Yosemite Community College District Policies and Administrative Procedures **No. 4-8074**

Policy

4-8074 Human Subject Research Protection

The District recognizes the importance of protecting research subjects and their rights to confidentiality as required by law and authorizes each college to develop its own procedures.

The Chancellor shall ensure that the colleges establish procedures to safeguard the rights and welfare of human participants involved in research and other activities related to research projects conducted within the District. Research involving human participants conducted within the District must be reviewed and approved prior to the gathering of data.

Cross References (see also):
YCCD Policy 2510 – Participation in Local Decision-Making
YCCD Policy 7-8049 – Academic Senates

References:
45 Code of Federal Regulations 46

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Administrative Procedure

4-8074 Human Subject Research Protection

Modesto Junior College Procedures

The Modesto Junior College Institutional Review Board Investigator Guidelines for Research Using Human Subjects may be found online.

Columbia College Procedures

The Regulations

According to Federal Policy (45 CFR 46), all research involving human participants must be requested, reviewed and approved prior to the project's or activity's start date, and before any data is gathered or activities commence.

The Process Overview

Project proposal requests that involve research on human subjects are to be submitted to the Columbia College Research Office by the project's Principal Investigator (PI). The Research Office will review the request and determine where the request falls within three risk or sensitivity levels. (See p.5, *Procedures for Approval, Step Two: The Levels of Review*)

Depending on the project's level of sensitivity or risk, an approval may be determined quickly, or if highly sensitive or of substantial risk, involve a full Human Subjects Research Committee (HSRC) review. Per CFR regulations, no research project may begin or commence prior to an authorized, written approval. This means that no college faculty, staff or administrator may allow a research project to begin unless the PI has received an official, written approval.

The following provides an overview of the procedure for submitting a research proposal request, and the approval process. The following is also outlined in greater detail in Section II, Review Procedures that follow. Basically, there are three levels of risk that, once determined, will dictate the level of review and the time needed to complete the process.

1. **Minimal or No Risk –** Typically, these research proposals need review and approval through the Research Office plus the approval from the appropriate administrator for the project. These are considered "exempt" as they will meet exempted criteria, and thus can be handled quickly as they involve fewer staff. Estimated time to allow for this process: Two to four weeks. (See Appendix, p. A1)

2. **Potential to Moderate Risk** – These research proposals involve more scrutiny and must therefore be reviewed by the HSRC in addition to the Research Office and an administrator. Estimated time to allow for this process: Three to up to six months. *Be advised that a project referred for a full HSRC review could be lengthy depending on the project and the documentation needed to complete the approval process.*

3. **Obvious to Substantial Risk** – Approval for this level of research proposal is very difficult to attain. Be prepared to submit substantial documentation regarding safeguards for participants, staff and the institution as requested or required by the HSRC. Estimated time to allow for this process: Three to six months. *Please note: Approvals at this risk level are highly unlikely to be approved as they involve risks that may be difficult to impossible for the institution to justify.*

Important Note: Some research projects will involve other institution's Institutional Research Boards (IRBs) and their approval process such as thesis or graduate study projects. Be advised that **approval from an outside institution's IRB does not release Columbia College from reviewing and approving research that will be conducted on campus or with Columbia College students or their data.**

Another Important Note: **Unless mandated by federal or state law, externally funded or externally sanctioned research may not be exempt from these policies and procedures.** Please check with the Research Office before agreeing to proceed with any research project for an external entity.

I. General Guidelines

By regulations, we must ensure that no one grants permission to begin a research project which has not been approved through the Columbia College *Human Subject Research Protection Policy and Procedures* review process.

Depending on the research project proposal's level of risk, a request can be reviewed and approved quickly, or can require a lengthier process if referred for a full HSRC review.

Regarding the Human Subjects Research Committee:

If the project requires a full Human Subjects Research Committee (HSRC) review, the members will be recommended through appropriate college constituent groups and appointed by the President or designee. The committee will be comprised of members with knowledge or expertise appropriate to the research being conducted, the subjects involved, and the institution. For example, a committee should represent those with a thorough knowledge of accepted research practices and/or the subject area of the research, advocacy for student concerns and student involvement in the research, Columbia College (and possibly YCCD) governance, and possibly legal counsel. The Principal Investigator (PI) along with each of the committee members will receive training for, and a copy of the policy and procedures contained herein. Additionally, the Columbia College *Human Subject Research Protection Policy and Procedures* with supporting materials will be made available through the Research Office in both hard and electronic format.

The HSRC members will be recommended through the appropriate constituent groups of college faculty, classified staff, students and administration. An *example* of the makeup of a committee could be:

- Faculty (other than the PI) who may be familiar with the subject or area to be researched,
- An administrator having oversight over the department of the project,
- A student representative or advocate,
- Appointments as directed by Administrative Council,
- Institutional researcher(s), and possibly

- Legal counsel

The Research Office will provide training and updates to the designated Human Subjects Research Committee members, the PI(s), and any project assistants. The College President or Administrative Council will ensure that the faculty and staff are made aware of the *Human Subject Research Protection* Board Policy 4-8074, and of the Columbia College *Human Subject Research Protection Policy and Procedures*.

II. Procedures for Approval

In accordance with the Federal Policy for the Protection of Human Subjects (45 CFR 46), **all research involving human subjects is subject to review and must be approved prior to the gathering of any data, including those projects that may fall within the federal exempt categories below.**

The procedure as detailed herein is a process that reviews proposed research projects that are to be conducted on the campus, and/or that will involve Columbia College students, staff and their information or data. The review is to be conducted prior to the commencement of the project's activities. The process could involve a minimal to comprehensive committee review depending on the level of risk or sensitivity for participants, the PI(s), and/or the institution.

Time required to complete reviews

Please be advised that proposals involving no, or even minimal risk should allow at least two to four weeks for the approval process prior to the proposed project's start date. For projects involving moderate risks, a minimum of three months lead time is strongly recommended. Why? By law the College cannot allow research projects to begin prior to the project's approval. Even though the research has been scheduled, without an approval it will not be permitted until the approval process is complete.

When in doubt, check with the Research Office. In most cases, the Research Office will be able to determine the anticipated level of risk for the project, the review process that may be likely and what it will entail, and will provide an estimate (with adequate information) as to how long it might take.

***Step One*: The Research Request**

The PI will submit the research project request to the Columbia College Research Office. A "Research Request Form" is available from the Research Office to help guide the requestor if needed. Requests should include the following components:

a) The project's purpose and proposed timeline,
b) The data needed or that will be collected,
c) The research methodology/design,
d) An "informed consent" letter and the process for distribution,
e) The means to be used to ensure voluntary participation,
f) The means to be used to ensure participant confidentiality, and
g) The measures that will be taken to protect individuals' data both during and after the conclusion of the project.

An "Informed Consent" information document (this is typically a letter) must be developed before a proposal is considered complete or can be approved. Ideally, this should be submitted as part of the proposal's documentation; however, it may be completed with the help of the Research Office. The project cannot be approved however, until the entire project proposal packet is complete including informed consent. The required contents of an informed consent letter/form are included in the Appendices of this document. Assistance throughout the project proposal process is available through the Research Office if needed.

***Step Two*: Levels of Review**

After the proposed research project has been submitted to the Research Office, the determination as to possible risk level (minimal, moderate, or substantial) will determine whether the project falls within the lowest of the three levels as outlined below, and can be approved with a simple review. The PI may wish to consider whether the project can be revised to attain a lower risk level. If not, the request will be forwarded to the Human Subjects Research Committee for their review and determination.

The Research Office will provide feedback and forward any written notifications of the outcome of the review(s) to the PI.

Levels of Risk

- **Minimal or No Risk** (See p. A1, Appendices: *The Lawyers' View of the Criteria for Exempted Research Involving Human Subjects*)

Projects determined to be "exempt" pose no risk to the human participants involved, the PI or assistants, or to the institution, its officers or staff. Examples include: research that does not identify individuals (such as aggregated/summarized data only), and has the capability to wholly protect the participants' anonymity and/or personal information (such as anonymous surveys), and provides participants with an option of participating or opting out of the research project or activity(ies) at any time and without consequence or personal detriment (per Informed Consent criteria).

Depending on the scope of the exempted research project, reviews at this level will generally be approved quickly—within two to four weeks.

- Project proposals that meet exempt criteria, but that have minor concerns or insufficiencies such as an incomplete Informed Consent letter, will be returned to the Principal Investigator for revisions and when complete and acceptable, will be approved.
- The Research Office will forward written notification to the PI regarding the results of the review with the approval.
- Once approved, should circumstances necessitate a change or changes to the research methodology, the informed consent, the data components, or the content of the research or activities, the project must stop and an updated proposal request must be submitted to the Research Office. Approval must be received prior to resuming the project.

- **Potential to Moderate Risk:**

Projects or research activities that pose potential to moderate risk to participants and/or the institution require additional steps to ensure the security and protection of individuals, their personal information, their participation in the project, and to minimize or eliminate risk to the institution. In addition to the proposal request components listed in Step One above, the PI must be ready to provide evidence as to how the project will ensure adequate protections will minimize risk.

Research projects of a moderate risk level will be referred to a full HSRC review and a determination of approval/denial will be made. The HSRC may request additional documentation from the PI before a decision can be reached.

The approval process for moderate risk projects may require substantial lead time to ensure that all documentation is available and that the HSRC can be assembled and meet. To allow enough time for sufficient review and discussion, and depending on committee members' availability, allow a lead time of between three to six months for the review process to be completed.

  - The PI will be ready to supply the required information as stated above plus any additional documentation requested by an administrator or by the HSRC. This could include attending committee meetings if requested.
  - Plans for, and contents of announcements, reports of project progress or final results, publications, public announcements, or other disseminated results from the research must be reviewed and approved by the HSRC prior to dissemination, publication or distribution.
  - The PI will be responsible for securely archiving the outcomes of the project including data collection or if this is not possible, may forward them to the Research Office for archiving. By law, documents must be archived for a minimum of three years.
  - If changes occur to the project after it has been approved that alter the research methodology, the informed consent, the data component, or the research activities, the project must stop and an updated project proposal request must be submitted for review, and must receive approval prior to resuming the project.

- **Obvious to Substantial Risk**

As a general rule, projects involving substantial risk to the participants or the institution will not likely be approved unless revised to a lower risk level. Examples of research projects that fall within this level include: publicizing highly sensitive or potentially damaging personal information or information that could be harmfully used against an individual or groups of individuals; participation in physically or psychologically threatening behaviors or scenarios; activities that constitute acts of hate or that involve illegal activities, or that would open the institution to liability(ies). In the event the request falls within this sensitivity level and the PI does not wish to revise the project the proposal must receive a full the HSRC review and possibly legal review.

  - Research proposals and requests that have been determined to pose an obvious to substantial risk to participants or the institution are unlikely to receive approval and will most likely be denied. If this happens, a special request or final appeal can be

sought from the Administrative Council. The Council will determine the final approval or denial for the project.

- The PI will be ready to supply any and all information requested by the Committee for making their determination, including the possibility of attending a committee meeting if requested.

Step Three: **The Appeal Process**

If the research project was disapproved, the PI may submit an appeal to the College Administrative Council one time. The PI will:

- Submit a written appeal to the Administrative Council with supporting documentation as to why the proposal should be reconsidered.
- Supply any supporting documentation as requested by the Administrative Council.
- Understand that the Administrative Council reserves the right to make the determination to approve, return for revision, request additional information, or reconvene the HSRC.

The decision following the appeal will be final.

Step Four: Project Completion and Reporting

Upon completion of the project, the PI will forward the project's final reports and findings, and all lists of publications or public access sites. The PI will be responsible for securely filing/archiving any working documentation, completed surveys, signed consent forms, etc., for a period of three years. If this is not possible, the project's documentation may be forwarded to the Research Office for archiving.

III. The Informed Consent (required)

"Informed consent" is required for all but classroom based research by law. It's also common sense and a good idea to inform the participants in any case…for any reason. Contact the Research Office for more information, the regulations (e.g., CFR 46) or for samples of informed consent letters.

Informed consent is a written preface to the research activity, survey or data gathering that provides full disclosure about the research, what will be expected from the participant, and how the information or data will be used. Briefly, informed consent provides the potential participant with all information relative to making an "informed" decision about their participation in the project before the activity begins. It is also a form that the participant can use as a reference (whether they participate or not) that includes the contact information for the parties who have oversight for the research. For a complete legal description of the contents for informed consent, please see the Appendices p. A2, *Content of an Informed Consent Letter*.

- All informed consent documentation, notices or letters must be reviewed and approved along with the project's proposal prior to starting the proposed project or activity.

Any proposed change to, amendment of, or addendum previously approved must be resubmitted for review before the change can be implemented or used. The Research Office can assist with this, or refer the request to the Human Subjects Research Committee in the case of moderate to substantial risk

projects.

IV. Unexpected Changes to Projects, Risk Level or Consent Forms

When unexpected change occurs, the PI must stop the research activities, and notify the Research Office as soon as possible to provide the details for the change, amendment, or activity affected:

1. A detailed description of changes needed for altering a research design, methodology, or data collection;
2. An estimate of the change to the risk level for the participants, the institution, or the PI or project's assistants;
3. The revisions to be made to the Informed Consent;
4. The change(s) in participant recruiting (where applicable and see below); and/or
5. The project will involve minors (typically disallowed).

Principal investigators are required to report unexpected findings involving risks, and to report any occurrence of an unexpected nature to the Research Office. Project activities must stop, and notification made without delay. Failure to report unexpected findings or risk will be cause for immediate suspension or termination of the project.

The Research Office, Administrative Council, and/or the Human Subjects Research Committee is responsible for determining whether a proposed change, amendment, or addendum will increase participant sensitivity or risk.

V. Advertising for or Recruiting Participants

Advertising or recruiting for prospective volunteers or participants must receive prior approval through the Research Office. No incentives or statements that appear coercive will be permitted. Any potential risks must be cited. Availability of remuneration must be commensurate with the time and inconvenience to the participants and must not appear to be, or perceived as coercive.

VI. Procedures for Review of Reoccurring/Ongoing Research Projects

Periodic review of a previously approved, long-term research project is to be conducted every three years to ensure that the rights and welfare of human participants and the institution continue to be protected. Project approvals cover a maximum time span of three years. Even if no substantive changes are, or will be made, the project must be resubmitted through the approval process by the end of the third year to ensure continuity.

The principal investigator will be responsible to submit the required paperwork (See: *II. Procedures for Approval, Step One*) for reoccurring/ongoing project(s). Please allow three months lead time prior to the end of the project's third year to complete the renewal process.

VII. Research involving minors as participants

Research involving minors is generally prohibited, but in some cases can be allowed if pre-authorized and parental consent can be obtained. Under no circumstances will research involving minors be allowed

without prior, pre-authorized approval. Contact the Research Office for details.

The Lawyers' View of the Criteria for Exempted Research Involving Human Subjects
Federal Policy for the Protection of Human Subjects (45 CFR 46.116)

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants, and (ii) any disclosure of the human participant's responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph 2 (above) of this section, if: (i) the human participants are elected or appointed public officials or candidates for public office, or (ii) Federal Statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, if these sources are publicly available or if the information is recorded by the principal investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Contents of an Informed Consent Letter
Any known risks, benefits, and/or uncertainties for participation must be disclosed to the participant before they engage in the research activity, with an explanation as to what is expected. They must also be informed of their opportunity to opt out of the research study or experiment at any time without any negative effects, penalties, or threats or denial of benefits in any way for nonparticipation.

Per regulations, the following information must be conveyed to each participant prior to participation:

1. Statements about the study that clearly outlines the reasons for the research, an explanation of how the results of the research will be used, the expected duration of the time for participation, a description of any procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the participant;
3. A description of any benefits to the participant or to others which may reasonably be expected from the research;
4. Where applicable, a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant;
5. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;

6. For research involving more than minimal risk, an explanation as to whether any compensation is available, or an explanation as to whether any medical treatments are available if injury occurs; and if so, what they will consist of, and/or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research, and the research participant's rights where applicable, and whom to contact in the event of a research-related injury to the participant;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
9. A line for indication that the participant is 18 years of age or older or similar way to identify age; and
10. A line for the signature of the participant or legal representative, or a means to electronically verify voluntary participation (except in the case for research with an approved waiver from the Research Office and/or HSRC indicating the written consent is not required).

Reference HHS regulations: 45 CFR 46, 45 CFR 46.116(a), (b) or (d), 45 CFR 46.117

Informed Consent Information (continued)

The Research Office and/or Human Subjects Research Committee may require additional information beyond the basic elements here to be given to participants during the informed consent process when, in the Research Office and/or Human Subjects Research Committee's judgment, the additional information would ensure the protection of the rights and welfare of the participants (45 CFR 46.109(b)).

Additionally, the consent form must be free of exculpatory language where the participant waives or appears to waive any legal rights or releases or appears to release the principal investigator, the sponsor, the institution or its agents from liability for negligence. The content of a consent form must explicitly state that by signing the form the participant does not waive any of his or her rights (e.g., for personal injury).

Unless the HSRC, Research Office and/or Human Subjects Research Committee waives the requirement for an informed consent document, the safe storage of the signed consent forms is the sole responsibility of the PI. These must be retained in a secure, confidential file for no less than three years after completion of the research (45 CFR 46.115(b)).

For more information please contact the Columbia College Research Office, (209) 588-5389.

References:
45 Code of Federal Regulations 46

Procedure Last Revised: ~~September 12, 2012,~~ August 9, 2017
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