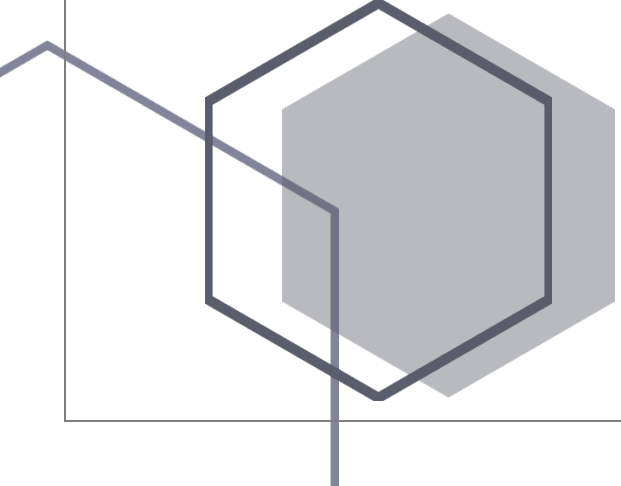




ORANGE COAST COLLEGE  
PROCESS AND GUIDELINES  
FOR CONDUCTING RESEARCH



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## OVERVIEW OF THE RESEARCH REVIEW SUBCOMMITTEE

The function of the Research Review Subcommittee at Orange Coast College is to ensure the well-being of participants who may volunteer for or participate in research studies or investigative inquiries. The Research Review Subcommittee assists researchers and members of the institution to:

- Comply with state and federal regulations that may apply to their studies or investigative inquiries
- Protect them from potential liability to which they may be exposed
- Protect Orange Coast College from any liability to which it may be exposed.

The Subcommittee is composed of three members of the Institutional Effectiveness Committee—an institutional researcher, a faculty member, and one additional member. All members of the Subcommittee shall have training in applied and theoretical research, understanding of state and federal guidelines protecting human subjects in an educational setting, and have completed human subjects research ethics training certification.

**Important:** Orange Coast College does not have a federally approved Institutional Review Board. As such, any approvals only allows for conducting this research project at this campus, and may not specifically meet Institutional Review Board requirements for publications or conference presentations.

### Purpose and Scope of the Research Review Subcommittee

At Orange Coast College, the main purpose of the Research Review Subcommittee is the protection of faculty, staff, students and management when research is being conducted at the institution and to assist with compliance with state and federal laws. This may be internal research directly related to the college or the district, research conducted on the institution by external entities, or research conducted by graduate students (district or non-district employees) seeking to fulfill degree requirements. Most internal research related to an employee's professional duties at Orange Coast College is exempt and does not require research review and approval. For instance, SLO assessment, in most cases, does not require research review. Orange Coast College's research guidelines delineates between exempt and non-exempt research and details proper protocol for research requiring research review and approval.

Additionally, OCC's Research Review Subcommittee ensures—both in advance and by periodic review—that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, the subcommittee uses a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

**Note regarding student research:** These guidelines do not regulate student research under faculty supervision. It is the responsibility of the faculty to ensure that all student research projects are ethical and follow established protocols for protection of human subjects.

### Guiding Principles of the Research Review Subcommittee

Under U.S. Department of Health and Human Services Office of Human Research Protections, an Institutional Review Board (IRB) is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. Orange Coast College does not have a federally approved IRB. As such, approvals by the Research Review Subcommittee only allows for conducting research projects at this campus, and does not meet requirements for publication or conference presentations that require IRB approval. However, the Subcommittee uses IRB guidelines to inform the review process.

The Belmont Report is the seminal work in establishing protocol for protection of human subjects. This report identifies three guiding principles that drive the Orange Coast College review process. The Belmont Report in its entirety can be accessed from [U.S. Office of Human Protections website](https://www.fda.gov/oc/ohrt/belmont-report).

1. **Respect for Persons:** Researchers should obtain the informed consent of all human subjects invited to participate in research. The consent process should include giving subjects full and understandable information about the research and provide a clear guarantee of the subjects' voluntary participation.
2. **Concern for the Well-Being of Subjects:** The risk of harm to subjects should be minimized. The overall benefits to the subjects and the importance of the knowledge to be gained should outweigh the remaining risk of harm to the subject as to justify a decision to allow this risk.
3. **Justice:** The selection of human subjects should be fair and equal. The risks and benefits of research should be distributed among subjects in a fair and equitable manner, with particular concern for subjects whose personal status or condition (such as children, prisoners, and/or patients) places them in a vulnerable or dependent status.

## RESEARCH GUIDELINES

Research projects that gather data from human subjects should undergo, at least, some review by a faculty member, administration, or department to determine if the activity requires research review. Thus, all members of the campus community who are involved in collecting data from the college must review their research according to these guidelines and submit their research proposal(s) for review if deemed necessary by the guidelines, even if the research is being conducted off campus. Additionally, members outside the campus community who wish to use or collect data from the campus or its students are required to undergo research review.

The Office of Institutional Effectiveness is excluded from research review for routine Institutional Research activities, provided all data collected is reported without reference to individuals. The Office of Institutional Effectiveness will coordinate with the campus Custodian of Records if there are any questions with regard to FERPA (Family Education Right to Privacy Act).

### No Application Review Required

Research in which Orange Coast College faculty, staff, and management are collecting data related to their professional role and in accordance with [FERPA requirements](#) is not subject to formal review. This research is applicable to archival research involving the collection or study of standard institutional data (such as, grades, success rates or demographics), documents, or records, 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. Examples of research not needing formal review include classroom- or job-related activities and/or observations that do not compromise anonymity, FERPA regulations, or have the potential for either physical or psychological harm. (Please see next section for further information on research which would compromise these things.)

Research which does not require formal review also includes observation of behaviors or processes within the parameters of professional practice such as (a) classroom observations of everyday conduct, (b) use of educational tests or assessment tools, (c) survey procedures, or (d) observations of public behavior. Most types of student learning outcomes assessment, program review studies, and program evaluations conducted by campus personnel fall under research not needing formal review. **However, formal review is required if any information has the potential of compromising subject anonymity or the information to be recorded could potentially put**

**the subjects at risk or hold the institution at risk of liability.** Additionally, formal review may be required if the research would impact a person's financial standing, employability, or reputation in terms of potentially putting individual subjects at risk of civil or criminal liability.

Although internal Orange Coast College surveys generally do not require formal review, there are some instances in which surveys must be reviewed by the Research Review Subcommittee (see below).

## Application Review Required

Collection of data requiring formal review is not permitted before approval from the Research Review Subcommittee. Principal investigators must submit a research request application to the college's Dean of Research, Planning, and Institutional Effectiveness.

Any research that requires any direct interaction with participants (such as face-to-face interviews or experiments) must go through formal research review. This excludes focus groups or interviews in the context of program evaluation, program review, or SLO/AUO assessment as long as the data will be collected and reported without reference to individual participants. Thirty (30) to sixty (60) days may be required for processing of a completed application. Please see Subcommittee calendar on the [Institutional Effectiveness website](#) for dates and deadlines.

At the discretion of Dean of Research, Planning, and Institutional Effectiveness and/or OCC's President's Cabinet, institutional priorities may be expedited and may only require evaluation from one member of the Research Review Subcommittee.

### EXTERNAL APPLICANTS

All research conducted on the institution by external entities or research conducted by graduate students (district or non-district employees) seeking to fulfill degree requirements requires formal review. The principal investigator must submit a completed [External Research Request Application](#) form a minimum of 60 days prior to the anticipated start of the research activities. The principal investigator will be notified within 14 days with a status update and a request to submit further information if required.

### INTERNAL APPLICANTS

Internal research directly related to the college or the district requires formal review is any of the following apply:

- College-wide surveys to all employees or students
- Surveys that target a specific constituent or special population (e.g., veteran students, part-time faculty, etc.)
- Surveys that inquire about sensitive information or would place the individual at risk of criminal or civil liability or be damaging to the subject's financial standing or employability within the district.

Internal OCC research (e.g., research for college operations, etc.) that requires formal review must submit a completed [Internal Research Request Application](#) form a minimum of 14 days to the anticipated start of the research activities. All internal requests require the signature of the Supervising Dean or Manager and Vice President of the area. Additional approval may be requested, depending on the nature of the proposal.

## EXTERNAL RESEARCH RESPONSIBILITIES

The principal investigator is responsible for submitting completed research requests with all supporting documentation and for completing revisions and/or providing additional documents as requested. These revisions and additional supporting documents must be forwarded by the principal investigator to the Chair of the Research Review Subcommittee. Research request submissions with incomplete documents or with revisions required will be denied and sent back to the principal investigator. The researcher may resubmit the application with supporting documents and/or revisions and the review process will resume, but may take an additional 30 days for processing from the date the revisions were submitted. Please note that there is a two submission limit (initial submission (no edits found), and a second submission (with edits) ). Also please note that Coast Colleges employees and affiliates/partners of Coast have priority administrative approval/decision of their application over external requests.

Direct written official communication will be provided to confirm the receipt of the Research Request Application Form and then once a decision has been made on the submission. The researcher may contact the Dean of Research, Planning, and Institutional Effectiveness at [sssterner@occ.cccd.edu](mailto:sssterner@occ.cccd.edu) if they have not received a decision within 30 days to check that status of their request. External researchers are responsible for:

1. Completing and assuring that the Research Request Application is complete and accurate, including attaching all required documents:
  - 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
2. Providing revisions and additional supporting documents to the Research Review Subcommittee as requested.
3. Providing all the necessary detail about the study in the application, including specifics about methodology as well as how the data will be collected or what institutional data are being requested.
4. Sending any questions after submission to the Dean of Research, Planning, and Institutional Effectiveness at [sssterner@occ.cccd.edu](mailto:sssterner@occ.cccd.edu). (NOTE: Thirty (30) days may be required for processing of a completed application.)
5. Reporting any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than anticipated, as well as any event(s) that prompt the temporary or permanent suspension of the research project (if research project is approved). Report all to Sheri Sterner @ [sssterner@occ.cccd.edu](mailto:sssterner@occ.cccd.edu).
6. Once the research is complete OCC requests the researcher to submit a copy of their Power Point and/or Dissertation/Project to the department of Institutional Effectiveness @ [occresearch@occ.cccd.edu](mailto:occresearch@occ.cccd.edu)
7. Submitting a Research Request Renewal Form, when applicable, before the expiration of the project's approval if the researcher wishes to conduct research at Orange Coast College past the project's expiration date. If renewed approval is not sought out or approved, all research project activities must stop until a new approval letter is received. *No exceptions.*

Additional required forms mentioned above will be sent directly to the principal investigator when are due.

## APPENDIX A: OCC RESEARCH RESOURCES

### **OCC Institutional Effectiveness Website**

[http://www.orangecoastcollege.edu/about\\_occ/Institutional\\_Effectiveness/Pages/default.aspx](http://www.orangecoastcollege.edu/about_occ/Institutional_Effectiveness/Pages/default.aspx)

#### **Forms:**

[External Research Request Application – Research Project Involving Human Subjects](#)

[Internal Research Request Application –Research Project Involving Human Subjects](#)

Adverse Effects Report (*forthcoming*)

Research Request Renewal (*forthcoming*)

Final Report of Findings (*forthcoming*)

### **Orange Coast College FERPA Policy**

[http://www.orangecoastcollege.edu/enrollment/Pages/FERPA-\(Family-Educational-Right-to-Privacy-Act.aspx](http://www.orangecoastcollege.edu/enrollment/Pages/FERPA-(Family-Educational-Right-to-Privacy-Act.aspx)

## APPENDIX B: EXTERNAL RESEARCH ETHICS RESOURCES

**The Belmont Report:** Ethical Principles and Guidelines for the protection of human subjects of research. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) <http://ohsr.od.nih.gov/guidelines/belmont.html>

### **Department of Health and Human Services (DHHS)**

DHHS Code of Federal Regulations 45 CFR 46

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>

Exempt Categories

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>

Expedited Categories

<http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm>

### **Family Educational Rights and Privacy Act (FERPA)**

FERPA Homepage

<http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

Title34 CFR 99

<http://www2.ed.gov/policy/gen/guid/fpco/pdf/ferparegs.pdf>

### **Food and Drug Administration (FDA)**

Title 21 CFR 50

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50>

Title 21 CFR 56

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56>

### **Office of Human Protections (OHRP)**

OHRP Home Page

<http://www.hhs.gov/ohrp/>

OHRP Glossary of Terms

[http://www.hhs.gov/ohrp/irb/irb\\_glossary.htm](http://www.hhs.gov/ohrp/irb/irb_glossary.htm)



***This report was prepared by the Office of Institutional Effectiveness at Orange Coast College.***

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