NIH Online Training

At Avila University, investigators involved in human subject research are required to take the NIH online training.

Directions for completing the NIH training:

1. Go to http://phrp.nihtraining.com/users/login.php and register before starting the online training.
2. Print into PDF your certificate of completion and submit it with your IRB application.

Avila University
Research With Human Participants

All research involving human participants carried on at the University or under the University's auspices must be reviewed and approved by the Institutional Review Board (IRB) of Avila University.

Rationale for the Policy

In keeping with the mission and values of the University, Avila seeks to safeguard the rights and welfare of persons who agree to be participants in research activities. All persons have the right of self-determination and the rights of persons who are asked to be participants in projects must be protected. These rights include the right not to be harmed, the right to self-determination, the right to privacy, the right to obtain and maintain services, the right to maintain self-respect and dignity, the right to have confidential material remain confidential and the right to withdraw or refuse to participate without recrimination. Informed consent is necessary to protect persons engaged as participants in a research endeavor.

Research is broadly defined by the University and includes any activity that involves the gathering of data from human participants in any form other than standard accepted education classroom practices. Examples requiring IRB approval include, but are not limited to, the following: non-exempt questionnaires or surveys, interviews, observations, documents, bodily samples, specimens, procedures involving bodily manipulations, procedures involving experimental intervention, research involving minors, and research involving individuals unable for any reason to give informed consent. The use of human participants is a privilege granted to the investigator rather than a right. It is the responsibility of the Institutional Review Board to assure that the research meets minimal criteria established by Federal law and Federal regulations 45CFR 46, revised June 18, 1991.

Certain categories of use of human participants may apply for, and receive, a general approval that would cover repeated data gathering which follow the same guidelines as approved. For example, a class assignment involving the use of human participants which an instructor uses each time the course is taught may request a "standing" or "repeated use" approval for that particular class assignment as long as the same guidelines are followed as approved by the IRB. However, if the instructor of the course changes or if changes are made in the class assignment, the instructor must reapply for approval of the use of human participants. Individual student research projects for class requirements are NOT eligible for approval under this category. Individual student research projects MUST submit an application for IRB review and approval.

Program or service areas that will make repeated use of the same data collection techniques may also apply for approval one time only for all subsequent data-gathering efforts as long as the guidelines outlined in the application are followed. Any changes in the procedures would require a new application for approval.

Application Process

1. Obtain a Request for Approval application for use of human participants from the Academic Affairs Office or on the Avila University web site or MyAU portal.
2. After completing the application, the investigator may **either submit the original application with the faculty supervisor's signature** to the Vice-Provost for Academic Affairs who serves as the Chair of the Institutional Review Board **OR submit the request electronically** to the Academic Affairs mailbox (AcademicAffairs@Avila.edu) and to the faculty supervisor. **If submitted electronically, the faculty supervisor must forward the email from the student indicating approval to the Academic Affairs mailbox.** Requests are reviewed on a continual basis during the fall and spring terms. Decisions are typically communicated to the investigator in two weeks or less during the fall and spring terms. If submitted between terms or in the summer, approval may take up to 60 days.
3. The chairperson of the Institutional Review Board informs the investigator of the decision of the IRB. A favorable decision is permission for the research to begin immediately. An application that is not approved may be resubmitted for approval with appropriate revisions.

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

Avila University Institutional Review Board
Request for Research with Human Subjects

Name of Principal Investigator: _____

Mailing Address: _____

_____

Email Address: _____

Phone Number(s): Home: _____

Cell: _____ Work: _____

Directions for Completing this form:

Check one of the following and complete the portions noted.

☐ Avila University Student—complete part A on this page and go on to the next page
☐ Avila University Faculty/Staff—complete part B on this page and go on to the next page
☐ Investigator not connected with Avila using Avila students, faculty, or staff to collect research data—skip the remainder of this page and go to the next page

Part A: To be completed by Avila University student applicants

1. Student classification (check one)
   - ☐ 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

Project/Research Information (To be completed by all applicants):

Project Title: _____

Project/Research Start Date: _____

Project/Research End Date: _____

Approximate number of subjects to be involved in the research: _____

Answer ALL of the following questions. *(Please see attached explanations for clarification.)*

1. Does the research involve any of the following? Check Yes or No. If Yes, provide an explanation in the spaced provided below the item.

   a. Access to subjects through a cooperating institution or agency? ☐ Yes ☐ No
   (A letter of cooperation from the agency or persons at the institution must be attached.)

   b. Payment to subjects for participation? ☐ Yes ☐ No

   c. Subjects 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. Any procedures that might place the subjects at risk (psychological, physical, social, or economic)? ☐ Yes ☐ No
   (A signed consent form is required.)

   e. Substances taken internally by or applied externally to the subjects? ☐ Yes ☐ No
   (A signed consent form is required.)

   f. Fluids (e.g., blood, saliva) or tissues removed from the subjects? ☐ Yes ☐ No
   (A signed consent form is required.)

   g. Deceiving subjects about the purpose of the research? ☐ Yes ☐ No

2. Will the subjects 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 4 – 10 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.

3. 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 subjects
- ☐ Individual (in person) administration or contact with subjects
- ☐ Group (in person) administration or contact with subjects
- ☐ Other distribution and collection involving no personal contact with subjects (including mail distribution, distribution through another person or agency, etc.)
- ☐ Written consent form for subjects to sign
- ☐ Data collected over more than one year

- ☐ 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)*
- ☐ Copyrighted materials *(permission required to be attached or source cited, as appropriate)*
- ☐ Debriefing procedures for deception projects

4. What is the purpose of the research?

5. Describe the proposed subjects. (Describe any special considerations such as age, gender, ethnicities, socio-economic status, etc.).

6. Describe how the subjects will be identified and recruited for participation in the project.

7. Describe the methodology for collecting data from subjects. (Attach another sheet if necessary.)

8. Describe how you will inform subjects of all of the following: (a) the purpose and benefits of the research, (b) assurances of confidentiality of responses, (c) voluntary participation, and (d) how and to whom results will be disseminated.

9. When and to what group(s) will the results be reported?

10. How will you store data and assure continued confidentiality of data collected from this project?

Be sure to attach supporting documents including surveys, questionnaires and consent forms. If the subjects will be addressed in person, verbal directions and required statements noted in question 8 above must be scripted and attached. Most research studies require a statement of informed consent with all the elements in question 8 above. If personal contact could result in the identification of the subject, a written consent is required. Examples of informed consent forms are attached.

CERTIFICATION:

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 subjects in research. I agree that I will notify and receive approval from the Avila University Institutional Review Board before any changes are made to the project described in this request. I certify that all information submitted is accurate.

_____ _____

Signature of Principal Investigator Date

By signing below, 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.

_____ _____

Signature of Faculty Supervisor (required for student projects only) Date

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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**

Example of a consent form for research with minimal risk to subjects:

The Department of _____ at Avila University supports the practice of protection for human subjects participating in research. The following information is provided for you to decide whether you wish to participate in the present study. You should be aware that even if you agree to participate, you are free to withdraw at any time without penalty.

We are interested in studying the effects of media on how people view themselves, their problems, and their futures. You will be participating in two sessions that will involve filling out some questionnaires, watching some videotaped materials, talking with the researcher, and doing some written and verbal tasks. It is estimated that this will take no more than two hours of your time.

The content of the videotapes and questions concerns _____, and so there is a chance that you might feel slightly uncomfortable with some of the materials and topics addressed in the research. Although participation will not directly benefit you, we believe that the information will be useful in evaluating the effects of media on viewers.

Your participation is solicited although strictly voluntary. We assure you that your name will not be associated in any way with the research findings. The information will be identified only by a code number. Results will be available in about 6 months and will be reported in the Communication Department at Avila University and in a presentation at a professional conference.

If you would like additional information concerning this study before or after it is complete, please feel free to contact me by phone or mail. If you have concerns or questions about your rights as a research participant you may contact the Avila University Institutional Review Board at 816-501-3759 or Sue King at kingsm@mail.avila.edu.

Sincerely,

Jane Doe,
Principal Investigator
Communication Dept.
Avila University
11901 Wornall Road
Kansas City, MO 64145
816-501-_____

J.D. Smythe, Ph.D.
Faculty Supervisor
Communication Dept.
Avila University
11901 Wornall Road
Kansas City, MO 64145
816-501-_____

_____

Signature of subject agreeing to participate

With my signature I affirm that I am at least 18 years of age and have received a copy of the consent, form to keep.