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**EXPEDITED REVIEW** is conducted by the IRB for protocols involving a normal population of subjects who are exposed to no more than minimal risk. **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.

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**8. STUDY SUBJECTS:** Human subjects involved in the proposed research protocol are:

|           |                   |                   |                   |
|-----------|-------------------|-------------------|-------------------|
| Minors    | Fetuses           | Abortuses         | Pregnant Women    |
| Prisoners | Mentally Retarded | Mentally Disabled | None of the above |

**9. EXPEDITED REVIEW** is requested because human subject involvement is restricted to (check all that apply):

\_\_\_\_(1) 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 (21 CFR Part 312) 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 device exemption application (21 CFR Part 812) 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.

\_\_\_\_(2) 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<sup>2</sup>, 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.

\_\_\_\_(3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) hair and nail clippings in a non-disfiguring 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.

\_\_\_\_(4) 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.

\_\_\_\_(5) Research involving materials (data documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.1 01 (b)(4). This listing refers only to research that is not exempt)

\_\_\_\_(6) Collection of data from voice, video, digital or image recordings made for research purposes.

\_\_\_\_(7) 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.

\_\_\_\_(8) Continuing review of research previously approved by the convened IRB as follows:  
 (a) where (i) the research is permanently closed to the enrollment of new subjects, (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or  
 (b) where no subjects have been enrolled and no additional risks have been identified; or  
 (c) where the remaining research activities are limited to data analysis.

\_\_\_\_(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**10. REPOSITORY:** Following the completion of the study, Human Subjects documentation will be stored for a period of no less than three years in:

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Repository: Room, Building, Organization

**11. FINANCIAL DISCLOSURE:** I certify that all *key study personnel*\* have a current and complete SUNY-2-UB financial disclosure statement on file with their dean(s). [All research protocols involving human research subjects must now be evaluated to ascertain whether any financial conflicts-of-interest exists.]

**12. EDUCATIONAL REQUIREMENT:** As part of this submission, I certify that all *key study personnel*\* have read **Ethical Principles and Guidelines for the Protection of Human Research Subjects (the Belmont Report)** and the **Responsibilities of the Research Investigator** section of UB’s Multiple Project Assurance of Compliance (M-1270) with Department of Health and Human Services Regulations for the Protection of Human Research Subjects and that they have completed one of the following two web-based tutorials on the protection of human research subjects: **NIH; UC-Irvine**. Names and signatures of all *key study personnel* are included in the attached certification **Addendum**. (The above referenced documents and tutorials may be accessed at the Vice President for Research website, [www.research.buffalo.edu/humansubjects](http://www.research.buffalo.edu/humansubjects).)

\* *Key study personnel* are those who are responsible for the design, conduct or reporting of the research.

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***I affirm the accuracy of this application, and I accept the responsibility for the conduct of this research, the supervision of human subjects, and maintenance of informed consent documentation as required by the IRB. This is to certify that the project identified above will be carried out as approved by the IRB, and will neither be modified nor carried out beyond the period approved below without express review and approval by the Board. I understand that responsibility for protecting human subjects is shared by the entire research team.***

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Signature: Principal Investigator

Date

**Protocol Approved      Protocol Disapproved**

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Signature: Board Chair/ Authorized Reviewer

Date

**Period of Approval:** \_\_\_\_\_

**Date of Next Review:** \_\_\_\_\_

**ADDENDUM**

**HUMAN SUBJECTS PROTECTION CERTIFICATION FORM**

**1. Education.** The following key personnel have completed a training program in the protection of human research subjects by:

- (1) reading and understanding the *Belmont Report - Ethical Principles and Guidelines for the Protection of Human Research Subjects*
- (2) reading and understanding the *Responsibilities of the Research Investigator* section (Part E.) of the UB Multiple Project Assurance of Compliance with Department of Health and Human Services Regulations for the Protection of Human Research Subjects and
- (3) completing one of the following web-based tutorials: NIH; UC-Irvine. The NIH's *Protection of Human Research Subjects* web-based training course was developed to orient NIH personnel to the special requirements associated with this research involving human subjects. UC-Irvine's *Research with Experimental Subjects, Human Experimentation* is composed of 20 sections with corresponding questions related to important aspects of the protection of human research subjects.

These documents and tutorials may be accessed through the Vice President for Research website ([www.research.buffalo.edu/humansubjects](http://www.research.buffalo.edu/humansubjects)).

**2. Financial Disclosure.** Each of the following key personnel also certify that they have on file with their respective Dean(s) a current and complete financial disclosure form (SUNY-2-UB).

**Study Title:** \_\_\_\_\_

**Key Personnel:** (type name)

**Signature:**

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**Principal Investigator**

**Institutional Official**

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