



Pima County Community College District Administrative Procedure

<i>AP Title:</i>	<u>Research Application</u> Human Subjects Review
<i>AP Number:</i>	AP 2.11.01
<i>Adoption Date:</i>	7/1/03
<i>Schedule for Review & Update:</i>	Every three to five years
<i>Review Date(s):</i>	4/18/16, <u>2/1/22</u>
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<i>Sponsoring Unit/Department:</i>	Office of the Provost <u>Strategy,</u> <u>Analytics and Research</u>
<i>Policy Title(s) & No(s):</i>	Research Involving Human Subjects, BP 2.11
<i>Legal Reference:</i>	Family Educational Rights and Privacy Act (FERPA); Department of Health and Human Services Title 45 Public Welfare, Part 46: Protection of Human Subjects
<i>Cross Reference:</i>	Data and Information Sharing, BP 1.20; Research Involving Human Subjects, BP 2.11; <u>Family Educational Rights and Privacy Act (FERPA), Educational Records Compliance and Procedures,</u> <u>AP 3.11.01</u>

PURPOSE

The purpose of this Administrative Procedure (“AP”) is to establish oversight and responsibility for the research practices performed of human subjects review at Pima ~~County~~ Community College ~~District~~ (the “College”) outside of the College’s regular business operations.

SECTION 1: ~~Definition~~

~~The intent of human subjects review is to protect the College, its students and employees from potential harm resulting from participation in research studies conducted by professionals external to the College or employees conducting research outside of the College's regular business (for example, employees conducting research for external educational purposes).~~

- ~~1.1—The human subjects process is designed to evaluate a given research project to determine whether, and to what degree, it poses potential risks to:~~
- ~~a. The subjects of the research in the form of physical, psychological, social, or other type of risk~~
 - ~~b. The College itself in the form of lawsuits, wasted resources, a diminished image, or other type of harm~~
- ~~1.2—Research projects involving human subjects will undergo human subjects review prior to their implementation, and also may be subject to human subjects review during their implementation.~~

SECTION 1: Scope of Research Application Review

The intent of research application review is to protect the College, its students, and its employees from potential harm resulting from participation in research studies conducted by persons external to the College or outside of the College's regular business operations.

- 1.1 The research application review process is designed to evaluate a given research project to determine whether, and to what degree, it poses potential risks to the following:
- a. To the College itself in the form of lawsuits, wasted resources, a diminished image, or other type of harm;
 - b. To the subjects of the research in the form of physical, psychological, social, or other types of harm or injury.
- 1.2 Research projects involving human subjects will undergo human subjects review prior to their implementation, and ~~also~~ may also be subject to further or ongoing human subjects review during their implementation.

SECTION 2: Roles and Responsibilities

- 2.1 The ~~Board of Governors assigns to the~~ Chancellor, ~~who~~ delegates to the Office of Strategy, Analytics and Research (“STAR”) responsibility for implementing the ~~human subjects~~ research application review process.
- 2.2 ~~STAR Institutional Research, Planning and Effectiveness~~ will review ~~human subjects~~ research applications, monitor and review changes to federal regulations regarding human subjects research, and facilitate adjustments to the College’s policies and procedures to reflect any changes to the above.
- 2.3 ~~STAR Institutional Research, Planning and Effectiveness~~ will be responsible for ~~implementing the College’s human subjects review process and~~ offering training on human subjects research ~~no less than two times each academic year~~ as needed for all applicable College employees.
- 2.4 All proposed research described in Section 1 above will be reviewed by the ~~Assistant~~ Vice Chancellor of Strategy, Analytics and Research (or designee) ~~Institutional Research, Planning and Effectiveness~~ to determine whether the research is exempt under the applicable Department of Health and Human Services regulations, ~~(including 45 C.F.R. 46, Code of Federal Regulations, Title 45 Public Welfare, Part 46: “Protection of Human Subjects”)~~, and, if not exempt, to determine the risk level of the proposed research.
- 2.5 The Vice Chancellor of Strategy, Analytics and Research (or designee) shall ensure that information about the College’ research application review process (e.g., “A Human Subjects User Guide” or similar publication), describing how to submit a research application and other relevant considerations, shall be posted on the STAR page of the College’s website.

SECTION 3: ~~The~~ Submitting Applications for Research and Review Procedure

~~A Human Subjects User Guide, describing how to submit a human subjects application, is posted on the Strategy, Analytics and Research Institutional Research, Planning and Effectiveness page of the College website.~~

- 3.1 All primary investigators wishing to perform ~~human subjects~~ research at or with the participation of the College, its employees, or students are required to submit a completed "~~Pima Community College~~ Application to Conduct Research at Pima Community College with Human Subjects" to the

~~Assistant Vice Chancellor of Strategy, Analytics and Research Institutional Research, Planning and Effectiveness, including:~~

3.2 Each application must include all of the following:

- Either
 - a. Completed online application form (preferred), or
 - b. Signed application form in MS Word or PDF format (available from the Office of Strategy, Analytics and Research);
- ~~A r~~Résumé ~~or c.v. for~~ of each researcher/investigator named in the application;
- ~~Copy~~ Copies of any surveys or questions that will be used during the research, including, but not limited to, interview scripts;
- ~~Copy~~ Copies of ~~the~~ all consent forms to be used with research subjects, or written reason explaining why a consent-form is not required and requesting a consent-form waiver ~~is requested;~~
- IRB documentation, if the research is approved by another institution;
- Any other supporting documentation necessary for review, as requested by STAR.

SECTION 4: Review of Applications for Research

~~4.1—Upon initial review of the application, the Assistant Vice Chancellor of Institutional Research, Planning and Effectiveness will determine whether the research is exempt under Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46: Protection of Human Subjects.~~

- ~~• If a human subjects project is determined to be exempt, the primary investigator will be contacted and the research will be recorded as such.~~
- ~~• If a human subjects project is not exempt, the review will continue to determine the level of risk of the project.~~

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~~4.1.2 If a human subjects project is not exempt, the review will continue to determine the level of risk of the project.~~

4.1 Upon initial review, the ~~The Assistant~~ Vice Chancellor of Strategy, Analytics and Research (or designee) ~~Institutional Research, Planning and Effectiveness~~ will ~~review the application and work with~~ notify the applicant if any needed materials are missing or if the applicant's responses are incomplete or unclear. Once all needed materials are received and reviewed, the risk level of the project will be determined. ~~and the following actions will be taken:~~

4.23 Application Review Process

4.2.1 The proposed research project's application will be assessed to determine whether any College resources would be needed for completion of the project as described in the application materials.

4.2.2 The topic and methodology of the proposed research will be assessed within the context of the mission of the College to determine if the proposed research would further the interests and values of the College or potentially raises any institutional concerns.

4.2.3 If the proposed research project raises FERPA concerns, the application will be forwarded to the Registrar Office in accordance with AP 3.11.01.

4.2.4 If the project is determined to be low risk, does not require any College resources, does not present any other issues, is not Human Subject research or is Human subject research authorized by IRB of a trusted institution, the ~~Assistant~~ Vice Chancellor of Strategy, Analytics and Research (or designee) ~~Institutional Research, Planning and Effectiveness~~ will notify the researcher and those administrators with authority over the area/s involved in the proposed research.

4.2.5 If the project is determined to be low risk, does not require any College resources, and does not present any other issues for the College, the application will be screened according to the applicable federal guidance to determine if it includes "Human Subject" research as that term is defined in 45 CFR 46.102(e)(1). If the application is found to include non-exempt Human Subject research (per 45 CFR 46), and the application was not previously submitted for Institutional Review Board ("IRB") review and authorized by a trusted institution, the application will be forwarded to the IRB of University of Arizona for review. If of the University of Arizona's IRB does not authorize

the human subject research, the applicant will be notified that the research may not be conducted at the College.

- ~~• If the project is determined to be high risk, the application will be referred to the Provost and Executive Vice Chancellor to carry out a final review. If the conclusion of the final review is that the project is high risk, the Assistant Vice Chancellor of Institutional Research, Planning and Effectiveness will notify the researcher that approval is not given for the project. If the final review determines that the project is low risk, then the Assistant Vice Chancellor of Institutional Research, Planning and Effectiveness will notify the researcher and those administrators with authority over the area/s involved in the proposed research. In the case of projects determined to be high risk, the decision of the Provost and Executive Vice Chancellor is final. There is no appeals process if a project is not approved at this point.~~

4.2.6 If a non-human subject research project or a human Subject research authorized by an IRB is assessed to potentially a) not to be low risk, b) require the use of College resources, or c) present other potential problems or expenses for the College, the application shall be referred to both the College's Office of General Counsel and the senior administrator over the area that would be included in the research for s further review in accordance with the Vice Chancellor of Strategy, Analytics and Research (or designee).

4.4 Further Review with General Counsel and Responsible College Administrator

4.4.1 If the Vice Chancellor of Strategy, Analytics and Research (or designee) assesses that a proposed research project is not low risk, would expend College resources, or potentially result in other problems or expenses for the College, the Vice Chancellor of Strategy, Analytics and Research, in consultation with the College's Office of General Counsel and the senior administrator responsible for the College area that would be affected by the research, shall consider the following:

- If the proposed research is, in fact, low risk (contrary to the previous determination) and may be approved without modification;

- If sufficient justification exists to approve the proposed research project notwithstanding the risks, expenses, and potential problems (e.g., the net benefit of the proposed research to the College or to higher education generally greatly outweighs the potential risks, expenses, and other problems),
- If there are reasonable ways the applicant could modify the proposed research to satisfactorily eliminate, reduce, or mitigate the identified risks, expenses, and other potential problems in order for the project to be approved.

4.4.2 If the further review determines that the proposed research project is, in fact, low risk, the Vice Chancellor of Strategy, Analytics and Research will notify the applicant research and those College administrators with authority over the area/s invoiced in the proposed research that the application is approved. ~~If the conclusion of the final review is that the project cannot be approved, the Assistant Vice Chancellor of Strategy, Analytics and Research Institutional Research, Planning and Effectiveness will notify the applicant researcher that approval is not given for the project the human subjects research application is denied. The decision of the final review is final. There is no appeals process if a project is not approved through this review.~~

4.4.3 If the further review determines that sufficient justification exists to approve the proposed research project, notwithstanding the risks, expenses, or other potential problems, the Vice Chancellor of Strategy, Analytics and Research shall document that determination, the specific bases why it is justified (e.g., how the benefits to be gained will offset the risks and/or expenses, etc.) and maintain it with the College's records for the specific research application. ~~If the final review determines that the proposed research project is, in fact, low risk, then the Assistant Vice Chancellor of Strategy, Analytics and Research Institutional Research, Planning and Effectiveness will notify the applicant researcher and those College administrators with authority over the area/s involved in the proposed research that the application is approved.~~

4.4.4 If the further review identifies reasonable measures by which the proposed research project could be modified to satisfactorily eliminate, reduce, or mitigate the identified risks, expenses, and other possible problems, the Vice Chancellor of Strategy, Analytics and

Research (or designee) shall notify the applicant researcher of the identified measures and work with the applicant to potentially amend the proposed research project such that it would be acceptable to both the applicant researcher and the College. However, the College is not obliged to find a way to make a proposed research project acceptable, and whether to approve an application for research remains solely at the discretion of the Vice Chancellor of Strategy, Analytics and Research (or designee).

4.4.5 If the conclusion of the further review is that the project cannot be approved, the Vice Chancellor of Strategy, Analytics and Research will notify the applicant researcher that the research application is denied. This decision is final, and there is no additional review or appeals process if a research project is not approved. ~~If the conclusion of the further review is that the project cannot be approved, the Assistant Vice Chancellor of Strategy, Analytics and Research Institutional Research, Planning and Effectiveness will notify the applicant researcher that approval is not given for the project the human subjects research application is denied. This decision is final, and there is no additional review or appeals process if a research project is not approved.~~

4.5 Final Approval or Denial of Applications for Research

The final decision to approve or deny an application for research (i.e., after any proposed modifications to the project have been made) shall be made by the Vice Chancellor of Strategy, Analytics and Research. The Vice Chancellor of Strategy, Analytics and Research (or designee) shall inform the applicant researcher in writing of the approval or denial. If the application is denied, the Vice Chancellor of Strategy, Analytics and Research (or designee) shall specify the basis for the denial.

SECTION 5: Records of Research Applications

Records of all applications for research received, processed, and decided by the College shall be maintained by the Office of the Vice Chancellor of Strategy, Analytics and Research in accordance with the College's applicable record-retention policies.