Avila University IRB
Research with Human Participants: INFORMATION SHEET

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. The Vice President for Academic Affairs (or designee) serves as the Chair of the Institutional Review Board.

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.

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.

Definition of Research

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***. Even if data are collected in the course of standard accepted education classroom practices, if those data are reported outside the classroom, the overall activity is not considered standard practice. When data are collected using standard accepted education practices, the investigators should not refer to the project using research terms (e.g., research project, research participants), but should instead use educational terms (e.g., classroom activity, student participants).

Research projects involving only publicly-available archival data are normally not subject to IRB approval. Institutional data collection (e.g., surveys of students where the applicant is the university or a group within the university) is also not subject to IRB approval, but is instead reviewed by the Institutional Effectiveness Committee (IEC: contact Academic Affairs for more information).

Examples requiring IRB approval include, but are not limited to, the following:

- questionnaires or surveys
- interviews
- observations
- documents
- procedures involving experimental intervention
- research involving minors
- research involving individuals unable for any reason to give informed consent
- procedures involving bodily manipulations
- data collected as part of standard accepted classroom practices that are then used as research data outside of the original classroom setting.
- specimens
- ingestion of substances
- bodily samples

Research projects involving specimens or ingestion of substances, may additionally require completion of a biological risk addendum in addition to the standard IRB application, unless the procedures are deemed by the IRB to be very low risk (no greater risk than may be experienced in everyday life). Research projects involving fluid or tissues removed from participants always require completion of a biological risk addendum in addition to the standard IRB application.

Modification of Previously Approved Projects

Investigators who have previously received approval for research projects, and who are making more than trivial modifications to the project, must re-submit an IRB application. Resubmissions must indicate the title and approval number of the previously-approved project, and should note on the new application only those aspects that have been changed.

Standing approval

Investigators within certain categories of use of human participants may apply for, and receive, a general approval that would cover repeated data gathering that follow the same guidelines as approved. For example, an instructor who uses the same class assignment involving the use of human participants each time the course is taught may request a "standing" 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. Students conducting individual research projects, including research projects for a class through an internship or clinical site, MUST submit an individual application for IRB review and approval.

Directors of program or service areas that make repeated use of the same data collection techniques may also apply for standing approval 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 or an application for revision.

Application Process

1. **Complete NIH Online Training.**
   At Avila University, all investigators involved in human participant research are required to have satisfactorily completed the NIH online training entitled "Protecting Human Research Participants" within the 36 months prior to submission. Instructions for completing the training are as follows:
   a. Go to http://phrp.nihtraining.com/users/login.php to register for training.
   b. Successfully complete the training.
   c. Print the certificate(s) of completion for all investigators into PDF and submit with your IRB application.

2. **Complete the IRB Request for Approval application.**
   Obtain an IRB Request for Approval application (fillable form) on the Avila University MyAU portal, and complete the application. Most projects require an Informed Consent form. An example of a Consent Form can be found at the end of this Information Sheet.

3. **Submit the application.**
   The principal investigator submits the completed application electronically, as follows:

   a. If the principal investigator is an Avila student, send the completed application by email to the Avila faculty supervisor. The supervisor then forwards the email, indicating approval, to the Academic Affairs mailbox (AcademicAffairs@Avila.edu).

   b. In all other cases, send the completed application directly to the Academic Affairs mailbox (AcademicAffairs@Avila.edu).

4. **Application review and response.**
   Requests are reviewed on a continual basis during the fall and spring terms. Decisions are typically communicated to the principal 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. The chairperson of the Institutional Review Board informs the investigator of the decision of the IRB by email. 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.

Example of a consent form for in-person research with minimal risk to participants:

The Department of Psychology at Avila University supports the practice of protection for humans 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 your attitudes towards controversial issues, 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. Raw data will be kept in a locked office and/or in secured digital files. Results will be available in about six months and may be reported in the Department of Psychology 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 us by phone or email. If you have concerns or questions about your rights as a research participant you may contact the Chair of the Avila University Institutional Review Board, Mary Knaus LeCluyse, by telephone at 816-501-3759 or by email at Mary.LeCluyse@avila.edu.

Sincerely,

Jane Doe
Principal Investigator
Dept. of Psychology
Avila University
11901 Wornall Road
Kansas City, MO 64145
Doe1234@avila.edu

J.D. Smythe, Ph.D.
Faculty Supervisor
Dept. of Psychology
Avila University
11901 Wornall Road
Kansas City, MO 64145
816-501-1234
JD.Smythe@avila.edu

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Signature of person agreeing to participate

With my signature I affirm that I am at least 18 years of age and that I agree to participate in this study.

For ONLINE RESEARCH
In lieu of the signature, a statement such as the following may be used at the bottom of the Informed Consent screen:

"By clicking [on this screen/to the next page], I affirm that I am at least 18 years of age and that I agree to participate in this study."

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