



PimaCommunityCollege

Human Subjects Review at Pima Community College

User Guide

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What is Human Subjects Review?

Human Subjects Review is the process at Pima Community College (PCC) that is designed to ensure that research carried out at the College meets all requirements and regulations specified in the Code of Federal Regulations Part 46: Protection of Human Subjects (see “Useful links”). The process is designed to evaluate a given research project to determine whether, and to what degree, it poses potential risks to:

1. The subjects of the research in the form of physical, psychological, social, or some other kind of risk
2. The College itself in the form of lawsuits, wasted resources, a diminished image, or some other kind of harm

The process is overseen by Board Policy BP-2.11, and Administrative Procedure AP 2.11.01 (see “Useful links”).

The purpose of this document is to explain how to submit a human subjects application to PCC.

Is my research subject to review?

Human subjects research projects carried out at PCC are required to meet the criteria outlined in the Code of Federal Regulations Part 46: Protection of Human Subjects (see “Useful links”). If you are carrying out research that involves interactions with students or employees of the College, then your project falls under the Human Subjects Review process. Projects that involve College data only are not subject to review. Please visit the Strategy, Analytics and Research (STAR) website to find out how to request research by the College in order to access those data (see “Useful links”). Note that some projects, as listed in the Code, are exempt from review. Please refer to the Code to see if your project may be exempt.

If you believe that your project is exempt, please contact the Office of Strategy, Analytics and Research (STAR) to discuss the research (see “Getting help”). We will make the final determination. If the project is exempt, we will send you written confirmation, including important guidelines. If we cannot determine whether the project is exempt from a brief discussion, we may ask you to submit a full application.

If your project is not exempt, you will need to complete a Human Subjects Review application packet.

How do I submit a human subjects application?

In order to review your project, we need the following:

1. Signed application form (see “Useful links”). If you carry the research as part of your master or doctoral dissertation, the application should also be signed by your scientific director.
2. Résumé of each investigator named in the application
3. Copy of any surveys or questions that will be used
4. Copy of the consent form, or reason a consent form waiver is requested (see “Useful links”)
5. Site authorization, if applicable.
6. Any other supporting documentation

These files need to be submitted to the Assistant Vice Chancellor for Strategy, Analytics and Research (STAR) via email (research@pima.edu) or at the following address:

Strategy, Analytics and Research (STAR), Pima Community College 4905C E Broadway Blvd
Tucson, AZ 85709-1275

If you need assistance preparing any of these files, refer to the “Useful links” section, which provides access to resources that you may find useful as you prepare your packet.

Common problems

Based on applications that have been submitted in the past, there are some common problems that we encounter during review. Please give these items careful consideration as you prepare your application:

1. Remember that this is your research project and that you are responsible for all aspects of it, including identifying participants. In most circumstances, the College will not release student personal information, email addresses or send out emails on your behalf. Please take that into account when you are determining how you will get people involved in your study.
2. Don't forget that you are submitting an application to carry out research yourself. Applications that require extensive assistance from PCC employees in order to carry out the research are typically not approved.
3. Protection of information is very important to the College, and this includes ensuring that the data you collect are appropriately safeguarded.

4. Please ensure you provide all of the material listed in the section “How do I submit a human subjects application?” If your application is incomplete, it will delay the review of your project.
5. If you only need access to data stored in the College’s databases for your research, then your project does not fall under the Human Subjects Review process. Please fill out the research request form on the STAR website if you are seeking access to data from the College’s data system (see “Useful links”).

I’ve submitted my application, what happens next?

After you submit your application, you will receive a confirmation email from STAR. Your application will then be reviewed. If the packet is complete and no information is missing then this stage in the application process will take about one month. If documents or information are missing, the process can take significantly longer. STAR may contact you during the initial review if there are questions about any aspect of your research.

Once STAR has reviewed the packet, the decision to approve or deny the application is emailed to you. In some difficult cases or if the project is determined to be high risk, your application with all pertaining materials would be forwarded to PCC legal department and/or 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 Strategy, Analytics and Research (STAR) 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 Strategy, Analytics and Research (STAR) will notify the researcher and those administrators with authority over the area/s involved in the proposed research.

Due to the diverse projects that are submitted for Human Subjects Review, the timeline for this stage in the process is very variable. However, if at any stage you would like to find out the current status of your application, please contact STAR (see “Getting help”).

My application was accepted

If your application is accepted by the College, you will receive a letter notifying you of the result. The letter will include important information about who will be your contact at the College for the

project, and any site authorization information. It is important that you follow all directions in the notification letter. Any deviation from the instructions may result in your research at the College being terminated.

Please be aware that you may need additional authorization from other College administrators. Approval by the Human Subjects Review process means that your research has been deemed low risk for the College. However, if you need access to specific College personnel or facilities, additional approval from a senior College administrator may be needed.

My application was rejected

In the event that the College is not able to accept your application, PIR will contact you to discuss alternatives that may work.

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.

Ongoing review of accepted applications

Please submit a short summary report each year to update the College on the status of your project. A one-page summary is adequate. The report should be submitted each year in the month in which you originally received approval for your research.

When you complete your project, please submit a final report. In addition, send the College copies of any publications resulting from the study.

In all cases, submit the reports to the Assistant Vice Chancellor for Strategy, Analytics and Research (STAR) at the address provided under “Getting help”.

Useful links

Application Form for Human Subjects Review at PCC

<https://pima.edu/administration/star/docs/human-subjects-application-for-review2.rtf>

Consent form guidelines from the Code of Federal Regulations:

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116>

In addition, a wide range of higher education institutions provide example consent forms on their websites. These can be located using any internet search engine.

Code of Federal Regulations: Part 46 Protection of Human Subjects:

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

PCC Policies:

<https://www.pima.edu/about-pima/leadership-policies/policies/index.html>

Strategy, Analytics and Research (STAR) at PCC:

<https://pima.edu/administration/star/index.html>

Getting help The Human Subjects Review process is overseen by the Office of Strategy, Analytics and Research (STAR). The STAR office can be contacted through any of the methods below:

- Visit us at the Pima Community College District Office in C-212
- Phone: 520-206-4934
- Email: research@pima.edu
- Fax: 520-206-4754
- Address:

Strategy, Analytics and Research (STAR) Pima Community College
4905C E Broadway Blvd
Tucson, AZ 85709-1275