SUNY Orange IRB

Human Subject Research

# EXPEDITED IRB REVIEW FORM

Research activities involving human subjects in the following categories may receive an expedited review by SUNY Orange Institutional Review Board. The College bears the responsibility for a determination based on notice provided by the principal investigator to the Institutional Review Board.

The following does NOT apply when (a) deception of subjects may be an element of the research; (b) subjects are under the age of eighteen; (c) the activity may expose the subject to discomfort or harassment beyond levels encountered in daily life; or (d) fetuses, pregnant women, human in vitro fertilization, children, or individuals involuntarily confined or detained in penal institutions are subjects of the activity.

EXCEPT FOR THE ABOVE EXCLUSIONS, the federally-approved Expedited Review qualifications are applicable to research activities that must incur no more than minimal risk for participants or represent a minor change in previously approved research that involves no additional risks to research participants, in accordance with HHS regulations 45 CFR 46.100. Examples of research activities reviewed on an expedited basis include:

**Research Categories for expedited review**

1. Research on medical devices for which 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.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation, permanent teeth if routine patient care indicates a need for extraction, excreta and external secretions (including sweat), 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, 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, mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings, 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.

Examples: 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, 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.

1. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE:This listing refers only to research that is not exempt.)
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. 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: This listing refers only to research that is not exempt.)
4. Minor changes in previously approved research.
5. Continuations of approval for previously approved no-risk research with no more than minor changes in procedures.

Expediting approval of an activity from review does not absolve the investigator(s) of the activity from ensuring that the welfare of subjects in the activity is protected and that methods used and information provided to gain subject consent are appropriate to the activity.

Questions about whether a research activity may qualify as expedited human subjects review can be directed to the Director, Grants Office or Chair of the Institutional Review Board.

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| \_\_\_\_ | **SUNY ORANGE IRB** | \_\_\_\_\_\_\_\_ |
| **Date Submitted** | **Human Subject Research** | **File Number** |

**Expedited IRB Review Form**

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**Title of Research Project**

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**Principal Investigator/Project Director Department Phone Extension Email address**

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**Co-investigator/Student Investigator Department Phone Extension Email address**

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| **Anticipated Funding Source:** |  |

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| --- | --- | --- | --- | --- |
| **Projected Duration of Research:** |  | **months** | **Projected Starting Date:** |  |

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| --- | --- |
| **Other organizations and/or agencies, if any, involved in the study:** |  |

**Research Categories for Expedited Review (see definitions on page one & two – check one box)**

 1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]  6 [ ]  7 [ ]  8 [ ]  9 [ ]

**Please submit the following documentation with this application**

1. **SUMMARY ABSTRACT: Please supply the following information below:**
* Purpose of the research
* Description of the participants, selection of subjects, how consent will be sought, how consent will be documented
* The location(s) of the project
* Describe the data to be collected, the procedures to be used for data collection, what is required of each subject
* Explain how confidentiality of data will be achieved , disposition of the data, who will have access to the data, how will confidentiality of data be maintained with publication
* Describe the risks to the subjects, describe how the data is monitored to insure the safety of the subjects, describe who will be responsible for collecting this information
* Describe the anticipated benefits of the research, the importance of knowledge expected from the results
* If any questionnaires, tests or other instruments are to be used include a brief description and a copy of such instrument, along with a verification of approval from the owner to use the instrument.
1. **A Human Subjects Research Consent Form**
2. **A copy of the Certificate of Completion for the NIH web –based training course, “Protecting Human Research Participants” from the investigators and research personnel**

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

* Any additions or changes in procedures in the protocol will be submitted to the IRB for written approval prior to these changes being implemented using the Revision to Research Form.
* Any adverse advents or problems connected with the use of human subjects once the project has begun must be communicated immediately to the IRB Chair using the Reporting an Adverse Event Form.
* The principal investigator is responsible for retaining informed consent documents for a period of three years after the project.
* The principal investigator assures the IRB that he/she will follow the principles, procedures and guidelines established in the present document and agrees to allow the IRB access to pertinent records or research.
* The principal investigator will present all information that will aid in evaluating the research for compliance with this policy.
* The principal investigator is responsible for the completing the periodic review using the Periodic Review & Continuing Research Form

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| Principal Investigator Signature |  | Co-Investigator/Student Signature (if appropriate) |  |
|  |  |  |  |
| **Signature of IRB Chair/Member:**  | **Date:** \_\_/\_\_/\_\_ |
| **Signature of IRB Member:** | **Date: \_\_/\_\_/\_\_** |
| **IRB Chair: Check 1 box:** | **[ ] Approved** | **[ ]  Approved with Stipulations** | **[ ]  Not Approved** |

 **[ ]  Deferred**

 **Periodic Review due –**

 **Comments from IRB Chairperson/Member:**