IRB Manual of Policies and Procedures

for Conducting Research with Human Subjects

Reviewed and Updated by Members of 2024-2025 IRB Committee

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Introduction

This policies and procedures manual was created to assist Anna Maria College community members who are engaging in research involving human participants. Those involved in such research must seek approval from the college's Institutional Review Board (IRB). The Anna Maria College Institutional Review Board's mission is to protect the rights and welfare of individuals who participate in research at or are affiliated with the college. Federal regulations and college policy require prospective review and approval of all human subject research conducted by faculty, staff, students, or those conducting research as affiliates of Anna Maria College. The IRB aims to ensure the safe and ethical treatment of research participants.

IRB review is required for all research involving human participants conducted at Anna Maria College or under its sponsorship at another location. A review is also necessary for research carried out under the sponsorship of another institution if the research is performed at the college. This requirement applies even if the IRB has approved the study at the sponsoring institution. The policies in this manual apply to all research conducted by any college community member, including faculty, staff, and students. The guidelines apply without regard to the scale of the project, its duration, and its source of funding. Specifically, the Anna Maria College IRB is charged with providing an independent determination concerning:

- Provisions for safeguarding the rights and welfare of each individual research participant.
- Independent determination concerning potential risk to research participants and, if risk is involved, the extent to which:
    - The risks to the participant are so outweighed by the sum of the benefit to the participant and the importance of the knowledge to be gained as to warrant a decision to allow the participant to accept such risks.

- The rights and welfare of any such participants(s) are protected.
- Legally effective informed consent will be obtained by adequate and appropriate means.

Federal Policies: Regulations and References

Anna Maria College adheres to federal law that requires prospective review and approval of human subject research activities be conducted by an Institutional Review Board (IRB). An IRB is defined as an administrative body whose primary mandate is to protect the rights and welfare of humans who are the subjects of research. In addition, the Anna Maria College IRB subscribes to the basic ethical principles for the protection of human participants in research that underlie The Belmont Report (U.S. Department of Health and Human Services, 2024), The Nuremberg Code (U.S. Department of Health and Human Services, 2024), the Declaration of Helsinki (World Medical Association, 2024), and the Patient Bill of Rights and Responsibilities (U.S. Department of State, 2024).

The Belmont Report (U.S. Department of Health and Human Services, 2024) addresses three basic ethical principles for research: respect for persons, beneficence, and justice. The concept of respect incorporates the ethical principle of autonomy. This principle ensures that the individual is free to make decisions without coercion

from others. Autonomy includes mental capacity (the ability to understand and process information), and voluntariness (freedom from the control or influence of others). Therefore, subjects have complete autonomy when they can understand and process information and volunteer for research without coercion or undue influence from others. Rules derived from the principle of respect for persons include:

- The requirement to obtain informed consent.
- The requirement to respect the privacy of research subjects.

Beneficence ensures that researchers will minimize harms and maximize benefits. The

derived rules include:

- The best possible research design is required to maximize benefits and minimize harms.
- The requirement is to ensure that the researchers can perform the procedures and handle the risks.
- The prohibition of research that is without a favorable risk-benefit ratio.

Justice refers to each individual receiving what is due or owed. As a research principle, it requires researchers to treat people fairly and to design research so that its burdens and benefits are shared equitably. Derived rules include:

- The requirement to select subjects equitably.
- The requirement to avoid exploitation of vulnerable populations or populations of convenience.

These principles of the 1979 Belmont Report should guide the researcher in creating the research design, selecting participants, developing written consents, and addressing proposal risk-benefit ratios.

The Nuremberg Code (U.S. Department of Health and Human Services, 2024), developed after the Nazi atrocities of human experimentation in World War II, protects research participants by providing informed consent. The 1949 Nuremberg Code specifies that the voluntary consent of the subject is essential and that experiments should be conducted to avoid all unnecessary physical and mental suffering and injury for participants.

In 1964, the World Medical Association developed a set of ethical guidelines for clinical research called the Declaration of Helsinki (World Medical Association, 2024). Revised and updated several times since 1964, this declaration identified the distinction between therapeutic and non-therapeutic research, stressing the protection of human rights.

The Patient's Bill of Rights, like The Nuremberg Code, addressed informed consent but went further to include privacy and confidentiality within institutional settings, especially hospitals. This document was developed by the American Hospital Association in 1992 and emphasized the rights of individuals to choose not to participate in research.

IRB Functions and Responsibilities

The Anna Maria College IRB has the authority to approve, require modifications to, or disapprove all research sponsored by college community members, per federal regulations [45 CFR 46.109 (a)]. As a committee, the college IRB is charged with following the written procedures described in this policy, and applicable state and federal regulations. To fulfill the requirements of this policy, the IRB shall, in compliance with federal guidelines [45 CFR 46.108]:

- Review all research involving human subjects before the commencement of data collection. The IRB will determine if the research is exempt from review, eligible for expedited review, or requires full review. These categories are defined in subsequent sections.
- Review proposed research requiring full review at regularly convened meetings at which a majority of IRB members are present, including at least one member whose background is in nonscientific areas. For research to be approved, it must receive the approval of the majority of those members present at the meeting and a quorum must be met (see page 12).

IRB Membership

Members of the IRB serve to protect the welfare of human participants. Per federal regulations [45 CFR 46. 107], all members shall possess the professional competence necessary to review specific research activities and be qualified to ascertain the acceptability of proposed

research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The Anna Maria College IRB shall consist of seven voting members and two alternates who will vote in the case of a conflict of interest for another member (e.g., another voting member is submitting their own proposal for review). The voting members are six full-time faculty members, including the IRB Chair, Vice Chair, and Recorder, and one judiciously selected community member with no affiliation to the college. The two alternate members will be two full-time faculty members. There will be one non-voting member who is the Dean of Institutional Research and Assessment (or designee) at Anna Maria College. At least one member will have a scientific focus, and at least one member will have a non-scientific focus. The faculty members will be drawn from various disciplines/schools and will be diverse in ethnicity, culture, and gender to the extent possible.

Faculty members interested in serving on the IRB may be nominated or self-nominate during the faculty committee voting process of the Faculty Assembly. Administrators who hold academic rank (President, Vice President for Academic Affairs, Deans, and some Program Directors) may also be eligible for nomination through the Faculty Assembly.

IRB members shall be elected at the Faculty Assembly for two years with potential reappointment. Terms will overlap so that no more than three terms (including the IRB air) expire simultaneously. Faculty members shall be elected every year in which there are vacant positions. The IRB Chair shall be a full-time faculty member with appropriate experience. Membership in the IRB will be posted publicly.

IRB Meetings

The IRB will meet on the third Tuesday from 3:00 PM-4:00 PM from September through May. Additional meetings with seven days' notice may be called by the IRB Chair or by any two members. The IRB Chair may call emergency meetings with one additional member to decide on

matters needing immediate attention. Members not present for such emergency sessions will be notified immediately (electronically) of the issue and the action taken by the two members present.

Because of the extraordinary circumstances of such a meeting, other members of the IRB may call for a recall of any decisions made under these circumstances within three days of notification of the extraordinary meeting. A simple majority vote of the whole IRB is required to overturn the decisions of the emergency session. Extraordinary emergency sessions aside, the IRB shall hold open meetings. However, dissemination of the meeting time and subject shall not be the responsibility of the IRB, nor may the IRB withhold such information.

Member Training

IRB members and others responsible for reviewing and approving research will receive detailed training in the regulations, guidelines, and policies applicable to human participant research. At the start of their elected term, IRB members must submit documentation showing completion of training for protecting human participants through an IRB-approved site such as the Association of Clinical Research Professionals (ACRP). The course can be found at https://acrpnet.org/courses/ethics- This training must be completed before the review of any proposal, as soon as possible, or before November 1st in the year of their term.

IRB Records

Records about human participants that come under the purview of the IRB will be kept in a secure location for three years after the completion of the approved project or the rejection of a proposal. As of January 2020, the Anna Maria College IRB uses the Engage learning management system (Moodle platform) to record all activities. Each academic year, a new "shell" will be created. Per federal guidelines [45 CFR 46.115 (a) (b)], records to be maintained include:

- Copies of all research proposals and supporting documents.
- IRB meeting minutes.
- Certificates of completed training regarding research with human subjects as defined above under member training.
- Copies of all correspondence between the IRB and researchers.
- A list of all IRB members identified by name, earned degrees, representative capacity, and any employment or other relationship between each member and theinstitution.
- Written procedures for the IRB.
- Records of continuing review activities.
- Statements of significant new findings provided to subjects.

Submitting a Proposal to the IRB

All researchers who propose conducting research in affiliation with Anna Maria College, including human participant research that gathers or creates data from outside the public domain and within the public domain (e.g., archival research), are required to submit their proposal to the IRB. Although studies of information in the public domain do not require IRB approval, researchers are still expected to notify the IRB of said research by submitting a proposal to the IRB and make every effort to protect the well-being of participants. Any individual intending to conduct research involving human participants, whether the research is supported by a grant, contract, or fellowship from any public or private agency, has the responsibility to submit a research proposal to determine whether the research activities require formal IRB review. The IRB determines exemption status. If a grant or contract application is involved, this application should be sent directly to the IRB sufficiently in advance of the application due date in order to allow time for the review process, should it be deemed necessary.

A review and approval of research activities will be made by the IRB only for studies

sponsored by members of the Anna Maria College faculty, staff, or administration. In those instances where individuals from another institution wish to conduct research on the college's campus, an Anna Maria College faculty member must sponsor the application. Faculty or staff members must sponsor student research.

When reviewing research proposals, the IRB is primarily concerned with protecting the rights and ensuring the safety of human participants. The IRB will examine the research design only to the extent that it affects the rights or the well-being of human participants. In analyzing the risk-benefit ratio of a research proposal, both the stated goals and the scientific merit of the research can be considered. Therefore, the research must be described to the IRB in sufficient detail to allow for adequate review of all aspects of the research. This description must be included with the appropriate proposal submission form (first-time or continuing), consent form, and other supporting materials (e.g., surveys, questionnaires, marketing and recruitment materials). Researchers should utilize the Anna Maria College IRB standardized templates for proposal submission and informed consent when submitting their proposal documentation in the formstack link provided in the documentation on Anna Maria's IRB webpage. These forms are available on the Anna Maria College Institutional Review Board website

Procedures for Review and Approval

Specific review and approval procedures of the IRB are as follows:

1. The committee will meet at a regularly scheduled time, on the third Tuesday of the month, from September through May and as needed from June through August. For a research proposal to be reviewed at a scheduled meeting, a copy of all materials with signatures shall be submitted via formstack least one week prior to the IRB meeting. For students, the materials should be submitted via email to IRB@annamaria.edu by the faculty sponsor. The researcher or faculty sponsor should ensure that all materials are

complete and free from grammatical, spelling and punctuation errors.

2. Upon receipt of the research proposal, the IRB Recorder will confirm that the required forms are present and properly completed and that the necessary description of the research is provided. Materials will then be uploaded into the Engage learning system by the Recorder and IRB members notified of a proposal for review.
3. Upon request of the IRB, the researcher may be asked to provide additional information through telephone conferencing, email, or to appear in person before the committee to present a full explanation of the risks and protection for human participants. Any researcher may be asked to conference with or appear before the committee to describe the proposed research or answer any questions that may arise during the review. In the case of student research, the faculty sponsor and student may be asked to participate in the conference or appearance at an IRB meeting.
4. In cases where it is deemed necessary by the committee, consultants to the IRB from the researcher's particular field may be asked to comment on a proposed research activity. A roster of consultants may be prepared in the event there are areas of expertise that the membership lacks and reasonably may be anticipated as a need. Credentials could be a combination of training/education and experience, availability, and freedom from other roles with the college. The identity and a brief summary of the consultants' credentials should be made available to the applicant and should be open to challenge for cause (e.g., perceived conflict). The Anna Maria College IRB makes the final decision on whether a consultant will be used.
5. A necessary quorum for the IRB to consider a proposal will be a majority of the total

membership. In addition, a non-scientist must be present for a quorum according to federal guidelines. The IRB may not have a member participate in the board's initial or continuing review of any project in which the member has a conflicting interest, except to provide information as requested by the IRB.

6. The IRB will decide by a quorum of the members present or by a majority of members reviewing the proposal and vote:
    - To approve the proposal.
    - To approve the proposal with restrictions or conditions.
    - To table the proposal, pending revisions.
    - To deny the proposal.

    If approval is granted, it is valid for 12 months. If the research is not completed within the 12-month period, an update regarding the initial proposal is required. The IRB will issue a new approval after reviewing the update. This process will continue every year until the research has been completed.
7. Minutes will be taken at all IRB meetings. Records will be retained in accordance with federal regulations.
8. The IRB Chair or designee will inform the principal researcher in writing of the committee's decision**.** If changes are recommended, the IRB Chair or designated member will communicate these promptly in writing to the researcher. The IRB Chair or designated member will be responsible for review and approval of the researcher's submitted modifications. If there are changes in the study that the IRB Chair or designated committee member feels may alter the level of risk to human participants, the researcher will be notified in writing that he or she is required to submit the proposal to the full committee for further review. If the

modifications change the protocol significantly from the original proposal a new review is necessary.

The IRB shall have the authority to suspend or terminate approval of research that is not being conducted by IRB requirements or that has been associated with unexpected harm to participants. A list of the reasons for any suspension or termination will be provided to the researcher by the IRB.

Responsibility of Researchers

IRB policies are intended to protect the rights of human participants. However, researchers have the primary responsibility of ensuring protection. In addition to the ethical principles enumerated earlier, researchers must abide by the guidelines summarized below, and they are encouraged to consult additional guidelines provided by their respective disciplinary groups. Specifically, researchers are responsible for:

- Complying with all state and federal regulations.
- Adhering to all applicable policies and procedures of the College, along with any cooperating institution or funder of the research.
- Obtaining informed consent from all participants.
- Minimizing the negative effects of participation by careful research design.
- Maintaining confidentiality of all information obtained in the research process.
- Supervising and training all staff and students conducting the study.
- Completing the IRB approved training course related to Research with Human Subjects. A copy of the certificate issued upon completion of the training must be included with each IRB proposal submission.

- Obtaining permission to conduct the study by submitting an adequately prepared proposal via formstack, including a description of the research with supporting documents.
- Submitting the research proposal to the AMC Institutional Review Board to request approval to conduct the study.
- Immediately notifying the IRB, Program Dean/Director and Vice President for Academic Affairs of any injury—physical, psychological, or social—suffered by a subject because of their participation.
- Keeping all records, documents, and informed consent forms in a secure location for at least three years or longer, up to seven, if requested by the IRB.
- Submitting a final report to the IRB at the completion of the project.

If a project is discontinued, a notice of discontinuation must be submitted with a statement about records maintenance and whether the project ended due to any issue or concern over the subjects' well-being.

Categories of Review

Depending on the risk associated with the research, a proposal may be classified as exempt from review, eligible for expedited review, or requiring a full review. Per federal regulations [45 CFR 46.110], research activity may be disapproved only after full committee review. A full review requires a quorum in attendance and a vote.

Criteria for Exempt Review

Per federal regulations [45 CFR 46. 110 (b)], all of the following criteria must apply for proposals to be exempt from IRB review. At least two members of the IRB must agree that the proposal has met the criteria. All members agree that the proposal meets criteria to be considered exempt.

Part A

1. The research does not involve participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research does not involve the collecting or recording behavior that, if known outside the research, could reasonably place subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, orreputation.
3. The research does not involve the collection of information regarding sensitive aspects of the subject's behavior (e.g., drug or alcohol use, illegal conduct, sexualbehavior).
4. The research does not involve subjects under18 (except as they are participating in projects that fall under categories 1, 3, 4, and 5 in Part B). Category B2 (see below) studies that include minors can be eligible for expedited review.
5. The research does not involve deception.
6. The procedures of this research are generally free of foreseeable risk to the subject.

Per federal regulations [45 CFR 46. 110 (b)], at least one of the following criteria must apply in order for proposals to be exempt from IRB review:

Part B

1. Research conducted in established or commonly accepted educational settings, such as on regular and special education, instructional strategies, or cognitive processes, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude,

achievement), survey procedures, interview procedures, or observation of public behavior, unless information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, or any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the researcher records the information in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.
4. Research and demonstration projects that are conducted by, or subject to the approval of, department or agency heads and that are designed to study, evaluate, or otherwise examine public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in, or alternatives to, those programs or procedures; or potential changes in methods or levels of payment for benefits or services under those programs.
5. Taste and food evaluation and consumer acceptance studies, if either wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient, agricultural chemical, or environmental contaminant that is present at or below the level and for a use found to be acceptable by one of the following: The U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Criteria for Expedited Review

An expedited review will be conducted by at least two members of the IRB. When

evaluating the proposal, the reviewer or IRB Chair has all the authority of the IRB except that of disapproving the research. Per federal regulations [45 CFR 46. 110 (b)], all of the following criteria must apply for expedited review of the research:

Part A

1. The research does not involve participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research does not involve the collection or recording of behavior that, if known outside the research, could reasonably place subjects at risk of criminal or Civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of this research present no more than minimal risk to the subject, where "no more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Per federal regulations [45 CFR 46. 110 (b)], at least one of the following criteria must apply for expedited review of the research:

Part B

1. Research that collects data from voice, video, digital, or image recordings.
2. Research on individual or group characteristics or behavior, including but not limited to

survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodology as follows:

- Involving adults, where the research does not involve stress to subjects and where identification of the subjects and their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- Involving children, where the research consists of neither stress to subjects nor sensitive information about themselves or their family, where no alteration or waiver of regulatory requirements for parental permission has been proposed, and where identification of the subjects and their responses would not reasonably place them or their family members at risk of criminal or civil liability or be damaging to the financial standing, employability, or reputation of themselves or their family members.

3. Continuations of projects previously approved by the IRB if no new human subjects are enrolled in the study, all research-related interventions on human subjects have been completed, and the research remains active only for long-term follow up of subjects; OR no additional risks to subjects have been identified or the remaining research activities are limited to data analysis.
4. Certain classes of clinical studies of drugs or medical devices (i.e., clinical studies of drugs for which a new investigational drug application is not required or research on medical devices for which an investigational device application is not required or the device is approved for marketing and is being used according to approved labeling).
5. Research involving existing identifiable data, documents, records, or biological

specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected prior to the research for a purpose other than the proposed research. These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio or videotapes, names will be recorded, even if they are not directly associated with the data).

6. Collection of data through the use of the following procedures:
    - Non-invasive procedures are routinely employed in clinical practice and not involving exposure to electromagnetic radiation outside the visible range(i.e., not involving X-rays, microwaves, etc.).
    - Physical sensors applied either to the surface of the body or at a distance and do not involve the input of significant amounts of energy into the subject or an invasion of the subject's privacy.
    - Weighing, testing sensory acuity, electrocardiography, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, Doppler blood flow, and echocardiography.
    - Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing involving subjects
    - Collection of blood samples by finger stick or venipuncture.
7. Continuations of projects that do not fall into the above categories and have been previously subject to the full review process by the IRB, which have been determined that the research involved poses no more than minimal risk and no additional risks have been identified.

Criteria for Full Review

A full review requires all IRB members to vote to approve the proposal. Per federal regulations [45 CFR 46], if any of the following criteria apply, the research must undergo a full review by the IRB:

1. The research involves participants who are prisoners, fetuses, pregnant women, the seriously ill, those at identified risk of serious illness (e.g., by genetic profile or other personal information), or mentally or cognitively compromised adults, including economically or educationally disadvantaged persons.
2. The research involves the collecting or recording of behavior that, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. The research involves the collection of information regarding sensitive aspects of the subject's behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the subject, where "more than minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research is more significant than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
5. Any research that does not fall into the categories explicitly identified as qualifying for exempt or expedited status.

Student Research

Students attending Anna Maria College (undergraduate and graduate) are bound by the research procedures and policies outlined in this manual. Moreover, no applications to the

IRB from either an undergraduate or a graduate student will be reviewed unless sponsored by a faculty or staff member familiar with the student and the proposed activity. The faculty sponsor must be familiar with the proposal protocol and accept responsibility for overseeing the research. All bound theses that include any human subject investigation must include a copy of the IRB approval.

Course-related research falls under the purview of IRB policies except when the research is a routine procedure that is employed on a regular basis in the course (such as piloting a study within the class prior to conducting the study with participants outside of the classroom). Any student research that involves more than minimal risk, includes participants outside of the class, or the research involves subjects outside the university requires IRB approval. In these cases, the complete application form and description of the research must be submitted to the IRB. Research conducted through an organization, agency, or other entity requires permission by that entity to conduct the study. Written permission from someone within the organization, agency or other entity, who has the ability to do so, must be provided as part of the IRB proposal packet. The IRB discourages the use of one's own students as participants in research projects.

Review of Continuing or Modified Research

IRB-approved research that is continuing or has been changed or modified from the original IRB proposal must be re-reviewed at least annually, depending on the level of risk. Research that has greater than minimal risk will be reviewed more frequently. Approximately one month before the first anniversary of the IRB approval date, the researcher will be sent a letter from the IRB chair or designee regarding the need for continuing review and is expected to complete the accompanying Review of Continuing Research form and submit it to the IRB Chair by the date indicated in the notice letter. Continuing review is required for all research

ongoing for more than one year from the date of the initial approval letter.

If the scope of the research changes or deviates from the description initially provided to the IRB, researchers must submit a memo to the IRB Chair describing such changes. The changes will be reviewed under the exempt, expedited, or full review process. Failure to comply with the continuing review process can result in suspension or termination of IRB approval for the project. After a proposal is underway, researchers must promptly report to the IRB Chair any unanticipated problems or adverse events that pose risks to subjects or others.

IRB Appeals Process

Any IRB decision may be appealed. The principal researcher(s) should initiate the appeal in writing to the IRB Chair via IRB@annamaria.edu in the form of a letter. In said letter, the researcher should submit information pertinent to the proposal, explicitly citing the reasons for the appeal, and may request a meeting with the IRB. The IRB may request additional information relevant to the proposal from the researcher or others. The appeal will be considered by the full IRB and the decision will be determined by the majority vote of all voting members of the IRB.

Informed Consent

Informed consent is a primary ethical requirement when conducting research with human subjects. The process that consists of two distinct parts: a conversation between researcher and potential participant and written documentation of consent. The first part involves a dialogue in which the researcher, in easily understandable language, provides sufficient information for the subject to consider what participation in the project entails fully. After adequate opportunity for questioning and when the participant is fully informed, written consent documentation is obtained. The language of the consent form should be clear and understandable to the participants, including those whose primary language is not English. Per federal guidelines [45

CFR 46.116], the written document may not waive any of the subject's legal rights nor relieve the college or the researcher of any responsibility for negligence.

Federal regulations [45 CFR 46 .116(a)] require that the following information be provided to each subject:

1. A statement that the study is research.
2. An explanation of the purpose(s) and description of the procedures along with the expected duration of the subject's participation. Specific identification of any experimental procedures is required.
3. A description of any risks or discomforts that may result from participation.
4. A description of any benefits to the subject or to others. Researchers should use care to promise of benefits that might be an overreaching and undue inducement to participation in the research.
5. A statement that all study subjects may switch to the experimental protocol if data analysis during the study indicates a clear benefit over the control group.
6. A disclosure of appropriate alternative procedures or courses of treatment.
7. A statement explaining the extent to which the subject's participation, including study records, and the procedures for doing so will be kept confidential.
8. An explanation of any compensation or medical treatment available if injury occurs and where further information can be obtained for any study involving more than minimal risk.
9. Contact information for additional questions regarding the study or the subject's rights.
10. A clear statement that participation is voluntary and that refusal to participate or a

decision to withdraw from the study will have no negative consequences.

In addition, Anna Maria College requires that participants be given the identification of the primary researcher and faculty sponsor and the name of any sponsoring or funding sources supporting the research. The college should be identified as the responsible institution or one of the responsible institutions. The Anna Maria College IRB email address should be included as well. The faculty advisor should also be listed if the project is a graduate degree thesis.

These requirements for informed consent will be adequate for most research conducted in affiliation with Anna Maria College. There are, however, additional federal requirements [45 CFR 46.116 (b)] that researchers must be aware of and must include in their informed consent document if they apply to the individual study, as follows:

1. A statement that the study may involve risks to the subject that are currently unknowable.
2. Circumstances under which the researcher can terminate the subject's participation without the subject's consent.
3. Any additional costs the subject may incur from participation in the research.
4. The consequences of a subject's decision to withdraw from a study and theprocedures for termination of the subject's participation.
5. A statement that significant new findings developed during the research may relate to the subject's willingness to continue participation.
6. The approximate number of subjects involved in the study.

Federal regulations [45 CFR 46 .116(c) (d)] do permit modifications to the consent

procedure, and thus the IRB may approve a consent procedure that does not include or alters some of the guidelines outlined. Informed consent may also be waived entirely under certain conditions. Decisions regarding modifications or waiver of informed consent will be made only after careful consideration by the Anna Maria College IRB and will be carefully documented in the IRB meeting minutes. The researcher cannot make these decisions.

When the IRB has granted a waiver of signed consent, or when a study seeks anonymous data, an information sheet should be used instead of an informed consent form (available at the end of this manual and on the Anna Maria website). An information sheet provides the same information as a consent form, but the participant does not sign it. Anna Maria College requires that all research studies submit an informed consent form or an information sheet with the proposal to the IRB for review.

Requirements for Consent of Parents or Guardians and Assent by Children

In the State of Massachusetts, a participant can legally consent to participate in a research study only if he or she is 18 or older. If the participant is a minor, written parental consent or consent from a legal guardian is required. In addition, the researcher should also obtain the minor's assent if that minor can provide it.

Per federal regulations [45 CFR 46. 402 (b)], assent is defined as "a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent." There may be instances in which the parent and the minor disagree about the minor's participation in a study. In those instances, Anna Maria College adheres to the policy that a "no" from a minor supersedes a "yes" from a parent or guardian.

If research is to be conducted in a school setting, it must be made clear that the study is separate from and has no positive or negative effect on regular school activity (e.g., grades). All information must be provided in a language that is understandable to the parents and child or

adolescent. Studies classified as not involving greater than minimal risk are eligible for expedited review and do not require parental or guardian consent or the child's permission. These studies involve no direct intervention and are limited to analysis of existing data, testing of curriculum, or observation of classroom behavior and educational testing.

Researchers should keep in mind that schools do not have the authority to provide consent for minors to participate in a research study. Only parents or legal guardians can give consent. However, a researcher conducting a study in a school must obtain permission from the school district. Granted authorization must be submitted on school district letterhead to the IRB with the proposal. Compliance with the Buckley Amendment, which mandates written consent from the parent, guardian, or student before disclosure of any personal information from school records, is required.

Vulnerable Populations

The Anna Maria College IRB requires researchers to follow special procedures when working with vulnerable populations. Per federal guidelines [45 CFR 46 (b) (C) (d)], these procedures provide for safeguards in research activities involving such populations as pregnant women, infants, prisoners, young children, and any individual with compromised or limited capacity. Because incarcerated individuals may be unduly influenced by their confinement, special measures must be taken to ensure that prisoners are protected from coercion.

Children are another vulnerable population requiring special protection (see previous section). In all research activities involving participants who are limited in capacity to the extent that their decision-making may be compromised or deficient, the researcher must provide evidence that additional protective measures have been taken. Impaired capacity is

understood to include, but is not limited to, individuals with neurological impairment, psychiatric disorders, or substance abuse problems. When conducting research with any vulnerable individual or group, it is IRB policy that the researcher must submit the proposal for a full review by the IRB committee.

Acknowledgments

The Anna Maria College IRB manual was prepared with assistance from the IRB manuals in use, either formerly or currently, at East Stroudsburg University, Skidmore College, University of Connecticut, University of Hartford, and University of St. Joseph. Information from these manuals was used with permission.

References

U.S. Department of Health and Human Services. (2024). *The Belmont Report.* Retrieved October 4, 2024, from https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html

U.S. Department of Health and Human Services. (2024). *The Nuremberg Code.* Retrieved October 4, 2024, from https://tinyurl.com/5x7wmbff

U.S. Department of State. (2024). *Patient Bill of Rights and Responsibilities.* Retrieved October 4, 2024, from https://www.state.gov/patient-bill-of-rights-and-responsibilities/

World Medical Association. (2024). *Declaration of Helsinki.* Retrieved October 4, 2024, from https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

Glossary of Terms

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).

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.

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 participants and stipulates the procedures through which compliance will be achieved.

Belmont Report, the: A statement of basic ethical principles governing research involving human participants issued by the National Commission for the Protection of Human Subjects in 1978.

Beneficence: An ethical principle discussed in The Belmont Report that entails an obligation to protect persons from harm (minimize possible harm) and to maximize possible benefits.

Children: Persons who have not attained the legal age for consent for treatment or procedures involved in the research as determined under the applicable law of the jurisdiction in which the research will be conducted.

Cognitively impaired: Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished.

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

Confidentiality: The treatment of information that an individual has disclosed in a relationship with trust and with the expectation that it will not be divulged without permission to others in ways that are inconsistent with the understanding of the original disclosure. Confidentiality must be maintained during all phases of the study, including record keeping, data storage, data retrieval, follow up, computing, reporting, and procedures.

Declaration of Helsinki: A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries.

Equitable: Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

Exempt activities: Categories of research that, although they involve human subjects, are exempt from IRB review because the research does not expose human subjects to physical, social, or psychological risks. Examples of research in which the human subject cannot be identified include educational practices in an educational setting, educational testing, the collection of existing data, documents or pathological specimens if subjects cannot be identified directly or through identifiers linked to the subjects, and taste and food quality testing.

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. Expedited review pertains to research that involves no more than minimal risk and/or minor changes in approved research.

Full board review: Review of proposed research at a convened meeting at which a majority of the IRB members are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, there must be a quorum, and it must receive the approval of a majority of those members present at the meeting.

Guiding principles: The fundamental principles that guide the ethical conduct of research and that involve respect for persons, beneficence, and justice.

Human subject: Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as living individuals about whom a researcher conducting research obtains data through intervention or interaction with the individual or through identifiable private information.

Individually identifiable information: Identity of the subject that may be readily ascertained by the researcher or associated with the information.

Informed consent: Consent obtained by the researcher to ensure that research participation is documented by obtaining the signature of the participant or the legally authorized representative on the informed consent document. Informed consent is a continuous communication process that spans the entire study. Federal law mandates that all people who elect to participate in scientific study give their written consent.
Human subjects have the right to withdraw from the study at any time, and their anonymity must be guaranteed. Before consenting to participate, subjects must be informed of the objectives, potential treatments, and all inherent risks of the study.

Institutional review board: A specifically constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

Interaction: Communication or interpersonal contact between researcher and subject.

Intervention: Both the physical procedures by which data are gathered and the manipulations of the subjects or the subjects' environment that are performed for research purposes.

Justice: An ethical principle discussed in The Belmont Report that is defined as fairness in distribution of burdens and benefits. The risks and benefits should be distributed fairly and without bias. Research should not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

Minimal risk: A situation 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. Special guidelines are applied to research involving children. Risks are categorized as physical, psychological, social, or economic.

Monitoring: Collection and analysis of data as the project progresses to ensure the appropriateness of the research, its design, and subject protections.

Nuremberg Code, The: A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

Permission: The agreement of parent(s) or guardian(s) to the participation of their child or ward.

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.

Qualitative research: Empirical research in which the researcher explores relationships using textual, rather than quantitative data, and generation of narrative data (i.e., words) rather than numerical data. Case study and observation are considered forms of qualitative research.

Quantitative research: Empirical research in which the researcher explores relationships using numeric or spatial data. Typically, a research survey is considered to be a form of quantitative research.

Principal researcher: The individual responsible and accountable for designing, conducting, and monitoring a protocol. Consultants and students may not serve as PIs on protocols. The PI assumes specific responsibilities to include writing the protocol document, assuring that necessary approvals are obtained, monitoring the protocol during its execution, and analyzing the results.

Research: Any systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

Researcher: In clinical trials, an individual who actually conducts an investigation.

Review of research: The concurrent oversight of research on a periodic basis by an IRB. In addition to annual reviews mandated by federal regulations, review may, if deemed appropriate, also be conducted on a continuous or periodic basis.

Survey: A research tool that includes at least one question, which is either open-ended or close-ended, and that uses an oral or written method for asking questions.

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

Vulnerable populations: Persons who are relatively or absolutely incapable of protecting their own interests. These populations include children, individuals with questionable capacity to consent, prisoners, developing fetuses, seriously ill individuals or those at identified risk of serious illness (e.g., by genetic profile or other personal information), students/employees, and comatose patients.

Definitions for this glossary were obtained from the Institutional Review Board Guidebook Glossary or http://wayback.archive-it.org/org-745/20150930182832/http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm

Definitions for this glossary were obtained from The University of Utah's Institutional Review Board website: https://irb.utah.edu/glossary.php (March 5, 2024).

Resources for Researchers

Code of Federal Regulations

- 21 CFR 50 Protection of Human Subjects www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50
- 21 CFR 54 Financial Disclosure www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=54
- 21 CFR 58 Good Laboratory Practice www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58&showFR=1
- 45 CFR 46 Human Subjects Research https://www.hhs.gov/ohrp/regulations-and-policy/guidance/index.html

National Institutes of Health

Definition of Human Subjects Research

https://grants.nih.gov/policy/humansubjects/research.htm

National Science Foundation Protection of Human Subjects
www.nsf.gov/bfa/dias/policy/human.jsp

U.S. Department of Education
Protection of Human Subjects in Research www2.ed.gov/about/offices/list/ocfo/humansub.html

U.S. Department of Health and Human Services Office for Human Research Protections www.hhs.gov/ohrp/

U.S. Food and Drug Administration
Clinical Trials www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm

HIPAA Research Resources

U.S. Department of Health and Humans Services

- Health Information Privacy https://www.hhs.gov/hipaa/index.html