



**USUHS FORM 3204**  
**RESEARCH INVOLVING HUMAN SUBJECTS**  
**(new or modification/addendum)**

REA Date Stamp

Protocol No.: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Department: \_\_\_\_\_ Phone \_\_\_\_\_

E-Mail: \_\_\_\_\_ Pager or Other  
Phone Number \_\_\_\_\_

Project Title: \_\_\_\_\_

**PLEASE PROVIDE RESPONSES TO THE FOLLOWING:**

1. \_\_\_\_\_ New protocol or \_\_\_\_\_ Modification/Addendum
2. Indicate the pages of proposal specifically applicable to the involvement or enrollment of volunteers, private information, or human-derived products.  
Pages: \_\_\_\_\_
3. Check procedure(s) to be used:
  - \_\_\_\_\_ Use of genetic testing or DNA analysis.
  - \_\_\_\_\_ Use of blood or blood products: ( ) Blood Draw ( ) Blood Bank  
( ) Other
  - \_\_\_\_\_ Use of human tissue and/or bodily fluids including excreta and external secretions (sweat, saliva, amniotic fluid at the time of rupture of membrane).
  - \_\_\_\_\_ Hair and/or nail clippings.
  - \_\_\_\_\_ Teeth and/or dental material including plaque and calculus.
  - \_\_\_\_\_ Prospective collection and use of donated, pathological and/or diagnostic specimens. (Refer to question 15)
  - \_\_\_\_\_ Use of existing pathological and/or diagnostic specimens.
    - From where are these specimens being obtained?
    - Can the subjects from whom these specimens were obtained be identified directly or by the use of encoded identifiers?  
( ) Yes ( ) No (Refer to question 15)
  - \_\_\_\_\_ Use of human cell lines: ( ) Primary ( ) Immortalized
  - \_\_\_\_\_ Moderate exercise by healthy volunteers.
  - \_\_\_\_\_ Recording of data using noninvasive procedures used in clinical practice.
    - Identify \_\_\_\_\_.
  - \_\_\_\_\_ Study of existing data, documents, and/or records.
    - From where are these data being obtained?
    - Can the subjects from whom these data were obtained be identified directly or by the use of encoded identifiers?  
( ) Yes ( ) No

- \_\_\_\_\_ Survey, interview, or educational (cognitive, diagnostic, aptitude, achievement) test or procedures or observation of public behavior.
- Can the subjects be identified directly or by identifiers?  
( ) Yes ( ) No
  - Do the data collected involve sensitive information (e.g., drug and alcohol use, sexual practices, child or spousal abuse, or other information that could be criminal or damaging to one's financial or social standing, employability, insurability, or psychological well-being)?  
( ) Yes ( ) No

\_\_\_\_\_ Use of normal educational practices in accepted educational settings such as instructional strategies, effectiveness of or comparison among instructional techniques, curricula or classroom management methods.

\_\_\_\_\_ Use of taste and food quality evaluation and consumer acceptance studies?

4. Indicate the age and sex as well as the physical and psychiatric condition of the volunteers to be enrolled.  
Age \_\_\_\_\_  
Gender: \_\_\_\_\_  
Physical & psychiatric condition: \_\_\_\_\_
5. Indicate the total number and rate of enrollment of volunteers.  
Total number: \_\_\_\_\_ (entire project)  
Rate: \_\_\_\_\_ (#/ time period)
6. If applicable, explain with a compelling rationale the exclusion or under representation of one gender and/or minorities from the subject population.
7. Explain the inclusion of any vulnerable population (e.g., children, pregnant women, prisoners, cognitively impaired persons) and why that population is being studied.
8. State how physical and psychiatric condition will be determined and by whom.
9. If normal volunteers are to be enrolled, state how this will be determined.
10. Describe the status of the volunteers relative to the principal investigator and/or USUHS (e.g., patient at Walter Reed, active duty, students, civilian employees, etc.)
11. Describe the status of the volunteer's Attending Physician to the project including his or her role in safeguarding the rights of the volunteer.

12. Identify the specific procedures, issues, and/or experimental drug administration involving the volunteers that are important for the IRB to consider. Describe possible risks, ethical issues, and/or side effects for each. Factors to consider including, but are not limited to, the following:
  - A. What is the volunteer being asked to do which they would not be doing unless part of this research project?
  - B. Does the research collect personally sensitive information (e.g., drug and alcohol use, sexual practices, child abuse)? If so, how is confidentially protected?
  - C. Does the research involve deception of the subject? If so, how is the subject debriefed after completion of the project?
13. If this study involves the administration of drugs not approved by the FDA, state how approval will be obtained.
14. Do any of the investigators have an equity or consultative relationship with a non-USUHS source related to this protocol which might be considered to be a conflict of interest? (If yes, please include a statement of disclosure.)
15. Unless otherwise contained in your protocol, if using prospectively collected tissue, or any tissue linked to subject/patient identifiers, indicate:
  - A. How, where, and for how long will tissue/samples be stored?
  - B. Will patient data that can or will be linked to the tissue/samples be collected?
  - C. Will linkage to subjects be maintained or will samples be delinked?
  - D. Will any tissue/samples be left over at the end of the study and if so, what will be done with the tissue/samples?
13. Describe fully the modification(s) to your existing protocol to include rationale, procedures, numbers of subjects, etc. (Use blank pages if additional space is required.)

**I have read and will comply with USUHS Instruction 3201, "*The Use of Human Volunteers in Research at the Uniformed Services University of the Health Sciences*," March 1999.**

**I have read, understood, and will comply with the tenets contained in the Belmont Report ("Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979. URL: <http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm>).**

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**Principal Investigator (signature)**

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**Date**