D'Youville

EXPEDITED REVIEW APPLICATION

Human Subjects Research: Institutional Review Board

IDENTIFYING INFORMATION

Researcher:_____ Telephone Number (____)_____
Email Address:_____ Program:_____
Address:_____

RESEARCH *IRB disposition letter will be electronically emailed.*

Research Director:_____
Research Title: _____

Please note: all applications must be written in the future tense. Exceptions include previous pilot work, CITI/NIH training, or creation of instruments (past tense), or instances when present tense makes sense (e.g. "I am a Professor of Nursing..."). Any recruitment, research to be conducted, etc. should be in the future tense.

CRITERIA *Check the box next to the criterion or criteria under which you are seeking expedited review.*

- ☐ 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 confidential surveys, interviews, oral histories, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies.
- ☐ 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). This includes the use of 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. It includes such procedures as weighing or testing sensory acuity, magnetic resonance imaging, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
- ☐ Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- ☐ 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).
- ☐ Collection of data from voice (such an investigation of speech defects), video, digital, or image recordings made for research purposes.
- ☐ Clinical studies of drugs or devices only when an IND or IDE are not required.
- ☐ Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adults, considering amounts drawn, and the age, weight, and health of the subjects.
- ☐ Prospective collection of biological specimens for research purposes by noninvasive means, such as hair and nail clippings in a non-disfiguring manner; deciduous or permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and subgingival dental plaque and calculus, provided the collection procedure is not invasive and the process is in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; or sputum collected after saline mist nebulization.
- ☐ Continuing review of research previously approved by the convened IRB.

DESCRIPTION *Summarize HOW the planned research meets the above criteria; attach more pages if needed.*

SIGNATURES *The proposed research may NOT begin until a formal Letter of IRB Approval has been received.*

The researcher's signature indicates that during all phases of the conduct of this research he or she will insure the practical application of the general ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, including respect for persons, beneficence, and justice. The researcher will respect the confidentiality of information obtained from or about subjects in this research and will protect all subjects' privacy by not disclosing any information in a way in which an individual may be identified.

The Graduate Research Director's signature indicates that all IRB application materials have been reviewed and approved by the Graduate Research Director prior to their submission to the IRB.

Researcher's Signature	Date	Graduate Research Director's Signature