April 2013

5.507 Human Subjects Protection (IRB)

April 2013

5.507 Human Subjects Protection (IRB)

Type of Policy ■ **University** □ **Campus** □ **Department/Unit** □ **Interim**	**Human Subjects Protection (IRB)** **Policy 5.507**
Academic Policies	**Effective date: November 1, 2016**

Policy History:	**Approved by:**	**Resolution #**	**Date**
Approved	**Board of Governors**	**6.4.11:5**	**June 4, 2011**
Revised			**October 27, 2016**
Revised	Chancellor		**April 13, 2018**
Responsible Office	**Responsible Administrator:**	**Contact information**	**Applies to:**
Office of Vice Chancellor of Academic Affairs	**Vice Chancellor of Academic Affairs**	**937-769-1890**	**All Faculty and Students**

I. Introduction

A. Purpose. The purpose of the Human Subjects Protection Policy is to inform students, faculty, staff, and contracted individuals who may be conducting research that involves human participants of the standards that Antioch University has established to protect these participants, to describe the structure of the University's Institutional Review Board program, and to delineate the authority and responsibilities of the various University's Institutional Review Boards for the Protection of Human Participants in Research.

B. Investigator Responsibility and Expectations of Antioch University. Faculty, staff, and students at Antioch University conduct research designed to create new knowledge and to promote and improve the quality of life of individuals locally, nationally, and internationally. University policy requires that all research involving human participants conducted by Antioch investigators (faculty, staff or students) be reviewed and approved by the appropriate Institutional Review Board (IRB). These rules are in place to assure the upholding of the following ethical principles of research involving human participants: respect, beneficence, and justice, as delineated by Federal Code CFR Title 45, Part 46, Protection of Human Subjects and in the report of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research entitled, Ethical Principles and Guidelines for the Protection of Human Subjects

of Research (known as the Belmont Report).

Safeguarding the rights and welfare of human participants in any research activity is the responsibility of the investigators. It is the policy of the University that no activity falling under the Federal definition of research with human participants be undertaken until those activities have been reviewed and approved by the campus and/or program level IRB according to the guidelines established by the University level IRB.

II. Authority for Research Compliance

A. Local Institutional Review Boards. Each Antioch University campus and program shall have an Institutional Review Board (IRB) designated to review and approve research involving human participants prior to the initiation of any such research, and to conduct periodic reviews of such research. The IRBs operate in accordance with Title 45 Code of Federal Regulations (CFR) Part 46, applicable state laws and regulations, and the Belmont Report.

Each local IRB has the authority to deny the investigator the ability to conduct the research and/or to place restrictions on any study in which the investigator has not met the University's requirements or when the IRB determines that the rights and/or welfare of human participants are at risk. Each local IRB may also suspend or terminate any study when it becomes aware that the investigator has failed to get prior approval or has failed to implement the study in a manner consistent with the approved research design.

B. Jurisdiction. The Human Subjects Protection Policy applies to all Antioch University faculty, staff and students, whether their research is conducted on or off one of the Antioch University campuses, and irrespective of funding source. The policy also applies to visitors and users of any of the campuses or any off-campus Antioch University facilities.

This policy pertains only to research (see Definitions) that includes the use of human participants. This policy does not address compliance with other Federally-mandated regulations.

III. Definitions

Federal Wide Assurance (FWA): A document that formalizes an institution's commitment to protect human participants and that is required for each institution that participates in federally supported human participant research. The FWA is an agreement between the IRB and the United States Department of Health and Human Services, outlining the responsibilities of the IRB in upholding the ethical principles of research involving human participants.

Investigator's Handbook for the Protection of Human Participants ("Handbook"): The University's official document that describes the policies and procedures associated with the review, approval, and monitoring of research involving human participants conducted by students, faculty, and staff affiliated with Antioch University. **Participants**: Living individual(s) about whom an

investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information (45 CFR 46.102(f)). Human participants may also be referred to as human subjects.

Institutional Review Board (IRB): A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research. Every campus and University-wide program is required to have a designated IRB that reviews research projects for that campus.

Research: The Department of Health and Human Services regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop and contribute to generalizable knowledge (45 CFR 46.102(d)).

University-wide Institutional Research Board: (UW-IRB): The chairs or designees of each local and University-wide program IRB make up the membership of the UW-IRB. The chair of the UW-IRB is appointed by the Vice Chancellor for Academic Affairs. The UW-IRB serves to coordinate efforts across the campuses, share regulatory changes and initiatives, and provide opportunities for consultation. The UW-IRB shall serve as the policy development committee for all policies related to institutional research in accordance with the University's Policy Development and approval process and is responsible for reviewing and updating the Handbook, in collaboration with the Counsel on Regulatory Affairs. The UW-IRB chair shall submit an annual report to the Vice Chancellor of local UW-IRB and local IRB activities.

IV. Membership of Institutional Review Boards

Each campus and program within the Antioch University system shall utilize a designated Institutional Review Board, with membership as follows:

A. The IRB shall consist preferably of five (5) members with varying backgrounds. In addition to possessing the professional competence necessary to review research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.

B. Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men, entirely of women, or entirely of members of a single discipline or profession.

C. Membership shall include at least one person whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews.

D. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. Affiliated members include, but are not limited to, individuals who are: part-time employees; current students; members of any governing panel or board of the institution; paid or unpaid consultants; healthcare providers holding credentials to practice at the institution; and volunteers working at the institution on business unrelated to the IRB. An individual that has no affiliation with the organization registering the IRB, other than as an IRB member, is considered unaffiliated with the entity operating the IRB. Unaffiliated members may include people whose only association with the institution is that of a patient, subject, or former student at that institution. Paying unaffiliated members for their services would not make the member "otherwise affiliated" as stated in the regulations, or cause the member to have a conflicting interest.

E. No IRB member may participate in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

F. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of complex issues that require expertise beyond, or in addition, to that available on the committee. Similarly, investigators may request, or be invited, to attend IRB meetings to clarify issues with the members concerning their proposed research activity. Such guests are present only to provide information and do not take part in committee deliberations or voting.

V. Administrative Procedure

The Antioch University Investigator's Handbook for the Protection of Human Participants (Handbook) provides an overview of the federal and state laws and regulations that govern the conduct of research with human participants and the guiding principles of the IRB review process, and is hereby incorporated by reference. All Antioch University students, faculty, and staff who intend to undertake research with human participants must follow the requirements of this Policy and the Handbook. In particular, the Handbook provides details on the factors that investigators must consider in conducting research with human participants; the types of projects that are subject to IRB review; the types of reviews conducted by the IRB; and the documentation required for each type of IRB review.

The Handbook is developed by the University-wide Institutional Review Board (UW-IRB) and is made available to all members of the Antioch community. The UW-IRB shall conduct an annual review of the Handbook, to assure currency of compliance with federal regulations that guide research involving human participants.

VI. Guiding Principles

The following three principles are basic to the protection of human participants and guide the work of the IRBs:

A. Respect. In consideration of respect for persons, investigators are required to seek voluntary, written, informed consent from potential subjects. Voluntary informed

consent means subjects are given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and are not under duress. The consent form shall also include adequate information about the study that will assist subjects in intelligently deciding whether to participate in research. In addition, respect means honoring the privacy of individuals and maintaining their confidentiality. Respect for minors and mentally disabled persons requires taking extra precautions to protect those individuals who are immature or incapacitated, perhaps even to the extent of excluding them from participation in certain research. The extent of protection depends on the risks and benefits of the research to the participants. The IRB must not approve a proposed research project when the IRB is unable to make the required determinations about research risks and benefits, the adequacy of privacy and confidentiality protections, or the adequacy of the informed consent process.

B. Beneficence. The principle of beneficence requires that investigators maximize the potential benefits to the subjects and minimize the potential risks of harm. Benefits to the subjects, or in the form of generalized knowledge gained from the research, should always outweigh the risks. Finally, if there are any risks resulting from participation in the research, then there must be benefits, either to the subject, or to humanity or society in general.

C. Justice. The principle of justice means that subjects are selected fairly and that the risks and benefits of research are distributed equitably. Investigators should take precautions not to systematically select subjects simply because of the subjects' easy availability, their compromised position, or because of social, racial, ethnic, sexual, economic, or cultural biases institutionalized in society. Investigators should base inclusion criteria on those factors that most effectively and soundly address the research problem.

VII. Categories and Procedures for Review

There are three levels of review under the Federal guidelines for projects that meet the definition of research with human participants: Exempt from Review, Expedited Review, and Full Committee Review.

Investigators may request an expedited review or an exemption, but the final determination of review level shall be made at the sole discretion of the IRB Chair in accordance with all relevant Federal regulations and the Antioch University Investigator's Handbook for the Protection of Human Participants. Investigators should carefully review the Handbook for more information on the levels of review.

1. Exempt Review Procedure

Any investigator may request an exemption status by submitting an application for approval of research involving human participants and explaining the rationale for the exempt status request. The IRB chair shall make a determination about eligibility for exemption, and communicate that decision to the investigator. If the study is deemed exempt, the IRB will retain a record of that decision, but no further IRB review or monitoring of the study will take place. If an exemption is not granted, the proposal will be referred for expedited or full review as appropriate.

2. Expedited Review Procedure

Expedited review shall be carried out by a single IRB member. The reviewer may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research (disapproval may only be decided at a meeting of the full committee). Once the review has been completed, the investigator will be notified regarding the status of the application. This written notification will indicate that the application was fully approved, required modifications and/or clarifications in order to secure approval, or was referred for full committee review.

3. Full Review Procedure

Full review is required when there is risk of direct harm from research procedures (e.g., treatments), as well as potential harm (harm may be financial, psychological, physical, harm to reputation, etc.), possible criminal or civil liability, or inconvenience to participants if information they provide were to be linked to their identity.

Full review is carried out by a quorum of the existing members of the IRB. A quorum is the minimum number and type of IRB member that must be present at a convened meeting for the IRB to conduct business. In order to review proposed research at a convened meeting, a majority of the members of the IRB must be present, including at least one member whose primary concerns are in nonscientific areas. If a majority of the IRB membership is not present, or if a nonscientist is not present, then quorum has not been met.

VIII. Meeting Procedures

1. A quorum is required for any official action to be taken.
2. Minutes are taken, identifying who was in attendance and the number of members voting for, against, or abstaining on a particular research proposal.
3. Meeting minutes must be retained for at least 3 years after completion of the research and must be accessible for inspection and copying by authorized representatives from OHRP and FDA at reasonable times and in a reasonable manner.
4. Members can attend via teleconference or videoconference as long as those members have received in advance of the meeting a copy of the documents for research proposals that are to be reviewed at the meeting.
5. Minutes should make clear which members, if any, participated in the convened meeting via an alternative mechanism, such as telephone or video conferencing.

IX. Records Retention

Proper retention of records relating to the research project (including but not limited to the original submitted protocol, signed consent forms, and all correspondence with the IRB) is the responsibility of the investigator. Records should be maintained for a minimum of three years after the completion of the research, unless other requirements by research sponsors or federal regulations apply. If several policies apply, the most stringent requirements shall be followed.

X. Sanctions

The IRB has the authority to deny approval, place restrictions on, suspend, or terminate any study in which the investigator has not met the requirements for conducting the approved research, as delineated in this Policy and the Antioch University Investigator's Handbook for the Protection of Human Participants, or in the event that the IRB determines that the rights and/or welfare of human participants are at risk.

Doing research with human participants without prior IRB approval constitutes a serious violation of University policy. Performing research with human participants without prior IRB approval or in contravention of IRB restrictions may result in serious disciplinary action according to the Faculty Academic Integrity Policy, the Student Code of Conduct Policy, and/or the Human Resources Disciplinary Procedures. In addition, performing research with human participants without prior IRB approval or in contravention of IRB restrictions may jeopardize federal funding to the University.