SUNY ORANGE IRB

Human Subject Research

# Exempt from Full IRB Review Form

## RESEARCH EXEMPT FROM COMMITTEE REVIEW

Research activities involving human subjects in the following categories may be exempt from full review by SUNY Institutional Review Board. The principal investigator/project director is authorized to make the first determination of eligibility for exemption; however, the College bears the responsibility for concurring in that determination based on notice provided by the principal investigator to the Institutional Review Board.

The following exemptions do 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 Categories of Exemption are:

1. Research conducted in established or commonly accepted educational settings involving normal educational practices, such as: (a) research on regular and special education instructional strategies; (b) research on the effectiveness of or the comparison among instructional techniques curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (a) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; or (b) any disclosure of the human subjects’ responses outside the research reasonably place the subjects at risk of criminal or civil liability or would be damaging to the subjects’ financial standing, employability, or reputation.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
4. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) public benefit or service programs; (b) procedures for obtaining benefits or services under those programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs.
5. Taste and food quality evaluation and consumer acceptance studies: (a) if wholesome foods without additives are consumed, or (b) if a food is consumed that contains a food ingredient or at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe by the U.S. Food and Drug Administration or approved by the U.S. Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempting 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 be exempt from human subjects review can be directed to the Chair of the Institutional Review Board.

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

**Exempt from Full IRB Review Form**

|  |
| --- |
|  |

**Title of Research Project**

|  |
| --- |
|  |

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

|  |
| --- |
|  |

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

|  |  |
| --- | --- |
| **Anticipated Funding Source:** |  |

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

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

**Exempt under code (see definitions on page one – check one)**  1 [ ]  2 [ ]  3 [ ]  4 [ ]  5 [ ]

1. **SUMMARY ABSTRACT: Please supply the following information below for justification of exemption: Description of the participants, purpose of project, the benefit of the project, the location(s) of the project, the procedures to be used for data collection, describe the data to be collected, what is required of each subject, risk to subjects, whether data will be confidential or anonymous, disposition of the data, who will have access to the data.**
2. **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 of the instrument.**
3. **A copy of the Certificate of Completion for the NIH web –based training course, “Protecting Human Research Participants” from all 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 events 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 completing the periodic review using the Periodic Review & Continuing Research Form

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

 **[ ]  Deferred**

**Periodic Review Due \_\_\_\_\_\_\_\_\_\_\_\_**

**Comments from IRB Chair/IRB Member:**