is the project “conducted” or “supported” by a Federal department or agency?, or (*32 CFR 219.104(d)(5)*) |  |  |  |
| 1. Is the project “subject to the approval of department or agency heads”? (*32 CFR 219.104(d)(5)*) |  |  |  |
| 1. Is the topic of the proposed research a public benefit program (this includes TRICARE Health Benefit programs)? (*32 CFR 219.104(d)(5)*) |  |  |  |
| 1. Is the activity designed to “study, evaluate, improve, or otherwise examine” the benefit program or service?   (*32 CFR 219.104(d)(5)*) |  |  |  |
| 1. Details of the research will be published on a publicly accessible Federal website prior to the commencement of the research? (*32 CFR 219.104(d)(5)(i)*) |  |  |  |

**Section 10: Category 6 Exemption**

*(Instructions: To use Category 6 Exemption, the first question must be answered “yes” and question 2 alone can be answered “yes” allowing the exemption, or if question 2 is answered “no” questions 3-5 must be answered “yes”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Involves a taste and food quality evaluation designed to assess “consumer acceptance”? (*32 CFR 219.104(d)(6)*)? |  |  |  |
| 1. Involves consumption of “wholesome foods without additives”? (*32 CFR 219.104(d)(6)(i)*) |  |  |  |
| 1. Involves consumption of food with ingredients “at or below” the safe level? (*32 CFR 219.104(d)(6)(ii)*) |  |  |  |
| 1. Involves consumption of food with agricultural chemicals “at or below” the safe level? (*32 CFR 219.104(d)(6)(ii)*) |  |  |  |
| 1. Involves consumption of food with environmental contaminants “at or below” safe level?   (*32 CFR 219.104(d)(6)(ii)*) |  |  |  |

*This is the only exemption that is also applicable to research that is regulated by the U.S. Food and Drug Administration.*

**Section 11: Category 7 Exemption**

*(Instructions: To use Category 7 Exemption, either question 1 or 2 must be answered “yes” and question 3 must be answered “no”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Will *identifiable private information* be stored or maintained for potential secondary research purposes for which broad consent is required?   (*32 CFR 219.104(d)(7)*) |  |  |  |
| 1. Will *identifiable biospecimens* be stored or maintained for potential secondary research purposes for which broad consent is required? (*32 CFR 219.104(d)(7)*) |  |  |  |
| 1. Is there a proposal to use the information or specimens collected for the current proposed study?1 (*32 CFR 219.104(d)(7)*) |  |  |  |
| ***Limited IRB Review Criteria (if allowed by the Institution)*** | | | |
| 1. Is *broad consent* for potential future research use of information or specimens included?2   (*32 CFR 219.111(a)(8)(i)*) |  |  |  |
| 1. Is *broad consent* appropriately documented in accordance with (*32 CFR 219.117(a) and (b)*), or is there a waiver of documentation in accordance with *32 CFR 219.117(c)(1)?*   (*32 CFR 219.111(a)(8)(ii)*) |  |  |  |
| 1. Are adequate provisions to protect privacy of subjects and confidentiality of information if changes are made in the way the information or specimens are stored or maintained for research purposes? (*32 CFR 219.111(a)(8)(iii)*) |  |  |  |
| 1. Are adequate physical security controls described (locks, facility security system, security cameras or guards, *etc*.)? |  |  |  |
| 1. Is recruitment free of undue command influence/coercion?   (*32 CFR 219.111(b)* and *DoDI 3216.02 Enclosure 3, paragraph 7.e.(1)(c)*) |  |  |  |
| ***Broad Consent Criteria (if allowed by the Institution)*** | | | |
| 1. Is *broad consent* **sought** separately and independently from consent for the protocol or procedure in which the information or specimens are collected? |  |  |  |
| 1. Is *broad consent* **documented** separately and independently from consent for the protocol or procedure in which the information or specimens are collected? |  |  |  |
| 1. Is the *broad consent* obtained from the subject or a legally authorized representative (LAR)?   (*32 CFR 219.116(a)(1)*) |  |  |  |
| 1. Is there sufficient opportunity for subjects or LARs to discuss and consider participation without coercion or undue influence?   (*32 CFR 219.116(a)(2)*) |  |  |  |
| 1. Is the language understandable to the subjects or LARs? (*32 CFR 219.116(a)(3)*) |  |  |  |
| 1. Is the information provided in the *broad consent* document what “a reasonable person would want to have” to make an informed decision to participate? (*32 CFR 219.116(a)(4)*) |  |  |  |
| 1. Is the *broad consent* document free of exculpatory language? (*32 CFR 219.116(a)(6)*) |  |  |  |
| 1. Is there a description of any reasonably foreseeable risks or discomforts included?   (*32 CFR 219.116(b)(2)*) |  |  |  |
| 1. Is there a description of any benefits to the subjects or others may reasonably expect included? (*32 CFR 219.116(b)(3)*) |  |  |  |
| 1. Is there a statement of the extent to which confidentiality of identifiable records will be maintained? (*32 CFR 219.116(b)(5)*) |  |  |  |
| 1. Is there a statement of voluntariness and subjects’ rights to stop participating without loss of benefits or other penalties?   (*32 CFR 219.116(b)(8)*) |  |  |  |
| 1. When appropriate, is there a statement that the subject’s biospecimens may be used for commercial profit? (*32 CFR 219.116(c)(7)*) AND |  |  |  |
| * 1. If biospecimens will be used for commercial profit, then is there a statement regarding whether the subjects will or will not share in the profits? (*32 CFR 219.116(c)(7)*) |  |  |  |
| 1. If the research involves biospecimens, is there a statement that the research will (if known) or might include whole genome sequencing such as sequencing of a human germline or somatic specimen in order to generate the genome or exome sequence of that specimen?   (*32 CFR 219.116(c)(9)*) |  |  |  |
| 1. Is there a general description of the types of research that may be conducted using the information or specimens?   (*32 CFR 219.116(d)(2)*) AND |  |  |  |
| * 1. Is the information about the types of research sufficiently detailed that a reasonable person would understand that the information or specimens could be used for such research purposes?   (*32 CFR 219.116(d)(2)*) |  |  |  |
| 1. Is there a description of the *identifiable private information* or *identifiable biospecimens* that might be used in the research?   (*32 CFR 219.116(d)(3)*) |  |  |  |
| 1. Is there information presented regarding the sharing of *identifiable private information* or *identifiable biospecimens*, and the institutions or researchers that might conduct the research?   (*32 CFR 219.116(d)(3)*) |  |  |  |
| 1. Is there a time period, including indefinite, for the storage or maintenance of *identifiable private information* or *identifiable biospecimens*?   (*32 CFR 219.116(d)(4)*) |  |  |  |
| 1. Is there a time period, including indefinite, for the research use of *identifiable private information* or *identifiable biospecimens*? (*32 CFR 219.116(d)(4)*) |  |  |  |
| 1. Unless they will be provided details about specific research studies, is there a statement that the subjects will NOT be informed of any specific research studies using the information or specimens? (*32 CFR 219.116(d)(5)*) |  |  |  |
| 1. When appropriate, is there a statement regarding whether clinically relevant research results will be disclosed, and if so, then under what conditions?   (*32 CFR 219.116(d)(6)*) |  |  |  |
| 1. Is there a statement noting that results of future research involving the information and specimens may NOT be disclosed to the subjects?   (*32 CFR 219.116(d)(6)*) |  |  |  |
| 1. Is there contact information included in the *broad consent* document for subjects who have questions about subject’s rights, storage and use of information and specimens, and to whom research-related harms can be addressed?   (*32 CFR 219.116(d)(7)*) |  |  |  |

*1Investigators seeking to use the information or specimens maintained in the repositories must submit a separate protocol for consideration at the time they propose the work.*

*2Broad consent documents must include the elements found at §219.116(a)(1)-(4), (a)(6) and (d).*

***Note: DoDI 3216.02 requires DOHRP approval for all uses of* broad consent**.

**Section 12: Category 8 Exemption**

*(Instructions: To use Category 8 Exemption, either question 1 or 2 must be answered “yes” and question 3 must be answered “yes”; in the blue set of questions, questions 4 and 7 must be answered “yes”, either question 5 or 6 must be answered “yes” and question 8 must be answered “no”.)*

|  |  |  |  |
| --- | --- | --- | --- |
| Element/Requirement | Met? | | Comments |
| Yes | No |
| 1. Will *identifiable private information* be used for secondary research purposes ONLY?   (*32 CFR 219.104(d)(8)*) |  |  |  |
| 1. Will *identifiable biospecimens* be used for secondary research purposes ONLY? (*32 CFR 219.104(d)(8)*) |  |  |  |
| 1. Is this proposal to ***use*** the information or specimens separate and independent of the proposal to ***store*** or ***maintain*** the information or specimens? |  |  |  |
| 1. Was *broad consent* for the storage, maintenance and secondary research use of the information and specimens be obtained for each subject’s information and specimens? (*32 CFR 219.104(d)(8)(i)*) |  |  |  |
| 1. Was documentation of informed consent be obtained in accordance with *32 CFR 219.117(a)* and *(b)*?   (*32 CFR 219.104(d)(8)(ii)*) |  |  |  |
| 1. If documentation of informed consent will not be obtained, was a waiver of documentation of consent obtained in accordance with *32 CFR 219.117(c)(1)*?   (*32 CFR 219.104(d)(8)(ii)*) |  |  |  |
| 1. Was a limited IRB review conducted as noted below?   (*32 CFR 219.104(d)(8)(iii)*) |  |  |  |
| 1. Does the protocol include any plans for the investigator to return individual research results to subjects?   (*32 CFR 219.104(d)(8)(iv)*) |  |  |  |
| ***Limited IRB Review Criteria*** | | | |
| 1. Are there adequate provisions to protect privacy of subjects and confidentiality of data?   (*32 CFR 219.111(a)(7)*) |  |  |  |
| 1. Will information be shared beyond the study team in an identifiable manner? |  |  |  |
| 1. Are adequate physical security controls described (locks, facility security system, security cameras or guards, *etc*.)? |  |  |  |
| 1. Is recruitment free of undue command influence/coercion?   (*32 CFR 219.111(b)* and *DoDI 3216.02 Enclosure 3, paragraph 7.e.(1)(c)*) |  |  |  |

**Section 13: Human Research Protections Program EDO Determination**

The DoD institution is engaged in the proposed activity

The activity is “Research”

The research activity involves “Human Subjects”

The research activity is exempt from IRB review in accordance with:

Exemption Category: **Choose one**

If more than one exemption category applies, identify other category/categories in the Reviewer Notes field, below.

The research activity is NOT exempt from IRB review in accordance with 32 CFR 219.104(d)

Reviewer notes, comments, rationale, justification:

Reviewer:  Date of Determination: **Click here**

