SUNY ORANGE IRB

 Human Subject Research

# FULL IRB REVIEW FORM

Research activities involving human subjects that involves greater than minimal risk, or for subjects requiring additional protection requires approval by a full SUNY Orange Institutional Review Board. The College bears the responsibility for determination based on notice provided by the principal investigator to the Institutional Review Board. Research that requires full committee review may include:

1. Research that potentially may expose subjects to greater than minimal risk
2. Non-exempt research that involves children, prisoners, pregnant women, human fetuses, neonates or other vulnerable populations
3. Research that involves experimental drugs or devices
4. Research that involves invasive procedures
5. Research that involves deception
6. Survey research that involves sensitive questions or information about sexual practice or illegal behavior
7. Survey research or interview that is likely to be stressful for the subject

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

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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 Full Review (see definitions on page one – check appropriate boxes)**

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

**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, how the data is monitored to insure the safety of the subjects, explain who is monitoring and reporting this data, whether any treatment or compensation is available if injury or discomfort occurs
* Describe additional safeguards that have been included in the study to protect the rights and welfare of children, prisoners, pregnant women, human fetuses, neonates, mentally disabled persons, or economically or educationally disadvantaged persons
* 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 to use the instrument. Examples would be permission from copywrite holder, current license to use software.
1. **A completed Human Subjects Research Consent Form with additional information**

Information must be added to the consent form indicating if any compensation is provided. and The consent form must indicate whether medical treatment is available when injury occurs and, if so, what they consist of, as well as where further information may be obtained.

1. **A copy of the Certificate of Completion for the NIH web –based training course, “Protecting Human Research Participants” from investigators and research personnel.**

**RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR:**

* Any additions or changes in procedures or 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 has ended.
* 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 and 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

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

 **[ ]  Deferred**

**Periodic Review due \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Comments from IRB Chairperson/Members:**