

**Avila University Institutional Review Board  
Request for Research with Human Participants**

**Directions for completing this form:**

- See the IRB Information Sheet (available on MyAU) for details about how to complete and submit this application.

**Principal Investigator Information**

Name of Principal Investigator: \_\_\_\_\_

Email Address: \_\_\_\_\_

Phone Number(s): Cell/Home: \_\_\_\_\_ Work: \_\_\_\_\_

**Project/Research Information:**

Project Title: \_\_\_\_\_

Project Status:

New Project

Modification of Previously Approved Project.

Title of Previous Project \_\_\_\_\_

IRB number of Previous Project \_\_\_\_\_

For modifications of approved projects, please describe only those aspects that have changed, in the box below. If applicable, attach additional/modified instrument(s) and/or consent form. Then proceed to signature page.

Project/Research Start Date: \_\_\_\_\_

Project/Research End Date: \_\_\_\_\_

Where will the project be conducted? \_\_\_\_\_

Check one of the following and complete the portions noted.

Avila University Student—complete part A and go on to the next section

Avila University Faculty/Staff—complete part B and go on to the next section

Investigator not connected with Avila using Avila students, faculty, or staff to collect research data—skip Parts A & B and go to the next section

**Part A: To be completed by Avila University student applicants**

Student Classification (check one)

1. Undergraduate Student  
Graduate Student  
Other: \_\_\_\_\_
2. Type of project (check all that apply)  
Class Project or assignment:  
Course Number and Title: \_\_\_\_\_

Independent Research

Thesis Research

Other: \_\_\_\_\_

3. Name of Faculty Supervisor: \_\_\_\_\_

**Part B: To be completed by Avila University faculty or staff applicants**

1. Department: \_\_\_\_\_

2. Type of project (check all that apply)

Personal research project

Thesis/Dissertation Research: Name of affiliated institution \_\_\_\_\_

Department or College/School Research

Institution-wide Research

Class Project for which you are instructor:

Course Number and Title: \_\_\_\_\_

Check if you are requesting Standing Approval

**Answer ALL of the following questions.**

1. Approximate number of participants to be involved in the research: \_\_\_\_\_

2. **Abstract describing Project and Purpose.** Briefly describe (a) the project or study and (b) what human participants will experience during the proposed study or project. Indicate what data, measures, or observations will be collected and used in the study or for the project. If any questionnaires, tests, or other instruments are to be used, include a brief description and attach a copy of the instruments.

3. Does the research involve any of the following? Check Yes or No. If Yes, provide an explanation in the space provided below the item.
- a. Access to participants through a cooperating institution or agency?      Yes      No  
(A letter of cooperation from the agency or persons at the institution must be attached.)
- b. Incentives offered for participation (e.g., money, extra credit for the class)?      Yes      No
- c. Participants who could be judged to have limited freedom of consent (e.g., minors, developmentally delayed persons, or those institutionalized)?      Yes      No  
(A consent form signed by a parent or guardian is required.)
- d. Personal contact that could result in the identification of the participant?      Yes      No  
(A consent form is required.)
- e. Substances applied externally to the participants?      Yes      No  
(A consent form is required.)
- f. Procedures involving bodily manipulation?      Yes      No  
(A consent form is required.)
- g. Deceiving participants about the purpose of the research?      Yes      No  
(Debriefing is required.)
- h. Specimens?      Yes      No      (*biological risk addendum* may be required)
- i. Ingestion of substances?      Yes      No  
(A consent form is required; *biological risk addendum* may be required)
- j. Fluid or tissues removed from participants?      Yes      No  
(A consent form is required; *biological risk addendum* must be completed)

4. Will the participants be asked to respond to any of the following areas of “sensitive” research (as defined by Public Health Service Act 301(d))? **Check all that apply.** Explanations and justifications should be included in questions 6 – 12 below.

Relating to sexual attitudes, preferences, or practices.

Relating to the use of alcohol, drugs, or other addictive products.

Pertaining to illegal conduct.

Information that, if released, could reasonably be damaging to an individual’s financial standing, employability, or reputation within the community.

Information that would normally be recorded in a patient’s medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.

Information pertaining to an individual’s psychological well-being or mental health.

Information in any other category that might be considered sensitive because of specific cultural or other factors.

5. Will the research use any of the following methodologies? **Check all that apply.**

Repeated administrations of the same instrument or data collected over several contacts with participants

Individual (in person) administration or contact with participants

Group (in person) administration or contact with participants

Other distribution and collection involving no personal contact with participants (including mail distribution, distribution through another person or agency, etc.)

Written consent form for participants to sign

Interviews

Observations

Surveys or questionnaires

Audio or video recordings

Usage of pictures or images of actual people (*permission required to be attached*)

Materials from websites (*permission required to be attached or source cited, as appropriate*)

Copyrighted materials (*permission required to be attached or source cited, as appropriate*)

6. Describe the proposed participants. Include any special considerations such as age, gender, ethnicities, socio-economic status, etc.

7. Describe how the participants will be identified and recruited for participation in the project. (Note that if an investigator is interested in recruiting students in a specific course, the instructor for that course may allow the investigator to address the students or the instructor may provide the students with the investigator’s information, but may not provide student information to the investigator, without the students’ informed consent.)

8. Describe the benefits of this research project to participants, and with regard to gains in knowledge or other larger benefits that may result from the project. Note that incentives to participate are not considered benefits of the research.
9. Describe the risks of this research project. Include all known and anticipated risks to the participants such as side effects, risks of placebo (inert) treatments, etc. Any procedures that might place the participants at risk (psychological, physical, social, or economic) require a consent form. For research that proposes substantial risk to human participants, describe emergency backup procedures that are in place, such as medical or counseling interventions.
10. How will you store data and assure continued confidentiality of data collected from this project?
11. When and to what group(s) will the results be reported?

12. Describe **how** you will inform participants of all of the following: (a) the purpose and benefits of the research, (b) the risks of the research, (c) assurances of confidentiality of responses, (d) voluntary participation, and (e) how and to whom results will be disseminated. If using a Consent Form, please attach the form. If not using a Consent Form, provide the statements to be read or provided to the participants.

**CERTIFICATION by Principal Investigator:**

By submitting this application, I am certifying that I have read, understand, and will comply with the policies and procedures of Avila University regarding human participants in research. I agree that I will notify and receive approval from the Avila University Institutional Review Board before any non-trivial changes are made to the project described in this request. I certify that all information submitted is accurate. My electronic submission of this form signifies my certification of this information.

Signature of Principal Investigator

Date

**CERTIFICATION by Faculty Supervisor (required for student projects only):**

By submitting this application, I accept responsibility for assuring that procedures and materials follow the proposal as approved by the Institutional Review Board. Any awareness of violations will be reported to the Institutional Review Board. My electronic submission of this form signifies my certification of this information.

Signature of Faculty Supervisor

Date

**Institutional Review Board Action:**

- ☐ The following information is still needed:
- ☐ Project is not approved due to:

Notification of additional needs sent to applicant: \_\_\_\_\_

- ☐ Project is approved

\_\_\_\_\_  
Signature of IRB Chairperson

\_\_\_\_\_  
Date

02/00; 05/04, 5/10, 7/10, 11/10, 2/11, 5/18