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| OCC logo in color | Orange Coast College |

# External Research Request Application | Research Project Involving Human Subjects

## Applicant Information

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| **Date:** |  | | | |  | | | | |  | | | |  | | | |  | |
| **Project Title:** | |  | | | | | | | | | | | | | | | | | |
| **Principal Investigator:** | | | |  | | | | | | | |  | | | | | | |  |
|  | | | | Last | | | | | | | | First | | | | | | | M.I. |
| **Organization:** | | |  | | | | | | | | | | | | | | | | |
|  | | | Name of Organization or Institution; if internal, name of Program/Department | | | | | | | | | | | | | | | | |
|  | | |  | | | | | | | | | | | |  | |  | | |
|  | | | City | | | | | | | | | | | | State | | Zip Code | | |
| **Phone:** | |  | | | | | | | **Email:** | |  | | | | | | | | |
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| **Timeline:** | | | | | | From: | |  | | | | | To: | | |  | | | |
| Chair or Project support name/email: | | | | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |  | | | | |  | | |  | | | |
| **Other Researchers /Personnel Involved in Project:** | | | | | | |  | | | | | | | | | | | | |
|  | | | | | | | *Names and relationship to study.* | | | | | | | | | | | | |

## Human Subjects Considerations

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| 1. Check each of the following that are included in your research (may require review): | |
|  | Survey or observational research in which the subject’s responses or behaviors, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability |
|  | Survey or observational research that deals with sensitive aspects of the subject’s own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.\* |
|  | Research involving the collection or study of existing data, documents, records, pathological specimen, or diagnostic specimens which are not publicly available OR from which information is recorded by the investigator in such a manner that subjects can be identified.\* |
|  | Research involving interviews, questionnaires, or observations that include college-wide, specific constituent/special population targets or sensitive information and triggering content.\* |
|  | Research involving tests not normally used in educational or clinical settings.\* |
|  | Specify: |
|  | Other |
|  | Specify: |

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| Special areas that require review: | | | |
|  | Research involving strenuous exercise by the subjects.\* |  | Research involving voice and video recordings.\* |
|  | Research involving noninvasive procedure routinely used in clinical practice. |  | Research that will involve manipulating the subject’s behavior in a way that is stressful to them.\* |
|  | Research involving minors (under 18).\* |  | Research involving subjects institutionalized as mentally disabled.\* |
|  | Research involving prisoners.\* |  |  |

\*These procedures generally require gathering Informed Consent from all participants. These items are likely to be reviewed if circumstances apply. Projects involving minors generally require Parental Permission and Child Assent.

## Project Summary

1. Summary/Abstract: Provide 100-120 word abstract stating the objectives and specific aims of the research. Describe concisely the research design and methods for achieving these goals.

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| **Abstract:** |  |

## Project Information

1. **IRB Approval.** *For graduate studies or dissertations.*

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| **Have you received IRB approval from your institution?** | | |  | Yes |  | | No | |
| **If yes, state duration of approval:** | From: |  | | | | To: | |  |
|  | | | | | | | | |
| **If no, please attach a draft copy of your institution’s unapproved IRB application in its complete state.** | Send | | | | | | | |
|  | *For example, have you submitted an IRB application to your institution? Do you have a draft of your application? Has your research proposal been approved by your advisor? Etc.* | | | | | | | |

* Attach the IRB approval from the granting institution. Or if approval has not yet been attained, attach any drafts or other supporting documentation. **NOTE: Draft methodology, research instruments, and recruitment/informed consent protocols are required to be considered for provisional approval.**
* Research projects submitted without official IRB approval from their granting institution are only eligible for provisional approval from Orange Coast College, which will be contingent on the researcher’s final approval from their institution’s IRB.

1. **Project Description**. Describe the project in language that can be understood by non-researchers (*no jargon or abbreviations)*. Include clearly stated major research questions, hypotheses, population selection (inclusion and exclusion criteria), recruitment, study procedures and timetable, sample size determination, outcome evaluation (i.e., measures, statistical analysis plan), safety review, criteria for stopping, and anticipated benefits.

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| **Description/ Protocol:** |  |

1. Participant Information

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| **No. of participants:** | |  | | | **Begin date**: |  | | **End Date**: |  |
| *Indicate total number and number per category (e.g., males/ females, etc.)* | | | | | *Indicate dates human subjects will be involved in the study.* | | | | |
| Est. Time Commitment for Participants: | | |  | Compensation for Participants: | | |  | | |
|  | | |  |  | | |  | | |
| \*\*Note regarding raffle prizes as compensation: | | | *A California court ruling has determined that drawing winners from among study participants constitutes holding a lottery/raffle. As such, one cannot restrict the pool of winners only to those who have participated in your study. Everyone must be given an opportunity to enter the raffle/lottery irrespective of whether they completed the study or were invited to complete the study. Thus, you must have a mechanism for anyone to enter the raffle/lottery. For example, you must include a message in your recruitment materials to participants indicating they may enter the prize drawing without completion of the study with instructions on how to do so.* | | | | | | |
|  | | |  | | | | | | |
| Recruitment Protocol: |  | | | | | | | | |
|  | *Describe how subjects will be recruited for participation in this research project. Include details on how participants will be identified and who will be responsible for identifying eligible participants. Attach copies of flyers, advertisements, emails, etc.* | | | | | | | | |

1. Risks. Describe potential risks to the study participants and/or to Orange Coast College. Include physical, psychological, emotional, privacy, and institutional reputation issues. Outline what support will be available to participants experiencing undesirable consequences of participations. ALL RESEARCH HAS SOME TYPE OF RISK – DO NOT STATE “NO RISK’

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| **Risk Classification**:  *Choose one* | |  | Minimal Risk |  | Greater than Minimal Risk |  | Unknown/Unsure |
| **Describe risks:** |  | | | | | | |
|  | *Please justify why category is appropriate. Describe all of the risks in detail and assess their seriousness.* | | | | | | |
| **Procedure to minimize risks:** |  | | | | | | |
|  | *What precaution have been taken to minimize risks listed above and what is the likely effectiveness of those precautions? Include provisions to protect confidentiality of data, subjects and institutions involved. For research involving more than minimal risk, describe how the research will be monitored to ensure subject safety.* | | | | | | |

1. Benefits. Describe potential benefits to the study participants, institution, or the field of study. THERE MUST BE SOME TYPE OF BENEFIT TO SOME PARTY OR FIELD OF STUDY. DO NOT RESPOND ‘NO BENEFIT’

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| **Direct benefits:** |  |
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| **Indirect benefits**: |  |

## Required OCC Resources

* **OCC Resources:** Indicate what resources and/or data are being requested from Orange Coast College. Please be as specific as possible.Attach copies of any grant research plan/specific aims, survey instruments, interview scripts, telephone scripts, etc.

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| **Resources requested:** |  |

1. **Justification for requesting OCC resources.** Please justify why you are requesting Orange Coast College’s participation for this project.

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| **Justification for resources:** |  |

## Attachment Checklist

Please ensure all documents in this list are attached to the request. The request will not be reviewed until all documents are received.

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|  | Research instruments (e.g., survey form, interview protocol, etc.) |
|  | Recruitment materials (e.g., flyers, advertisements, emails, etc.) |
|  | IRB approval from granting institution (for graduate students) |
|  | Informed consent form for participants |

## Assurance and Signature

The undersigned assures that the protocols involving human participants described in this application are complete and accurate, and are consistent with applicable protocols submitted to other external sources. All protocol activities will be performed in accordance with College, State, and Federal regulations. No activities involving the use of human participants will be initiated without prior review and approval by Orange Coast College.

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| Name: |  | Signature: |  | Date: |  |