Investigator's Handbook for the Protection of Human Participants in Research

Institutional Review Board

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Dear Antioch University Principal Investigator:

This handbook is intended to provide you with basic information about conducting research with human participants at Antioch University. Prepared by members of the University-wide Institutional Review Board, this document provides a brief 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. Review of this document will help you to understand:

- the factors that you 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.

Please note that while the Antioch University system has a single IRB that is responsible for the oversight of research at the university, schools or departments may have specific requirements. In addition to taking note of the University wide IRB manual and documents you should consult with school or departmental guidelines for application submission procedures and timelines. It is also important to keep in mind that in addition to federal laws and regulations, states have their own laws and regulations pertaining to research with human participants.

We hope that you will find this handbook to be a useful resource.

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Chapter 1: Introduction

1. Community Expectations and Researcher Responsibility

Faculty 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 researchers (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, Federal Policy for the Protection of Human Subjects and by the Belmont Report.

Safeguarding the rights and welfare of human participants in any research activity is the responsibility of the researchers. 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 according to the procedures established by the University's IRB. Review of research projects occurs at the campus/program IRB level.

2. Purpose

The purpose of the Human Research Protection policy (Code) is to inform students, faculty, and staff who may be conducting research that involves human participants of the standards that the University has established to protect these participants, to describe the structure of the University's IRB program, and to delineate the authority and responsibilities of the various University's Institutional Review Boards for the Protection of Human Participants in Research.

3. Ultimate Authority for Research Compliance

Antioch University has a single university-wide Institutional Review Board (IRB) designated to review and approve research involving human participants prior to the initiation of such research, and to conduct periodic reviews of such research. The IRB operates in accordance with the Belmont Report federal, state, and international guidelines. Codes cited within this handbook refer to Title 45 Code of Federal Regulations (CFR) Part 46.

The AU-IRB Chair oversees compliance efforts within the university and reports to the Vice Chancellor for Academic Affairs (see Definitions below for additional information on the structure of the IRB system at AU). The Antioch University Policy governing the IRB is 5.507 Human Subjects Protection (IRB).

The IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the University's requirements, or in the event that the IRB determines that the rights and/or welfare of human participants are at risk.

4. Jurisdiction

All human subjects research carried out at the University or under its auspices must be reviewed and approved by the AU IRB prior to the start of the research. The Human Research Participant Policy applies to all Antioch University faculty, staff, students, and contracted individuals whether their research is conducted on or off one of the Antioch University campuses, and irrespective of funding source.

University-designated IRBs review projects when:

1) the research is sponsored by this institution,
2) the research is conducted by or under the direction of any employee or agent of this institution in connection with his or her institutional responsibilities,
3) the research is conducted by or under the direction of any employee or agent of this institution using any property or facility of this institution, or
4) an employee or agent of this institution (including students) meet the criteria for "engaged in research" as defined in OHRP guidance of October 16, 2008,
5) the research involves the use of this institution's non-public information to identify or contact human subjects.

The guidelines in this policy pertain only to research, as defined by federal code (see Definitions), that includes the use of human participants. The guidelines do not address compliance with other federally-mandated regulations, for example, those that govern animal subjects, recombinant DNA, and radioisotopes.

II. 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. The Antioch University FWA number is FWA00005527, and our IRB registration number is IRB00007422.

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.

Human 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)]. May also be referred to as human subjects.

Identifiable Private Information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. An ***identifiable biospecimen*** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or added associated with the biospecimen.

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. The University has a single AU-wide IRB.

Intervention includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
Interaction includes communication or interpersonal contact between investigator and subject.
Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (for example, a medical record).
Protected Health Information is defined as any individually identifiable health information collected or created as a consequence of the provision of health care by a covered entity, in any form, including verbal communications. A description of protected health information can be found here: www.hipaa.com/2009/09/hipaa-protected-health-information-what-does-phi-include/.
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 Structure:

- School based IRB chair assignments based on historical application data.
- Graduate School of Counseling, Psychology, and Therapy – 3 (Counseling, Clinical Psychology, and Relational Therapies [including CA programs])
- School of Education – 1
- The School of the Environment – 1
- Graduate School of Leadership and Change – 1
- Undergraduate Studies and Management – 1
- Graduate School of Nursing and Health Professions – 1

School-based chairs will be selected from among the faculty in the respective schools. School-based chairs will perform initial reviews of applications and serve as a resource about research ethics and IRB processes for their school/division. The University-Wide IRB Committee will be chaired by one of the school-based chairs for an elected, two-year term on a rotating basis. The University IRB Chair will convene a monthly meeting to address full reviews as well as conduct ongoing IRB business, workload management, and policy review. The school-based chairs will review applications within their assigned schools/divisions, with potential for redistribution in order to assure equitable workload. If full review is indicated, the application is referred to the University-Wide IRB Committee, which will be composed of the school-based chairs, plus two external community reviewers.

Federal guidelines for IRB membership are described below:

1. The IRB shall consist preferably of five (5) members with varying academic 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.
2. Every effort will be made to ensure that the IRB has a diverse membership including race, gender, and cultural backgrounds.
3. 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.
4. 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.
5. 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.
6. The IRB may, at its discretion, invite individuals with competence in special areas (Consultants) 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.

III. Policy Details and Administrative Procedures

The Antioch University Investigator's Handbook for the Protection of Human Participants (Handbook) provides a brief 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. Review of this document will help Antioch University students, faculty, and staff understand:

- the factors that they 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 federal regulations that guide research involving human participants.

IV. Guiding Principles

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

Respect
In consideration of respect for persons, investigators are required to seek voluntary informed consent from potential subjects. Voluntary informed consent means that subjects are given explicit assurances of the voluntary nature of their participation in terms that are easy to understand and 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 individuals with impaired decision-making capacity 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.

Regulations for the protection of human subjects in research require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless (1) the research is exempt under 45 CFR 46.101(b); (2) the IRB finds and documents that informed consent can be waived (45 CFR 46.116(c) or (d)); or (3) the IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings. When informed consent is required, it must be sought prospectively and documented to the extent required under HHS regulations at 45 CFR 46.117.

Beneficence
The principle of beneficence requires that researchers 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.

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, unless these latter categories are integral to the research question. Investigators should base inclusion criteria on those factors that most effectively and soundly address the research problem.

V. Categories of Review

There are *three levels of review* under the Federal guidelines for projects that meet the definition of research with human subjects:

1) Exempt From Requirements of the Common Rule
2) Expedited Review
3) 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 and in accordance with all relevant Federal regulations.

A submission may also be determined to not meet the definition of research with human participants, and therefore not subject to IRB review.

VI. Sanctions

Performing research with human participants without IRB approval may jeopardize federal funding to the University. Sanctions for performing research with human participants without IRB approval are established according to the following Codes:

- Students: Student Code of Conduct Policy
- Faculty: Faculty Academic Integrity Policy
- Staff: Human Resources Disciplinary Procedures

The IRB has the authority to suspend, terminate, or place restrictions on any approved study in which the investigator has not met the requirements for conducting the approved research, as delineated in the Handbook, or if the IRB determines that the rights and/or welfare of human participants are at risk.

VII. Records Retention

Proper retention of records relating to the research project (original submitted protocol, all signed consent forms, correspondence with the IRB, etc.) is the responsibility of the researcher. 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 should be followed. The IRB has the authority to inspect records, and to observe (or have a third party observe) the process of any activity that it approves.

Chapter 2: Overview

The University-wide Institutional Review Board (UW-IRB) at Antioch University (AU) is a committee designated to oversee the conduct of research on human participants. The IRB operates according to Title 45 Code of Federal Regulations (CFR) part 46 (*see Appendix 1*), Federal and State guidelines, and the Belmont Report.

Faculty 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. The IRBs support these efforts by:

- Reviewing proposed research involving human participants in order to protect them against potential risks of research participation while promoting high-quality studies that can provide benefits to participants and/or society;
- Educating the larger university community about ethical issues in human participants research; and
- Overseeing compliance with federal, state, and university regulatory requirements for human participants research.

Beyond these formal policies, and consistent with Antioch University's expressed commitment to social justice, the UW-IRB will seek to be a resource for facilitating enhanced sensitivity to ethical matters in all manner of community engagement activities, whether or not such activities meet the federal definition of research. In any communications related to non-research activities, the IRBs will be acting in a purely consultative role, with no authority or oversight over decisions related to those activities.

Focus of IRB Review

IRB review focuses on such issues as risks to participants, voluntary participation, informed consent, and confidentiality. We consider the scientific merit of the research *only* if the project is deemed to involve greater than minimal risk to participants (see criteria for Expedited Review), in which case we are obliged to weigh those risks against the potential benefits of the research.

The guidelines in this policy pertain only to the use of human research participants, and do not address compliance with other Federally-mandated regulations, for example, those that govern animal subjects, recombinant DNA, and radioisotopes. Any investigator who wishes to employ such methods in his or her research should contact the Office of Academic Affairs on his or her campus. Reports of violations of this policy or complaints from research participants will be brought before the IRB at a convened meeting, and appropriate action taken.

IRB Roles and Responsibilities

IRB members

All faculty IRB members are appointed for a renewable, two-year term. Reappointments will be made by divisional or school leadership, with recommendations approved by the AU IRB Chair and the University Chief Academic Officer. All members have full voting rights; no proxy voting is permitted.

Each departmental representative to the IRB will serve as local consultant and first level of review for their constituency, and will serve as a resource for IRB questions within their school or division. Each representative thus serves as the liaison between the research investigators and IRB.

IRB Chair

The University Chair will convene full review meetings, manage policy and handbook revisions, and manage university reporting and coordination. The Chair will also manage the university's Federal Wide Assurance and contracts with the Collaborative Institutional Training Initiative (CITI Program). The Chair will also be available to consult with school-based chairs if questions arise about whether a full review is required or to provide support on unusual or complicated applications. The University-Wide IRB Chair will also track the numbers of submissions across the schools and reassign, as needed, to maintain a balance among all school-based chairs.

The IRB Chair will ensure that new members receive a copy of this document, and that any additional details concerning committee functions and procedures are discussed. The IRB Chair maintains the following IRB records:

- Current list of IRB membership and qualifications
- Minutes of meetings, including information regarding member attendance, discussions held, decisions made, and voting results.
- All materials submitted to the committee for initial and continued review of each study, including:
    - IRB applications,
    - submitted and final consent forms,
    - adverse reaction reports,
    - proposed amendments,
    - progress and summary reports,
    - and all correspondence generated between the committee, the investigators, and, where applicable, sponsoring agencies.
    - This information is retained for a period of seven years following the inactivation of a project.

Chapter 3: Defining Research

Research

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

Research generally does not include operational activities such as defined practice activities in psychology or social work, or studies for internal management purposes such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted-for services. However, some of these activities may include or constitute research in circumstances where there is a clear intent to contribute to generalizable knowledge. If you plan to present or publish the work or otherwise share results of the study, it is probably research. If the research being conducted is only used for instructional purposes, it may not meet the definition of research. Researchers should err on the side of caution and submit an application if there is any question, and may consult with the IRB Chair.

Human Participant (Subject)

The DHHS Regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, (2) identifiable private information (45 CFR 46.102(f)), or (3) protected health information.

The Office of Human Research Protections (OHRP) has published a helpful guide on this topic: https://www.hhs.gov/sites/default/files/ohrp-what-is-research-and-what-it-is-not.pdf

Chapter 4: Categories of Research & Levels of IRB Approval

Under the Federal guidelines (45 CFR; Part 46), the only research activity involving human participants that is exempt from prior review and approval from the IRB involves the emergency use of an investigational drug (i.e., not approved by the Food and Drug Administration). Emergency use is defined as the use of a test article on a human participant in a life-threatening situation in which there is no standard acceptable treatment available and in which there is not sufficient time to obtain IRB approval. Such emergency use must still be reported to the IRB within 5 days. It is highly unlikely that research conducted at or by the Antioch community will encounter these circumstances. In all other circumstances, prior IRB review and approval of research involving human participants is mandatory.

There are *three levels of review* under the Federal guidelines: a) Exempt Research (including Limited Review), b) Expedited Review, and c) 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 and in accordance with all relevant Federal regulations.

We recommend that researchers review the decision charts found in the Documents tab on the AU IRB webpage for guidance on the level of review required for submitted applications. General guidelines for each of these categories are as follows:

Exempt Research

Under the DHHS regulations, some research is exempt from the requirements in the regulations. Although the regulations allow these exemptions to apply to research involving more than minimal risk to participants, the IRB will not grant an exemption determination to research involving more than minimal risk to participants.

It is important to note that all research–even research that investigators believe falls into one of the exempt categories–must be submitted to the IRB prior to the beginning of data collection. It is the IRB, not the individual researchers, that determines the appropriate review categorization of each study. It is also within the IRB's purview to establish procedures that are consistent with the protection of the participants, even if the research is found to be exempt.

Consent forms are usually not required for exempt studies, but information sheets and/or verbal consent are typically appropriate, and this information must be submitted with the supporting documentation for the study. Secondary research that requires limited review may require broad consent. Broad consent is described below and in the Informed consent section. The extent of the consent process will be determined by the IRB.

If the IRB determines a study is "exempt," the researcher will receive a letter/e-mail confirming the exemption. If the study does not qualify as "exempt" or if the issue is not clear and/or any of the required approvals are missing, the researcher will be notified as to what is required before approval can be granted.

Categories of Exemption

Research that falls into any of the following categories and involves minimal risk is generally exempt from regulatory requirements unless it involves children or prisoners as participants.

General Category Additional category information follows this table	**Level of Exemption**
1) Research conducted in established or commonly accepted educational settings	Exempt
2) Research interactions involving the use of educational tests, survey procedures, interview procedures or observation of public behavior **if confidentiality can be assured** or **if confidentiality cannot be assured**	Exempt Exempt/Limited Review
3) Research involving benign behavioral interventions with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information collected **if confidentiality can be assured** or **if confidentiality cannot be assured**	Exempt Exempt/Limited Review
4) Secondary research for which consent is not required	Exempt
5) Research and demonstration projects which are conducted or supported by a Federal department or agency, or subject to the approval of DHHS or Federal Agency heads	Exempt
6) Taste and food quality evaluation and consumer acceptance studies	Exempt
7) Storage or maintenance of identifiable biospecimens for potential secondary research use	Exempt/Limited Review
8) Secondary research for which broad consent is required	Exempt/Limited Review

Additional Details for Exempt Categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices that are not likely to adversely impact students' ability to learn required content or the assessment of educators who provide instruction such as:
    a. Research on regular and special education instructional strategies
    b. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods
2. Research interactions involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), provided:
    a. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subject, **or** any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.
    b. If the subject's identity can be ascertained, the research can be considered under the exempt category if the IRB conducts a Limited Review.
3. Research involving benign behavioral interventions (defined later) in conjunction with the collection of information from an adult subject through verbal or written responses or audiovisual recording if the subject prospectively agrees to the intervention and information collected and one of the following criteria is also met:
    a. Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subject; or
    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation.
    c. If the subject's identity can be ascertained, the research can be considered under the exempt category if the IRB conducts a Limited Review.
4. Secondary research for which consent is not required.
5. Research and demonstration projects which are conducted or supported by a Federal department or agency, or subject to the approval of DHHS, Federal Agency heads, and which are designed to study, evaluate, improve, or otherwise examine:
    a. Public benefit or service programs,
    b. Procedures for obtaining benefits or services under those programs,
    c. Possible changes in or alternatives to those programs or procedures, or
    d. Possible changes in methods or levels of payment for benefits or services under those programs.

    In addition:

    - The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act).
    - The research or demonstration project must be conducted pursuant to specific federal statutory authority.
    - There must be no statutory requirement that the project be reviewed by an IRB.

- The project must not involve significant physical invasions or intrusions upon the privacy of participants.
- The exemption must have authorization or concurrence by the funding agency.

6. Taste and food quality evaluation and consumer acceptance studies, if:
    a. Wholesome foods without additives are consumed, or
    b. A food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below a level found to be safe, by the Food and Drug Association (FDA) or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. Storage or maintenance for secondary research for which broad consent is required:
    a. Storage or maintenance of identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 46.111(a)(8)
8. Secondary research for which broad consent is required:
    a. Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
        i. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 46.116(a)(1) through (4), (a)(6), and (d), see the Informed Consent section for a description of Broad Consent;
        ii. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 46.117;
        iii. An IRB conducts a limited IRB review and makes the determination required by 46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; AND the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

<u>Exempt research involving children</u>

- The regulations allow research with children to be exempt for categories 1, 4, 5, 6, 7, and 8 above. The regulations do not permit the exemption of research with children that includes identifiable information and is reviewed under a limited IRB review.
- Observation of the public behavior of children under Category 2 is allowed only if the researcher does not participate in the activities being observed.
- Surveying and interview procedures with children may not be exempt.

Exempt Review Procedure

Any investigator may request an exemption status by submitting the Application for Approval of Research Involving Human Participants and explaining the rationale for the Exempt Status request. The IRB Chair or her or his designee may 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.

Exempt/Limited IRB Review

In a limited IRB review, the IRB is making and documenting the determination the research is Exempt from IRB review and that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens in the proposed research.

Exempt/Limited IRB review is a condition for exemption of the research activities that involve:

- Identifiable and sensitive educational tests, survey procedures, interview procedures, or observation of public behavior (see 46.104 [d][2][iii])
- Identifiable and sensitive benign behavioral interventions (see 46.104 [d][3][i][c]) [see definition below.]
- Secondary research use (see 46.104 [d][8])

Benign Behavioral Intervention

"Benign behavioral intervention" is described in 46.104(d)(3) as behavioral (not biomedical) interventions in conjunction with collecting information from an adult subject through oral or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and certain conditions are met. This exemption is for research activities that pose little risk to subjects. Benign Behavioral Interventions must be brief in duration, painless, harmless, not physically invasive, not likely to have a significant adverse lasting effect on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

A new limited IRB review criterion (46.111[a][8]) adds additional broad consent determinations for approval of activities that store and/or maintain private information or identifiable biospecimens for secondary research use under exemption 46.104(d)(7). Broad Consent is described in the Informed Consent section of this Handbook.

Expedited Review

Two categories of research may be eligible for Expedited Review:

1. Research already reviewed and approved by an IRB at another institution. In these instances, the applicant is directed to submit, in lieu of an Antioch IRB application, a copy of all materials submitted to the external IRB, along with documentation of that IRB's decision (note that the researcher should complete the first section of the online application and then attach the documentation requested on the attachments tab).
2. Research involving no more than minimal risk**,** defined by the Federal Code of Regulations as circumstances in which "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" (Title 45 CFR; Part 46 Protection of Human Subjects Section 46.102i). The following are examples of such activities:

a. Research on individual or group characteristics or behavior where there is no psychological intervention, physiological intervention or deception.
    i. This category may include research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior.
    ii. This category may include research employing survey, interview, oral history, focus group, program evaluation or quality assurance methodologies.
    iii. Some research in this category may be exempt (as noted above) and this applies only to those projects that are not exempt.
    iv. Note that interviews and surveys involving minors, including those in schools (except where the interview or survey is itself a standard educational practice) cannot be exempt and must be reviewed at least at the expedited level.
b. Secondary analysis of existing data (that is, research involving materials that have been, or will be, collected solely for non-research purposes, such as medical treatment or diagnosis).
c. Collection of data from voice, video, digital, or image recordings made for research purposes.
d. Recording of data using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the participant or an invasion of the participant's privacy.
e. Moderate exercise by healthy volunteers.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

Expedited Review Procedure

Expedited review will be carried out by a single committee 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.

Full Review

In addition to any risk of direct harm from research procedures (e.g., treatments), this category includes potential harm (harm may be financial, psychological, physical, harm to reputation, etc.), criminal or civil liability, or inconvenience to participants if information they provide were to be linked to their identity. Examples include:

- Research involving psychological or physiological intervention.
- Research involving deception, or for which the investigator seeks to otherwise waive informed consent.

- Interviews or surveys on sensitive topics (e.g., illegal conduct, substance use, sexual behavior) where there is greater than minimal risk of breach of confidentiality.
- Research on designated vulnerable populations (e.g., pregnant women and fetuses, minors, prisoners, persons with diminished mental capacity, and those who are educationally or economically disadvantaged). Note that some research with these populations may be exempt or expedited, depending on other factors.
- Most research conducted outside the United States, regardless of the procedures involved.

For all research involving participants who have been determined to be "at risk," written documentation of legally effective informed consent is required. Research on minors or participants incompetent to give consent requires permission by a parent or legal guardian (unless the IRB approves a modification to the consent process).

Criteria for Approval

For applications subjected to full review, a **quorum** (majority) of members, including at least one non-scientific member, must be present for a meeting to be held. Each protocol is assigned to a primary reviewer who presents the application and begins the committee deliberations. The action taken on each application will depend on the majority vote of the members present. Voting by proxy or in absentia is not permitted. After the meeting, the investigator is notified regarding the status of the application. Action taken on the application may include approval, a request for clarifications and/or modifications in order to secure approval, a deferral (i.e., response from investigator must be brought back to full committee), or disapproval. Requests for waiver of this policy will be considered on a case-by-case basis by the IRB Chair and in accordance with Federal guidelines.

For applications subjected to an expedited review, one member must review the applications. The action taken on each application will depend on the recommendations of the reviewer. Action taken on the application may include approval, a request for clarifications and/or modifications in order to secure approval, a deferral (i.e., response from investigator must be brought back to IRB chair), or referral to the IRB Committee for full review.

In order to approve a research activity, a majority of the entire membership of the IRB if a full review or one reviewer if an expedited review must determine that all of the following requirements are satisfied:

- Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to physical or psychological risk, and, whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.
- Risks to participants are reasonable in relation to anticipated benefits, if any, to participants and the importance of the knowledge that may reasonably be expected to result.
- Selection of participants is equitable, in relation to the purposes of the research and the setting in which the research will be conducted.
- Informed consent is obtained in compliance with IRB policy as outlined in these guidelines
- Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of participants.

- Where appropriate, there are adequate provisions to protect the privacy of participants and to maintain the confidentiality of data.
- Where some or all of the participants are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons with cognitive limitations, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the study to protect the rights and welfare of these participants.

If these conditions are satisfied, IRB approval periods are granted on the basis of degree of risk associated with the particular protocol (but no greater than 1 year).

Conditional Approval

Institutional Review Boards (IRBs) may approve research conditionally provided that the following criteria are met to the satisfaction of the IRB:

By *IRB approval with conditions* (sometimes referred to as "conditional approval" or "contingent approval"), OHRP means that at the time when the IRB reviews and approves a research study (or proposed changes to a previously approved research study), the IRB requires as a condition of approval that the investigator (a) make specified changes to the research protocol or informed consent document(s), (b) confirm specific assumptions or understandings on the part of the IRB regarding how the research will be conducted, or (c) submit additional documents, such that, based on the assumption that the conditions are satisfied, the IRB is able to make all of the determinations required for approval under the HHS regulations. The researcher may not begin their study until they submit further documentation and receive final approval.

In addition, IRBs cannot conditionally approve research under the following circumstance:
The IRB must not approve a proposed research project undergoing initial review when the IRB (a) 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 because the research protocol provides insufficient information related to these aspects of the research, and (b) is unable to specify changes to the research protocol that if made would allow the IRB to make these required determinations.

In this circumstance, the IRB can defer or disapprove the project. One key piece is that if a project is deferred at a convened meeting, it cannot be approved until the next convened meeting. However, projects given conditional approval can have the conditions verified by the Chair (or another designee) and does not need another convened meeting for approval.

The IRB may require the following as conditions of approval of research:

1. Confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted (e.g., confirmation that the research excludes children);
2. Submission of additional documentation (e.g., certificate of ethics training);
3. Precise language changes to protocol or informed consent documents; or
4. Substantive changes to protocol or informed consent documents along with clearly stated parameters that the changes must satisfy.

Another key component is the IRBs may approve some components of a proposed research study and defer taking action on other components. This means that researchers can get started on approved components but not on deferred ones.

Disapproval

Disapproval of an activity is determined at meetings of a majority of the entire membership of the IRB only. If the IRB does not approve a research activity, the principal investigator has the right to appeal that decision either in writing or in person at an IRB meeting. If the investigator is not satisfied with the decision subsequently reached by IRB, the investigator may request re-review by IRB whenever significant changes are made to the research protocol or significant new information becomes available.

Examples of Activities That Require IRB Review

- Secondary Analysis of Data and/or Specimens which Include PII or PHI: The use of existing personal identifiable information about living individuals, such as data collected from medical or academic records, for research purposes may constitute human research as defined by this policy and the federal regulations.
- Recruitment and Screening Activities: IRB approval is required before recruitment or screening for a human research project begins.
- Pilot Studies: Pilot studies that meet the definition of human research, regardless of the number of subjects enrolled or the duration of the studies, require IRB review and approval or Certification of Exemption from IRB review.
- Student-Conducted Research: Antioch University student-conducted research which includes activities that meet the definition of human research requires IRB review and approval or Certification of Exemption from IRB review. Thesis or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable and therefore meet the regulatory definition of research. Such thesis or dissertation projects require IRB review and approval when the research being conducted involves human subjects.
- Academic Presentation, Publication: Living individuals commonly provide private identifiable information about themselves for non-research purposes. Such data represent useful information for investigators. Investigators who want to access such information for research purposes with the intent to present, publish or disseminate the data in academic/professional medical or at academic/professional meetings or settings are required to obtain IRB review and approval, Certification of Exemption from IRB review, or a determination that the activity is not human research prior to accessing the data for research purposes.

Examples of Research Activities that May Not or Do Not Require IRB Review (Because they do not meet the definition of Research with Human Subjects).

Certain research projects may not be subjected to IRB review because they do not meet the definition of Research with Human Subjects. Examples include:

- Analysis of Data or Specimens that Do Not Include private information or personal health information: Under specific, limited circumstances, research involving only de-identified or coded

private information or specimens may not fit the definition of human research and therefore may not require IRB review or certification as exempt from IRB review. The determination is made and certified by the Principal Investigator. Generally, if researchers are using data or specimens that do not include private information or personal health information, were not collected specifically for purposes of the study, are not being used in research covered by the FDA and the researchers do not have access to the code linking the data to private information or personal health information, then the research may not require IRB review or exemption from IRB review.

- Studies Using Public Data Sets/Specimens: If the data and/or specimens are publicly available, then the project does not meet the definition of "human research." Therefore, neither IRB review nor certification of exemption from IRB review is required. However, note that the term "publicly available" means that the general public can obtain the data/biological specimens. Sources are not considered "publicly available" if access to the data/specimen source is limited to researchers.

- Individual Case Studies: In general, the review of medical records for publication of "case reports" of three or fewer patients is not considered human-subject research and does not typically require IRB review and approval because case reporting on a small series of patients does not involve the formulation of a research hypothesis that is subsequently investigated prospectively and systematically for publication or presentation.

- Quality Improvement Activities: Most quality improvement efforts are not research subject to the DHHS protection of human subject regulations. However, in some cases, quality improvement activities are designed to accomplish a research purpose as well as the purpose of improving the quality of care, and in these cases the regulations for the protection of subjects in research (45 CFR 46) may apply.

- Oral History Activities in general which are solely designed to create a record of specific historical events and, as such, are not intended to contribute to generalizable knowledge are not considered research.

Researchers who are unsure whether their project meets the definition of Research with Human Subjects should consult with the IRB Chair.

Cooperative Research

For research involving multiple institutions, the lead institution may propose which IRB will serve at the IRB of record. Institutions may still choose to conduct their own review of research.

Federally-funded collaborative research projects located in the U.S. will be required to use a single IRB (commercial, academic, or hospital-based) starting in January 2020. The federal department or agency funding the research makes the final decision as to which IRB will serve as the IRB of record.

Student and Classroom-Based Research Activities

This section is designed to distinguish class-related activities involving human participants that do ***not*** require IRB review, from student activities that do require IRB review. The key distinction is whether the activity meets the earlier quoted federal definition of research, specifically, whether it is "designed to contribute to generalizable knowledge." One relatively straightforward test of this distinction is whether the student wishes to preserve the option to publish or present the research in any public forum; to do so establishes a prima facie claim of contribution to generalizable knowledge.

Student Activities That Do Not Require IRB Review

In general, classroom activities that are ***not*** intended to contribute to generalizable knowledge, but instead represent a learning exercise, will not fall under the purview of IRB review. Classroom assignments should still be conducted in accordance with the ethical standards outlined in this policy, and faculty instructors are responsible for ensuring the ethical conduct of the projects they assign to their students, such as voluntary consent to participation and respect for participant privacy.

General guidance for survey projects. Each survey participant should be made aware of the following information. This awareness may be accomplished by a verbal presentation or through introductory information in the survey instrument.

- The student's name and affiliation with Antioch;
- The title of the class in which the assignment was made;
- The class instructor's name;
- The nature of the assignment and the purpose of the survey;
- The voluntary nature of participation; and
- The level of confidentiality provided for the identity of the participant and individual responses to the survey questions.

Please note: If a student's classroom assignment has the potential to develop into a "research" project that could be viewed as contributing to generalizable knowledge, the IRB should be consulted ***before*** any project activities are initiated.

Student Activities That Do Require IRB Review

Typically, thesis research or other independent research projects required of graduate students will meet the definition of research described above. All student research that uses human participants must be supervised by a faculty member. No application from a student for IRB approval will be considered unless the research project has been approved by a faculty supervisor, who ultimately carries responsibility for ethical conduct of the student's research project.

Suspension or Termination of IRB Approval of Research

The IRB shall suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension

or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Chapter 5: Materials Required for New Applications

Research activities that involve human participants, as described in Chapters 4 and 5, must be filed with IRB and must be approved prior to commencement of the activity. All applications and subsequent correspondence must include the original and submitted Application for Approval of Research Involving Human Participants (see form for submission details) along with required email attachments. The schedule for full IRB committee meetings are available on the IRB website. All new applications must include the following materials:

IRB application

Complete with the signature of the investigator, who ensures accuracy of the information contained within the submitted materials, and, upon approval, promises compliance with all aspects of Chapter 9 entitled "Responsibilities of Investigators." Student research requires the signature of the faculty supervisor who assumes responsibility for: a) accuracy of the information contained within the submitted materials, and b) compliance with all aspects of this policy.

Project description that clearly discusses, in lay language:

1. Project purpose
2. The types of people to be recruited as participants (how many, desired characteristics of the study sample)
3. How participants will be recruited, including copies of all advertisements, posters, incentives or compensation, etc.
4. Inclusion/exclusion criteria for participant entry. Include justification if women, minorities and/or minors are to be excluded from the research activity (federally required). Disclose if investigator proposes to include him/herself or members of his or her family as participants in the proposed research
5. Details on all materials and procedures with which human participants are involved
6. Discussion of the possibility of harm and the potential benefits, and an assessment of the balance of risk
7. How the rights and welfare of the participants will be protected, including specific information about protection of privacy
8. Whether electrical or mechanical devices will be used, and how.
9. Copies of all interviews, surveys, questionnaires, consent/permission/assent forms, etc. Any documents that will be used to recruit participants or gather data should be submitted to the IRB.
10. Researchers must attach a copy of their CITI modules training certificate documenting that they have completed the required ethics training.

Consent/Permission/Assent form(s)

Printed on departmental letterhead and standardized to conform to IRB requirements. See the next chapter for additional information required for consent, permission, and assent.

Research Oversight by an External Institution

When research is conducted by an employee or student of Antioch University under the auspices of an institution other than Antioch University, written documentation must be provided articulating the responsibilities that Antioch and the external institution will undertake to ensure compliance with the requirements of Antioch University human research policy. This may take the form of a written agreement, documentation of institutional policy, or procedures set forth in a research protocol.

Chapter 6: Informed Consent

Regulations for the protection of human subjects in research require that an investigator obtain the legally effective informed consent of the subject or the subject's legally authorized representative, unless:

1. The research is exempt under 45 CFR 46.101(b);
2. The IRB finds and documents that informed consent can be waived (45 CFR 46.116(c) or (d)); or
3. The IRB finds and documents that the research meets the requirements of the HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings.

When informed consent is required, it must be sought prospectively, and documented to the extent required under HHS regulations at 45 CFR 46.117.

When requesting consent, the participant or his/her representative must be given enough time to consider whether to be in the study so that the possibility of coercion or undue influence is minimized. Information provided to the participant or representative must be written in simple language (approximately 8th grade reading level, which can be assessed with tools in most word processing programs), so that all aspects of the research (e.g., purpose, risks, benefits) are clearly stated, and an informed decision may be made about whether to participate. Alternatively, the investigator may make a case for why a higher than 8th grade reading level is appropriate for the target population. Finally, the investigator may need to consider a 4th grade reading level when adolescents are the target population.

For those consent forms that must be translated into a foreign language, both English and the foreign language versions must be provided, and an affidavit of accurate translation must be provided from an appropriate translator who is unaffiliated with the study.

Types of Consent

Note that there are three types of consent, named in accordance with the age of the participant:

- **Consent** is obtained from participants 18 years or older,
- **Permission** is obtained from parents or guardian of participants 17 years or younger (since the participants themselves cannot consent to being in the study),
- **Assent** is obtained from the minor participant (11-17 years of age) to be in the study; for those participants under age 11 parental permission forms are the only requirement.

The term "consent" in this handbook is used generally and may refer to seeking consent, permission or assent, as applicable to the age of the research participants. Samples of consent, permission, and assent forms are available in the *Documents & Links* tab on the IRB webpage.

Documentation of Informed Consent

Documentation of informed consent is required in ***most*** cases (see above sections on permitted waivers). Among other things, the consent form describes the purpose and procedures of the study, risks and benefits to participants, and their rights as research participants. Consent is documented by having participants sign two copies of the form. A written copy must be given to the person signing the consent

form. A second copy should be kept for the researcher's records. When electronic signatures are used a written copy of the consent form shall be given to the person signing the informed consent form.

In cases where the requirement of documentation is waived (e.g., use of an anonymous survey is proposed), a consent document in IRB-required format must still be used. However, the document is written in letter format ('Dear Participant'), and, rather than requiring the participant's signature to verify consent, the following text is used to end the letter:

'If you _____(e.g., complete the attached survey, answer these few questions etc.), it means that you have read (or have had read to you) the information contained in this letter, and would like to be a volunteer in this research study. Thank you, (signatures of investigators)'

Elements of Informed Consent Forms

General guidelines

Documentation of "legally effective informed consent" usually involves the use of a written consent form signed by the participant or the participant's legal representative containing all of the information relating to the research in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject's or legally authorized representative's understanding of the reasons why one might or might not want to participate. It should be emphasized that the consent form is merely the documentation of informed consent and does not, in and of itself, constitute informed consent. The fact that a participant signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent. Informed consent is a process that is documented by a signed consent form.

Required Elements

Informed consent forms must begin with a concise and focused presentation of key elements of information that is most likely to assist in understanding why to participate (or not) in the research. The consent form **must be organized and presented in a way that facilitates comprehension and** include the following elements:

- a statement that consent is being sought for research
- a statement that participation is voluntary and that consent may be withdrawn at any time without penalty.
- explanation of the project (including specific purposes)
- what is expected of the participant (including activities/procedures to be followed and expected duration of the participant's involvement
- a description of any reasonably foreseeable risks or discomforts to the participant
- a description of any benefits to the participant or to others which may reasonably be expected from the research
- a disclosure of appropriate alternative activities, procedures or courses of treatment, if any, that might be advantageous to the participant

Your informed consent and parental permission forms must include the material above. In addition, you must have a section at the end of the consent that states:

- **If you have any questions about the study, you may contact [Dr. P. Investigator], via telephone at [insert phone number] or via email at [insert email address].** (Note: we do not recommend that investigators provide their home phone number. A campus office phone number is more appropriate.)
- **If you have any questions about your rights as a research participant, you may contact [insert name and office phone number of AU IRB Chair].**

Additional Elements (as appropriate)

A description of how confidentiality and privacy will be assured if this is possible given the research design

- A statement about any audio or video recording taking place, with affirmative permission for that recording.
- Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent.
- A statement describing use of data as part of secondary future research.
- Any additional costs to the participant that may result from participation in the research.
- The consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant.
- A statement that describes situations of mandated reporting by the researcher
- A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus, if the participant is or may become pregnant), which are currently unforeseeable.
- A statement about the collection of private information or identifiable biospecimens for future research, either: identifiers might be removed and the de-identified information used for future research without additional informed consent or the information will not be used for future research even if the identifiers are removed.
- A statement that significant new findings developed during the course of the research, which may relate to the participant's willingness to continue participation, will be provided to the participant,

<u>Consent Form Qualities</u>

A consent form should be designed to meet the needs of the particular research project where it is being used; no one form can be used in every research project. However, it is recommended that consent forms meet four criteria.

1. **Be brief, but begin with required basic information.** Many potential participants do not read long consent forms. The longer the form, the fewer the number of people who read it in its entirety, and the smaller the fraction of it that is read by the rest. That is, the quest to be more comprehensive by including more information may result in the information transmitted being less comprehensive. Include only the basic information needed by potential participants ("basic" are the items required by federal regulations) and do not try to answer every conceivable question. "Non-basic information" can be given in a separate handout, perhaps in a Question-and-Answer format. One suggestion is to include a list of questions at the beginning of the handout, to permit each person to go to those questions that most interest him/her.

2. **Be readable and understandable to most people.** Articles in most popular magazines are at the 8th grade level. Several computer programs estimate readability by the Flesch, Flesch-Kincaid, and FOG measures. Factors that improve readability include the following:
   - Technical terms should be replaced with ordinary language (see appendix);
   - Use active tense rather than passive tense verbs ("We did" rather than "It was done");
   - Write shorter sentences in general; and
   - Make clear the links of logical sequences and of cause-and-effect, even if doing so makes the sentence much longer. ("We will do this, because that happened".)

   Readability statistics are available in MS Word version 14.0 and higher. Follow these instructions to determine the readability level of your text:
   - Click on the "Word" pull-down menu at the top left of the screen.
   - Click on "Preferences."
   - Click on the "Spelling and Grammar" icon.
   - Check the box labeled "Show readability statistics."
   - Select the text in the relevant document.
   - Click on the “Tools” pull-down menu at the top of the screen.
   - Click on "Spelling and Grammar.”
   - A dialog box will alert you to grammatical errors. When finished resolving errors another dialog box appears that provides a Flesch-Kincaid grade level readability score.

3. **Be in a format that helps people comprehend and remember the information**. Format can be used to help people comprehend and remember complex material. Good format uses are:
   - headings;
   - indents;
   - bolded type;
   - lists;
   - extra spacing between sub-topics;
   - repetition;
   - reasonable-size type; and
   - plenty of margins and empty space in general. (Think of the daunting insurance policy statements with their wall-to-wall and top-to-bottom writing in small print).

   Those formats help the reader to: A) organize the information; B) recognize, know, and remember the key points; and C) go back later to the consent form and retrieve important information (such as telephone number of the investigator to call with questions).

4. **Serve as a script for the face-to-face discussions with the potential participants.**

   Face-to-face discussions between researcher and potential participant are the most important part of the process of informed consent. These sample forms can be the script for the verbal explanation by the researcher. If the verbal explanation is almost identical to the written consent form, each will reinforce the other and potential inconsistencies will be avoided.

One benefit of this approach is that the form/script prompts the researcher to use simple language for the verbal explanation. Another benefit is that the same form/script can be used for potential participants who have difficulty reading or low literacy or who need a translation, which also should improve consistency of explanation among all participants. i.e.., researchers need develop only one form/script, not two, to permit people of all literacy levels to be potential participants. The script could also be used in videotaping the explanation. On the other hand, it is not advisable simply to read the consent form to participants - it must be explained!

Use of Short Form Consent

In some cases, the IRB may approve a consent process that is conducted orally with the participant or the participant's legally authorized representative. This consent must contain all the required elements of informed consent. When this method is used, there shall be a witness to the oral presentation. The IRB shall approve a written summary of what is to be said and the short form written informed consent.

Only the short form itself is to be signed by the participant or the participant's legally authorized representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the participant's legally authorized representative, in addition to a copy of the short form (45 CFR 46 117(b)(2)).

Broad Consent for Secondary Research

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or non-research purposes) is permitted as an alternative to regular informed consent requirements.

When appropriate, broad consent will inform participants that information that has been stripped of identifiers might not be traceable and thus it might not be feasible to withdraw consent for future use of the information.

Note that such consent is not required for de-identified data, but for the secondary data with identifiable private information.

Broad Consent requires some basic elements of informed consent, namely statements about:

- Risks
- Benefits
- Confidentiality
- Voluntary statement
- Commercial profit (when appropriate)
- Whole genome sequencing (when appropriate)

Further requirements are:

- Requires a general description of the types of research that may be conducted.
- The IRB must assess whether the description of the research included in the broad consent form is adequate to permit a reasonable person to provide consent for the currently proposed secondary research study.

- Requires a description of the information or biospecimens that might be used in future research; whether sharing might occur; and the types of institutions or researchers that might conduct research.
- Requires a description of the length of time that the information or biospecimens may be stored, maintained, and used.
- Requires a statement whether subjects will or will not be informed of the details of any subsequent research.
- Requires a statement that research results either will or will not be disclosed to subjects.
- Requires contact information to be provided in the broad consent.

Waivers of Consent

Waiver of informed consent documentation.

The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds that:

- The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern; **or**
- The research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context; **or**
- Members of a distinct cultural group in which signing forms is not the norm and the research is minimal risk.

The IRB may require that each participant be asked whether s/he wants documentation linking the participant with the research, and the participant's wishes will govern. In this case, there would still be a need for informed consent, but the requirement for signed documentation could be waived.

Waiver of informed consent process*.*

The IRB may waive the requirement for the investigator to engage in an informed consent process for some or all participants if it finds that **all** of the following apply:

- The research presents no more than minimal risk of harm to the participants,
- The research cannot reasonably be conducted without the waiver,
- Waiving informed consent will not adversely affect participants' rights and welfare.

Whenever appropriate, participants will be provided with additional pertinent information after their participation. Typically, when the informed consent process is waived, documentation of consent is also waived.

Consent when the research involves deception

Sometimes, particularly in behavioral research, investigators plan to withhold information about the real purpose of the research or even give subjects false information about some aspect of the research. This means that the subject's consent may not be fully informed. When the IRB reviews research involving

incomplete disclosure or outright deception it must decide whether the information to be withheld would influence the decision of prospective subjects about participating in the research.

The IRB will consider the risks to which subjects will be exposed and then decide whether to waive or alter consent requirements. To receive a waiver of consent requirements, the study must present no more than minimal risk and the waiver must not adversely affect the rights and welfare of subjects, and must be essential to the ability to carry out the research.

Whenever appropriate, subjects should be given additional pertinent information after they have participated in such a study. The IRB will determine if a debriefing form is necessary and will guide the Investigator in what information should be disclosed.

Chapter 7: Off-site Permission Letters

When an investigator conducts his/her research activities at or with the assistance of an organization, Antioch's IRB requires a letter of permission from a person at that agency who is authorized to approve the agency's role in the research. For example, a researcher conducting a series of interviews of employees at an organization would need the permission of the appropriate authority at the organization, as well as the appropriate letters of consent/assent from the participants themselves. Similarly, a researcher proposing to conduct research at a school would need permission from the principal or school district superintendent as well as the appropriate letters of consent/assent from the participants themselves.

There are **two exceptions** to the requirement:

1. Where the only research activity involves asking a contact person to forward surveys (either paper surveys with return postage provided or links to electronic surveys) where there is only minimal risk.
2. If the research is being conducted at an agency where only the senior member of the staff will be interviewed, then a signed site letter of permission is not necessary. In that case, the person being interviewed would only need to provide consent.

Seeking permission

When seeking a site's permission, you need to make sure you are obtaining the permission from the appropriate authority. It is not always obvious who the appropriate authority is for any given project. Please contact your advisor and/or the IRB Chair for guidance. For example, if you intend to use a school in your research study, you may need to contact the school district's superintendent for permission.

A permission letter is not the same as a consent form. If you are conducting research at an organization, school, or any site other than Antioch University you are required to obtain a permission letter in addition to following the consent process. A permission letter is a document you obtain from a potential research site. You could be seeking permission to use their facilities, ask for time and/or information from their employees, contact their members, or access data that is owned by them. In contrast, an **informed consent** form is a document you distribute to potential research participants. This document provides information to the participants about the research study that includes specific informational elements (see p. 16 of this handbook). This form cannot be sent to participants until you have received IRB approval from Antioch University.

Does the research site have an Institutional Review Board?

You will need to check if the site has an Institutional Review Board (IRB). If it does, you may need to seek their approval before submitting your IRB application to Antioch University's IRB, if the site is engaged in the research (see http://www.hhs.gov/ohrp/policy/engage08.html for a definition of engagement). When you are completing the IRB application for Antioch, you will need to indicate the existence or non-existence of an IRB at the research sites. Once you obtain permission from another IRB it should be scanned and attached to your Antioch University IRB application. Please contact your advisor or IRB Chair if you have questions about this process.

Permission letter requirements:
A permission letter must be obtained from every location where research will be conducted. The permission letter must:

1. include the researcher's name and title, the title of the research study, with a brief summary of the project to confirm their understanding of the study,
2. include a statement that, if requested, they will receive a copy of the IRB-approved informed consent document,
3. define whether the investigator will *contact* and/or *recruit* employees and if permission is granted to *collect data* at the location,
4. state what they have agreed to allow the researcher to do, including any restriction or limitations and what responsibilities, if any, they are assuming, and whether they will receive any benefits, including a copy of any aggregate results,
5. specify if publication is intended and, if so, who the intended audience will be (e.g. scholarly, conferences),
6. define if the name of the organization or its employee/volunteer participants will be used in any published materials,
7. include the time frame involved or any time restrictions.
8. be on company letterhead,
9. be hand-signed by the appropriate authority,
10. be scanned and attached as a part of the IRB application.

An e-mail from the site will not be accepted as a valid permission letter. A sample permission letter can be found in the documents section of the IRB site.

International Research
In the case of research conducted outside of the United States of America, the researcher must demonstrate knowledge of the local cultural environment and any regulations or guidelines applicable to human participants research in that setting. Regulatory information from an applicable governmental or educational organization from the country within which the research is to be conducted should be cited or included.

The US Department of Health and Human Services provides the following resource regarding laws, regulations, and guidelines that govern human participants research in 126 countries, as well as standards from a number of international and regional organizations: *International Compilation of Human Research Standards* *www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html*

Chapter 8: Research Involving Vulnerable Populations

Certain groups of participants are considered to be particularly vulnerable to coercion or undue influence in a research setting. These groups, as outlined in 45 CFR 46.111(b) are children, wards of the state, prisoners, pregnant women and fetuses, persons who are mentally disabled or otherwise cognitively impaired, and economically or educationally disadvantaged persons.
In reviewing research studies involving all categories of vulnerable participants, AU must determine that their use is adequately justified and that additional safeguards are implemented to minimize risks unique to each group. A summary of the additional requirements for review and approval of research involving vulnerable populations are provided below.

Children

Federal regulations (45 CFR 46, Subpart D) require that investigators explicitly address the measures taken to protect the rights and welfare of children participating in research.

Definition Of Children (45CFR46.402(a))
Children are defined as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted."

Categories of research involving children
Subpart D of 45CFR46 classifies children involved in research into one of four categories depending upon the risks and benefits of the proposed study, which can be approved as follows:

Category of Risk to the Child	Risk/Benefit Conditions	Consent Requirements
Category 1(Section 46.404) Not greater than minimal risk	None	Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available. The IRB may determine that permission of one parent is sufficient, even if the other parent shares legal responsibility for the care and custody of the child, and is alive, known, legally competent to provide permission, and is reasonably available.

		Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.
Category 2 (Section 46.405) More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being,	The risk involved is justified by the anticipated benefit, and the relation of the anticipated benefit to the risk is at least as favorable as that presented by alternative approaches	Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available. The IRB may determine that permission of one parent is sufficient, even if the other parent shares legal responsibility for the care and custody of the child, and is alive, known, legally competent to provide permission, and is reasonably available. Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.
Category 3 (Section 46.406) More than minimal risk to children is presented by an intervention or procedure that does <u>not</u> hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject	The research is likely to yield generalizable knowledge about the participant's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, and the risk represents a minor increase over minimal risk, and the research presents experiences reasonably commensurate with those inherent in the participant's actual or expected medical, dental, psychological, social or educational setting.	Permission of both parents, unless one of the parents has sole legal responsibility for the care and custody of the child, or one of the parents is deceased, unknown, legally incompetent to provide permission, or is not reasonably available. Assent of the child is required, unless the IRB determines that assent is not a requirement or waives assent.

Permission of Parents or Guardians and Assent of Children

- ***Assent*** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- ***Permission*** means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- ***Guardian*** means an individual who is authorized under applicable State or local law to act on behalf of a child.

Permission of parents or guardians, and assent of children shall be obtained as indicated in the table, above.

Waiver of Permission of Parents or Guardians

One set of conditions under which Waiver of Permission may be granted are as follows:

- The research protocol is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (for example, neglected or abused children), and
- The PI has provided an appropriate substitute mechanism for protecting the children, and
- The waiver is not inconsistent with Federal, state or local law.
- Another set of conditions under which Waiver of Permission may be granted are as follows:
- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Assent of Children

The IRB can determine that assent is not a requirement of some or all children, when one or more of the following is true:

- The children were not capable of providing assent based on the age, maturity, or psychological state.
- The capability of the children was so limited that they cannot reasonably be consulted.
- The intervention or procedure involved in the research holds out a prospect of direct benefit that was important to the health or well being of the children and was available only in the context of the research.
- The assent can be waived.
- Criteria under which Waiver of Assent may be granted are when all of the following are met:
- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Assent shall be obtained either in writing, using an assent form or a signature block on the informed consent form, or may be obtained orally if approved by the IRB.

Note: there are no exemptions for research involving children's involvement in surveys or interviews. 45 CFR 46.401(b) allows exemptions for research involving children that are listed at 46.101(b)1, and (b)(3 through (b)(6). The exemption at 46.101(b)(2) regarding educational testing is also applicable to this subpart.

Wards of the State

Where children are wards of the state or another agency or institution, additional restrictions apply. Children may only be included in research that is related to their status as wards or which is conducted in schools or other institutions in which a majority of children are not wards. If the IRB approves research under this provision (45 CFR 46.409), it must appoint an advocate for each child that is a ward.

Emancipated Minors

There are exceptions to the rule of obtaining assent and seeking parental consent for individuals considered emancipated minors by the state. Emancipated minors ***may*** include individuals under the age of 18, living on their own and financially independent from their parent or legal guardian, individuals who have borne a child, or individuals who are married. Emancipation may also be sought through legal means, and may be stipulated by the state. ***Consent*** is sought from an emancipated minor rather than assent. A court document must be included in the supporting documentation application designating the individual as an emancipated minor.

Prisoners

45 CFR 46, Subpart C, provides additional safeguards for prisoners since "Prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and un-coerced decision whether or not to participate as participants of research." Research involving prisoners does not qualify for exemptions from IRB review.

Categories of research involving prisoners (45 CFR 46.306(a))

- Studies regarding the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- Studies of prisons as institutions, or of prisoners as incarcerated persons, if those studies present no more than minimal risk or inconvenience to the subjects.
- Research on conditions affecting prisoners as a class after DHHS publishes a notice in the federal register.
- Research on practices that are intended, and reasonably likely, to enhance the well-being of the subjects; however, if some of the prisoners will be assigned to control groups which will not benefit from the research, then the study must first be approved by DHHS.

In addition to the general requirements for review, in reviewing prisoner research, IRBs are required by 45 CFR 46.305(a) to:

- Ensure that the membership of the IRB reviewing the protocol includes a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, and that the majority of the IRB is not associated with the penal institution involved. If no current member of the IRB meets the prisoner or prisoners‟ representative criteria, then the VPR and the IRB Chair will identify and recruit a qualified individual to fulfill this requirement and advise the IRB. In addition, a majority of the IRB members at the meeting must not be associated with the prison.
- Ensure that any advantages prisoners will realize as a result of participating in the research, when compared to the general living conditions within the prison, are not so great as to impair prisoners' ability to weigh the risks and benefits of participation and freely choose whether to participate.
- Ensure that the risks involved in the research are commensurate with risks that would be accepted by non-prisoner volunteers.
- Review procedures for selecting participants to determine whether they are fair, and free from arbitrary manipulation by prison authorities or prisoners.
- Ensure that control participants will be selected randomly from among the group of eligible volunteers, unless the PI justifies a different procedure.
- Review the information presented during the recruitment and consent procedures to ensure that the language and level of complexity is understandable to the target population.
- Ensure that the parole board will not take participation in the study into account, and that each prisoner will be informed that participation will have no effect on parole.
- Ensure that adequate provision will be made for follow-up care as necessary.

When an IRB reviews research falling within this category, its assurance provides for OHRP to be notified that the above criteria have been met.

NOTE: *Do not enroll a prisoner in an ongoing IRB approved study without the approval of the committee. If a study participant becomes a prisoner during the course of the research, notify the IRB immediately. The term "prisoner" means someone who is incarcerated or under adjudication, whether an adult or a minor.*

Pregnant Women and Fetuses

45 CFR 46, Subpart B, provides additional protections for research involving pregnant women. Pregnant women should not be excluded from research as participants if the risk to the fetus is minimal. If pregnant women are included in a research protocol, the informed consent must address the research activity and its possible impact on the fetus.

Researchers who conduct studies targeting conditions specific to pregnant women must obtain informed consent from both the pregnant woman and the father of the fetus. Consent by the father is not necessary if:

- The purpose of the study is to meet the health needs of the mother.
- The identity or whereabouts of the father cannot be reasonably ascertained.
- The father is not reasonably available.
- The pregnancy is the result of rape.

Cognitively Impaired

The participation of cognitively impaired individuals in research typically falls in categories that will not be considered exempt at USU. In addition, projects involving cognitively impaired individuals must specifically address how an individual's capacity to give informed consent will be determined. *Examples of cognitive impairment include: diagnosed mental retardation, dementia, and coma.* The IRB is not in a position to determine if an individual identified with a cognitive impairment has the capacity to give informed consent. Therefore, the IRB uses a decision algorithm tool when it is unclear if an individual with a cognitive impairment may prevent the participant from giving informed consent and to assist PI's in making this determination.

Economically or Educationally Disadvantaged

For research involving economically disadvantaged participants, special care must be taken to assure that the financial incentives offered do not represent the sole grounds for the individual's participation in the research protocol. Financial incentives should also not be used to assume risks that participants would not ordinarily incur. The consent form for research involving educationally disadvantaged participants must be written in language and with terminology familiar to the participant. The PI must discuss orally every aspect of the study with the participant to insure his/her understanding.

Illiterate English Speaking Subjects

A PI who has received IRB approval for a study may enroll individuals who can speak and understand English, but cannot read or write. The potential participant must be able to place a written mark on the consent form.

The participant must also be able to:

- Comprehend the concepts of the study and understand the risks and benefits of the study as it is explained verbally, and
- Be able to indicate approval or disapproval for study enrollment.

If a PI uses the above method to obtain consent, there must be documentation **on the participant's consent form** specifying what method was used to communicate the information and the specific means that the participant communicated agreement to be in the study.

Students as Participants

In many research studies students are recruited as participants. PIs should be aware of possible coercion when using students in their research. For example, if students believe their participation (or lack of participation) will be made known to someone who holds power over his or her academic status (e.g., course instructor), the student may perceive coercion. How the PI plans to handle potential problems of coercion and undue influence must be addressed when the study is submitted to the IRB. In particular, activities that involve students who report directly to the PI or who attend a class for which the PI has responsibility must be described.

Non-English Speaking Participants

Non-English speaking individuals may not be excluded from research studies on the basis of language if there is a possibility that they might benefit by participating in the study.
If a research participant does not understand English, the informed consent document should be in a language readily understood by the participant. If the PI anticipates that consent interviews will be routinely conducted in a language other than English, the IRB requires a certified translated consent document be submitted with the original protocol for approval. It is the PI's responsibility to ensure that the translation is accurate.

A copy of the consent document must be given to each participant. While a translator may be helpful in facilitating conversation with a non-English speaking participant, verbal translation of the consent document must not be substituted for a written translation.

If a non-English speaking participant is unexpectedly encountered, enrollment of the participant may not occur until the IRB has prospectively reviewed and approved a written consent document in language understandable to the participant.

At the time of consent for non English-speaking participants, the following is required:

- Short form document should be signed by the participant or the participant's legally authorized representative.
- The English language informed consent document should be signed by the person obtaining consent as authorized under the protocol.
- Short form document and the summary should be signed by the witness.

Abuse Reporting

Researchers are responsible for adhering to all state laws regarding the reporting of abuse and neglect, and must be aware of what laws are applicable in their jurisdiction.

Chapter 9: Responsibilities of Investigators

Once a project is approved by the IRB, the investigator must adhere to **all** of the following:

- conduct every aspect of the project as approved by the IRB
- promptly report any revisions or amendments to the research activity for review and approval by the IRB prior to commencement of the revised protocol. (The only exception to this policy is in situations where changes in protocol are required to eliminate apparent, immediate hazards to the participant; however, these changes must still be reported to the IRB.)
- promptly report any unanticipated problems involving risks to participants or others
- assume full responsibility for selecting participants in strict accordance with the inclusion/exclusion criteria outlined in the application materials
- where consent/permission/assent form(s) have been approved for the research activity, only IRB-approved forms may be used in the consent process.

The IRB has the authority to suspend, terminate, or place restrictions on any study in which the investigator has not met the above requirements, or in the event that the IRB determines that the rights and/or welfare of human participants are at risk.

Approved Activities

There are two main types of amendments to approved activities: revisions and addenda. For the purposes of this policy, the term ***addenda*** will refer to additional information about the approved activities and ***revisions*** will refer to proposed changes to the approved activities, including the cessation of any portion of an approved activity. Both types of amendments will be treated in the same manner. Investigators should submit to the committee if a full review, the original and six copies, if an expedited review, the original and one copy, and if an exempt review, the original and one copy of the proposed amendments.

Reporting Amendments

In accordance with the levels of review discussed in Chapter 4, amendments to approved activities may be exempt from review, undergo an expedited review, or a full committee review.
All amendments must be submitted to the IRB for the appropriate full, expedited, or exempt review and approval prior to commencement of the revised study or the use of a revised consent/permission/assent form. **In order to submit amendments, revisions, unanticipated problems, or renewals please email the IRB Chair, who will unlock your application so that you may add the forms as an attachment.**

Reporting Errors

Investigators should also let the IRB know if errors are made and protocols are not carried out as approved. For example, a study coordinator who has had to revise a consent form many times may distribute the wrong version of the form to the research staff. Errors need to be reported as soon as they are identified so they can be fixed and their solutions noted in the official record. (Protocols are subject to external audit at any time.)

Materials to Submit for Review

A formal application is not required for amendments. Investigators should send a memorandum to the IRB Chair outlining any amendments to approved activities. For ease of review, it is requested that the investigator provide a brief summary of the study and information on the procedure(s) as they were originally approved, as well as the proposed amendments, the rationale for the amendments, and an analysis of whether the amendments should be considered to alter the risks:benefits ratio. Along with the memorandum, the investigator must include copies of any new or revised materials. Examples of such materials may include new or revised questionnaires, surveys, interview questions, or consent/permission/ assent forms, among others. In the case of revised consent/permission/assent forms, the revised version can only be used to admit new participants for enrollment in the study; *however*, participants who are already enrolled in the study must be notified of and consent to the changes to the study.

Unanticipated Problems Involving Risk to Participants or Others

Unanticipated Risks Investigators must report to the IRB any unanticipated harm or discomforts to the participants. Harms or discomforts could include those that occur as a result of the research activities themselves (severe distress brought on by study questions) or those related to the protection of study data (inadvertent breach of confidentiality).

Investigators should also inform the IRB if other researchers have identified unanticipated risks in similar contemporaneous studies.

Generally, a study with unanticipated risks resulting from study procedures will be stopped while the investigator and the IRB review possible responses and consider changes to the protocol. Changes to the protocol resulting from the review would have to be approved by the IRB before the study could be resumed.

An Unanticipated Problem is any event, outcome, or experience that meets the following three criteria:

1) ***unanticipated*** in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;
2) ***related or possibly related*** to participation in the research means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research; and
3) the problem suggests that the research places participants or others at a ***greater risk of harm*** (including physical, psychological, economic, social harm) than was previously known or recognized.

If an Unanticipated Problem occurs, the researcher will report the event using the Unanticipated Problem Report Form provided by the IRB.

Reporting of Adverse Events

An Adverse Event is defined as any untoward or unfavorable medical occurrence in a human participant, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or

disease, temporally associated with the participant's participation in research, whether or not considered related to the participant's participation in the research. Adverse Events are typically seen only in medical research, and the IRB only approves non-medical research involving human participants. As such, Serious Adverse Events are extremely unlikely to occur, but if they do, the investigator will utilize the form for reporting Unanticipated Problems Involving Risk to Participants and Others.

Chapter 10: Continuation and Status of Approved Activities

Continuation Policy

IRB approval periods are granted at intervals appropriate to the degree of risk, not less than once per year. Unless the IRB determines otherwise, continuing review of research for minimal risk studies is not required in the following circumstances:

- Research eligible for expedited review
- Research reviewed by the IRB in accordance with the limited IRB review
- Research that has progressed to the point that it involves only one or both of the following, which are part of the IRB-approved study:
  - Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
  - Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.

Investigators of studies that do not qualify by the criteria above and who wish to continue their research activities beyond the approval period must submit an application for a continuation of approval. Studies require annual continuing review until the following criteria are met:

- enrollment is permanently closed to new participants,
- all study-related interactions/interventions are complete,
- long-term follow-up of participants is complete,
- analysis of *identifiable* data is complete.

Projects are automatically inactivated at the end of the approval period if the Application for Continuation is not received by the IRB 30 days before their approval expires. The IRB requires that all activities involving human participants that were covered under the originally approved protocol be stopped immediately upon expiration of approval. A full application must be made to the IRB if and when the investigator wishes to reactivate the study if expired prior to renewal. Activities may resume upon approval by the IRB. Researchers will receive a reminder letter approximately 30 days prior to approval expiration.

Required Continuation Materials

Studies that originally went through expedited review can continue as expedited review at renewal. Studies that were originally approved by full committee review may be renewed by expedited review if any of the following conditions is met:

(a) (i) the research is permanently closed to the enrollment of new participants; (ii) all participants have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of participants; ***OR***

(b) Where no participants have been enrolled and no additional risks have been identified; ***OR***

(c) Where the remaining research activities are limited to data analysis.

Required continuation materials must include the following**:**

- **A new Application form** must be completed, with all of the content updated to reflect the current status of the application, and including the following:
- **Monitoring Report**, which is a summary of the human participant aspects of the project over the approval period, including # of participants run, adverse consequences, new information, preliminary results, resulting publications or conference presentations, etc.
- **Consent/Permission/Assent form(s)** to be used for the upcoming approval period. Indicate whether these forms are currently approved by the IRB, or contain revisions/addenda for the renewal period.

Summary Report

At the close of each study, a summary report must be submitted to the IRB. The Summary Report Form is located in the documents/forms section online, and may be attached to the application. **Again, to submit renewals or summary reports, please email the IRB Chair who will unlock your application so that you may attach the form via the attachments tab.**

Chapter 11: Ethics Training Modules

The IRB requires that all Principal Investigators and faculty advisors receive training in research ethics through the Collaborative Institutional Training Initiative (CITI). The AU IRB requires that you to complete a series of training modules on research with human subjects prior to submitting an application.

Collaborative Institutional Training Initiative (CITI)

When you first set up a new account select "Antioch University" then follow the prompts. Select the learner group for your specific campus or program (if applicable). The learner group will provide directions and indicate the required CITI modules. Depending on the nature of your research you may be required to complete additional modules.

When you finish all required modules an email will be sent to the Chair of the IRB who will keep track of completed modules. To log in to the CITI modules click here: CITI Login.

Selected refresher modules are required at three, six and nine year intervals after initial completion. An automated email will be sent to inform you when it is time to take the refresher modules.

Appendix A – Lay Language for Consent, Assent & Permission Forms

Acute: new, recent, sudden
Adverse Effect: side effect
Assay: lab test
Benign: not malignant or threatening, usually without serious consequence
Chronic: continuing for a long time
Clinical Trial: a study with patients
Controlled Trial: a study in which the experimental treatment procedures are compared to a standard (control) treatment or procedure
Double Blind: a study in which neither the investigators nor the subjects know what drug the subject is receiving
Efficacy: effectiveness
Monitor: check on; keep track of; watch carefully
Morbidity: undesired result or complication
Mortality: death or death rate
Placebo: an inactive substance like a sugar pill
Protocol: a plan of study
Random: by chance, like the flip of a coin
Relapse: the return of a disease
Retrospective Study: a study looking back over past experience

Appendix B – Glossary

Adverse effect
An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention *(e.g.,* headache following spinal tap or intestinal bleeding associated with aspirin therapy).

Anonymity (see also confidentiality)
Providing anonymity of information collected from research participants means that either the project does not collect identifying information of individual subjects (e.g., name, address, Email address, etc.), or the project cannot link individual responses with participants' identities. A study should not collect identifying information of research participants unless it is essential to the study protocol.

Archived
On the shelf prior to submitting an application to the IRB

Assent
Agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research. An assent form may be required for subjects between seven and thirteen years of age.

Assurance
A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures the institution will institute to maintain compliance.

Benefit
A valued or desired outcome; an advantage.

Benign Behavioral Intervention
Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing.

Blind Study Designs
See: Masked Study Designs; Double-Masked Design; and Single-Masked Design.

Broad Consent
Seeking prospective consent to unspecified future research.

Capacity (to make decisions)
The ability of an individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision *(e.g.,*to participate in a particular study). *(See also, Cognitively Impaired, Competence.)*

Case Controlled Study
A study comparing persons with a given condition or disease (the cases) and persons without the condition or disease (the controls) with respect to antecedent factors. *(See also: Retrospective Studies.)*

Clinical Trial
A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Cognitively Impaired
Having either a psychiatric disorder *(e.g.,* psychosis, neurosis, personality or behavior disorder, or dementia) or a developmental disorder *(e.g.,* mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. *(See also: Capacity.)*

Compensation
Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

Competence
Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. *(See also: Capacity.)*

Confidentiality (see also Anonymity)
Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure. Maintaining confidentiality of information collected from research participants means that only the investigator(s) or individuals of the research team can identify the responses of individual subjects; however, the researchers must make every effort to prevent anyone outside of the project from connecting individual subjects with their responses.

Control (normal) Subjects
Subject(s) used for comparison who are not given a treatment under study or who do not have a given condition, background, or risk factor that is the object of the study. Control conditions may be concurrent (occurring more or less simultaneously with the condition under study) or historical (preceding the condition under study). When the present condition of subjects is compared with their own condition on a prior regimen or treatment, the study is considered historically controlled. The term "normal" implies that a subject with a given condition is not "normal". Therefore, the IRB prefers the term "control" to the term "normal".

Controlled Study
Research that involves at least two groups: one that receives the intervention being evaluated, and the other that receives either a placebo or another intervention (usually one that has been prove safe and effective). Sometimes the study also is described as ‘’**blind" '‘masked"** (in which the subjects do not know which treatment they are receiving) or **"double blind"** or **"double-masked"** in which neither the subjects nor the researchers know the treatment assignments of individual subjects. In a **cross-over design**, each subject receives, at different times during the trial, both the experimental intervention and the control intervention, usually without knowing which is being given at any time *(i.e.,* a blind or double-blind study). The subjects thus become their own controls.

Cross-Over Design
A type of clinical trial in which each subject experiences, at different times, both the experimental and control therapy. For example, half of the subjects might be randomly assigned first to the control group and then to the experimental intervention, while the other half would have the sequence reversed.

Debriefing
Giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English, in which debriefing is obtaining rather than imparting information.)

DHHS
U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW). http://www.hhs.gov/

Double-Masked Design
A study in which neither the investigators nor the subjects know the treatment group assignments of individual subjects. Sometimes referred to as "double-blind."

Ethnographic Research
Ethnography is the study of people and their culture. Ethnographic research, also called fieldwork, involves observation of an interaction with the persons or group being studied in the group's own environment, often for long periods of time. *(See also: Fieldwork.)*

Expedited Review
Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [45 CFR 46.110].

False Negative
When a test *wrongly* shows an effect or condition to be *absent (e.g.,* that a woman is *not* pregnant when, in fact, she *is).*

False Positive
When a test *wrongly* shows an effect or condition to be *present (e.g.,* that a woman *is* pregnant when, in fact, she is *not).*

Fieldwork
Behavioral, social, or anthropological research involving the study of persons or groups in their own environment and without manipulation for research purposes (distinguished from laboratory or controlled settings). *(See also: Ethnographic Research.)*

Full Board/Committee Review
Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [45 CFR 46.108].

Guardian
An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care [45 CFR 46.402(3)]. A guardian may also be appointed by a court to make decisions for an incompetent adult.

Human Subject
Individuals whose physiologic or behavior characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: 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)].

Informed Consent
A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [45 CFR 46.116].

Institution (1)
Any public or private entity or agency (including federal, state, and local agencies) [45 CFR.102(b)].

Institution (2)
A residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease hospitals; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential schools for the mentally or physically handicapped; and homes for dependent and neglected children.

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.

Institutionalized
Confined, either voluntarily or involuntarily *(e.g.,* a hospital, prison, or nursing home).

Institutionalized Cognitively Impaired
Persons who are confined, either voluntarily or involuntarily, in a facility for the care of the mentally or otherwise disabled *(e.g.,* a psychiatric hospital, home, or school for the retarded). Individuals in nursing homes who are suffering from dementia are also institutionalized cognitively impaired.

Investigator
In clinical trials, an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions *(e.g.,* drugs) involved in the study are administered to subjects under the immediate direction of the investigator. *(See also: Principal Investigator.)*

IRB
See: Institutional Review Board

Legally Authorized Representative
A person authorized either by statute, by court appointment, or by a health care proxy to make decisions on health of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [45 CFR 46.102(c)].

Longitudinal Study
A study designed to follow subjects forward through time.

Masked/Blinded Study Design
Study designs comparing two or more interventions in which either the investigators, the subjects, or some combination thereof do not know the treatment group assignments of individuals subjects. Sometimes called "blind" study designs. *(See also: Double-Masked Design; Single-Masked Design.)*

Mature Minor
Someone who has not reached adulthood (as defined by state law) but who may be treated as an adult for certain purposes *(e.g.,* consenting to medical care).

Minimal Risk
A risk is minimal when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test [45 CFR 46.102(i)]. For example, the

risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.
The definition of minimal risk for research involving prisoners differs somewhat from that given for noninstitutionalized adults. *[See 45 CFR 46.303(d)]*

NIH
National Institutes of Health: a federal agency within the Public Health Service, DHHS, comprising 21 institutes and centers. It is responsible for carrying out and supporting biomedical and behavioral research. www.nih.gov.

Open Design
An experimental design in which both the investigator(s) and the subjects know the treatment group(s) to which subjects are assigned.

Pregnancy
The period of time from confirmation of implantation of a fertilized egg within the uterus until the fetus has entirely left the uterus (i.e., has been delivered). Implantation is confirmed through a presumptive sign of pregnancy such as missed menses or a positive pregnancy test [45 CFR 46.203(b)]. This ''confirmation'' may be in error, but, for research purposes, investigators would presume that a living fetus was present until evidence to the contrary was clear. Although fertilization occurs a week or more before implantation, the current inability to detect the fertilization event or presence of a newly fertilized egg makes a definition of pregnancy based on implantation necessary.

Principal Investigator
The scientist or scholar with primary responsibility for the design and conduct of a research project. Defined by AULA as a researcher with a faculty appointment. (See *also: Investigator)*

Prisoner
An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial, or sentencing; and (3) detained in other facilities *(e.g.,* for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution [45 CFR 46.303(c)].

Privacy
Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

Protocol
The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

Random, Random Assignment, Randomization, Randomized
Assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically *(e.g.,* as dictated by the standard or usual response to their condition, history, or prognosis, or according to demographic characteristics). Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention.

Remuneration (payment)
Payment for participation in research. (NOTE: It is wise to confine use of the term "compensation" to payment or provision of care for research-related injuries.) *(Compare: Compensation.)*

Research
A systematic investigation *(i.e.,* the gathering and analysis of information) designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)].

Risk
The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." *(See also: Minimal Risk.)*

Secondary Research Use
Reusing, for research purposes, identifiable and non-identifiable information or biospecimens that are collected for some other 'primary' or 'initial' activity, such as, from research studies other than the proposed research study.

Single-Masked Design
Typically, a study design in which the investigator, but not the subject, knows the identity of the treatment assignment. Occasionally the subject, but not the investigator, knows the assignment. Sometimes called "single-blind design."

Written or In Writing
Refers to writing on a tangible medium (e.g., paper) or in an electronic format.

Voluntary
Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

Vulnerable Population
Category of participants who may be at risk of coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.