Manual of Policies and Procedures
for Conducting Research with Human Subjects

Prepared by Dr. Shannon Cousineau, LICSW (Chair, 4 AY 2020-2021)

Approved by Faculty Assembly

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Introduction

This policies and procedures manual was created to assist members of the Anna Maria College community 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 people who take part in research at, or in affiliation 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. Consistent with the traditions of the Sisters of Saint Anne, it is understood that all research involving human subjects should reflect the mission of the College and be consistent with the teachings, values, and beliefs of the Catholic Church. The goal of the IRB is 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. Review is also required for research carried out under the sponsorship of another institution if the research is performed at the college. This requirement applies even if the study has already been approved by the IRB at the sponsoring institution. The policies in this manual apply to all research that is conducted by any member of the College community, including faculty, staff, and students. The policies 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 (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978), The Nuremberg Code (1949), the Declaration of Helsinki (World Medical Association, 2008), and the Patient’s Bill of Rights (American Hospital Association, 1992).

The Belmont Report 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. Elements of autonomy include mental capacity (the ability to understand and process information), and voluntariness (freedom from the control or influence of others).
Therefore, subjects have full autonomy when they have the capacity to understand and process information and the freedom to 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 requirement to use the best possible research design to maximize benefits and minimize harms.
- The requirement to ensure that the researchers are able to 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 the risk-benefit ratios of proposals.

The Nuremberg Code, developed after the Nazi atrocities of human experimentation in World War II, protects research participants by providing for informed consent. The 1949
Nuremburg Code specifies that the voluntary consent of the subject is absolutely essential and that experiments should be conducted as 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. Revised and updated several times since 1964, this declaration identified the distinction between therapeutic and non-therapeutic research, stressing protection of human rights.

The Patient’s Bill of Rights, like The Nuremburg Code, addressed informed consent but went a step further to include privacy and confidentiality within institutional settings, especially hospitals. This document was developed by the American Hospital Association in 1992 and placed emphasis on 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 members of the College community, 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, as well as, applicable state and federal regulations. In order 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 prior to the commencement of data collection. The IRB will determine if the research is exempt from review, ineligible 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. In order for research to be approved, it must
receive the approval of the majority of those members present at the meeting.

**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 6 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 terms of ethnicity, culture, and gender to the extent possible.

Faculty members who are interested in serving on the IRB may be nominated or they
may 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 a term of two years with
potential reappointment. Terms will overlap so that no more than three terms (including the IRB
Chair) expire at the same time. In years ending with an even digit, three faculty members shall be elected, and in years ending with an odd digit, three faculty members shall be elected. 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 of the month from 3:00 PM- 4:00 PM from September through May and as needed in June through August. Additional meetings may be called by the IRB Chair or by any two members with seven days’ notice. The IRB Chair may call emergency meetings with one additional member to decide on matters that may need immediate attention. Members who are 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, it shall be the practice of the IRB to hold open meetings, although dissemination of meeting time and subject shall not be the responsibility of the IRB, nor may the IRB withhold such information.

The IRB Chair shall close any meeting under the following two conditions:

- The meeting is a review hearing that may have bearing on subsequent disciplinary or employment action.

- The researcher requests a closed meeting for stated cause and this is approved by a simple majority of the IRB via electronic vote or a voice vote of the quorum (a majority of the total membership, as defined on page 12 of this manual).
**Member Training**

IRB members and others charged with the responsibility for reviewing and approving research will receive detailed training in the regulations, guidelines, and policies applicable to human participant research. At least once per calendar year, the College will provide the necessary training to ensure that members are adequately prepared to fulfill their responsibilities. In addition to the training provided by the College, at the start of their elected term, IRB members are required to submit documentation showing completion of training through the Association of Clinical Research Professionals (ACRP), an online training course for the protection of human participants. The course can be found at [https://acrpnet.org/courses/ethics-human-subject-protection/](https://acrpnet.org/courses/ethics-human-subject-protection/).

**IRB Records**

Records pertaining to 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 the institution.

• 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 IRB and make every effort to protect the well-being of individuals. 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 application in order to determine whether the activities proposed 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 proposal submission form, consent form, and other supporting materials. Researchers should utilize the Anna Maria College IRB standardized templates for proposal submission and informed consent. These forms are available through the IRB Chair or other committee member, at the end of this manual, and on the Anna Maria College website under Academic Agreements.

The components of the research proposal should include:

- A purpose statement, including rationale and aims.
- A description of the participants, including sampling procedures.
- A full description of all procedures and instruments, including copies of all questionnaires and surveys.
- Informed consent forms.

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 email to IRB@annamaria.edu at 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 copies, 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 in accordance with 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 Association of Clinical Research Professionals (ACRP) online training course related to Research with Human Subjects. A copy of the certificate issued by ACRP at the end of the course must be included with each IRB proposal submission.
• Obtaining permission to conduct the study by submitting an adequately prepared proposal via email to IRB@annamaria.edu including a description of the research with supporting documents.

• 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 his or her participation.

• Keeping all records, documents, and informed consent forms in a secure location for at least three years or longer, 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 level of risk associated with the research, a protocol 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 a review of the full committee. 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 in order for proposals to be exempt from IRB review. At least two members of the IRB must be in agreement that the proposal has met the criteria. There can be no members who disagree 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 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 research does not involve subjects under the age of 18 (except as they are participating in projects that fall under categories 1, 3, 4, and/or 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 research 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 information is recorded by the researcher 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 possible 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/or 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 involves 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/or 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 use of the following procedures:

   - Non-invasive procedures 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 that are applied either to the surface of the body or at a distance and do not involve 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 has determined that the research involved poses not more than minimal risk and no additional risks have been identified.
Criteria for Full Review

A full review requires all IRB members 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 collection 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 subjects’ 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 greater 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 any of the categories explicitly identified as qualifying for exempt or expedited status.

Student Research

Students attending Anna Maria College (both 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 proposal protocol and accept responsibility to oversee 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 prior to the one-year 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 originally 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 under way, 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, specifically 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 either 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. It is a 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 fully consider what participation in the project entails. After sufficient opportunity for questioning and when the participant is fully informed, written documentation of consent is obtained. The language of the consent form should be clear and understandable to the participant,
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 can it 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 procedures that are experimental 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 in the 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 course of the study indicates 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, will be kept confidential and the procedures for doing so.
8. An explanation of any compensation offered or any 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.

11. A summary of the study results.

In addition, Anna Maria College requires that participants be given the identification of the primary researcher and/or 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. If the project is a graduate degree thesis, the faculty advisor should also be listed.

These requirements for informed consent will be adequate for the majority of 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 are applicable 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 subject’s participation can be terminated by the researcher 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 the procedures for termination of the subject’s participation.

5. A statement that significant new findings developed in the course of 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 give consent to participate in a research study only if he or she is 18 years of age 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 assent of the minor if that minor is capable of providing 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 the regular school activity (e.g., grades). All information must be provided in 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 assent. 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 to do so. Granted permission 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 prior to disclosure of any personal information from school records, is required.

**Vulnerable Populations**

The Anna Maria College IRB requires researchers 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/or any individual with compromised or limited capacity. Because incarcerated individuals may be unduly influenced by virtue of 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 altogether 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, and/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 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


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 closed-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 [www.hhs.gov/ohrp/archive/irb/irb_glossary.htm](http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm).
Resources for Researchers

Code of Federal Regulations
- 21 CFR 50 Protection of Human Subjects
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=50
- 21 CFR 54 Financial Disclosure
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=54
- 21 CFR 58 Good Laboratory Practice
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=58&showFR=1

National Institutes of Health
Research on Human Specimens: Are You Conducting Research on Human Subjects?

National Science Foundation Protection of Human Subjects

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 www.hhs.gov/ocr/privacy/
- HIPAA Privacy Rule
  www.hhs.gov/ocr/privacy/hipaa/understanding/special/research/index.html
- Summary of the HIPAA Privacy Rule
  www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf
Institutional Review Board Proposal Submission Form

This form should be completed by any principal researcher who is proposing to conduct a study with human subjects as affiliated with Anna Maria College. Please complete all aspects of the Proposal Submission form. Submit this form along with all additional documents including Consent Forms, Research with Human Participation Training Certification and any other supporting information as one file via email to IRB@anamaria.edu. Please allow 30 days for the review of your proposal. A letter providing the results of the review will be sent at that time.

Note: Students conducting research should do so in consultation with their faculty sponsor. Both the student and faculty sponsor must sign the submission form. The faculty sponsor will submit the form via email to IRB@annamaria.edu. If this proposal has not yet been approved by the research committee of your program or school (as determined by the college department), please do not submit it for IRB review. It will not be reviewed until this requirement has been met.

Part A: Researcher and Basic Project Information

Project title:

Principal researcher:

Street address:

City, state, zip:

Anna Maria College Email:

School or program:

The principal researcher is (check one):

☐ Anna Maria College faculty member
☐ Anna Maria College staff member
☐ Anna Maria College Student
☐ Other (please explain):
Names and email addresses of other researchers, as applicable:

If an Anna Maria College student, or other person not affiliated with Anna Maria College is the principal researcher, provide the following information regarding the faculty or Anna Maria College sponsor:

Name:

Campus Address:

Campus telephone:

Anna Maria College email:

**Part B: Type of Review Requested**

Depending on the level of risk associated with the research, a proposal may be classified as exempt from review, eligible for expedited review, or requiring a full review. Definitions for the types of review are in accordance with federal regulations [45 CFR 46.110] and can be found in the Anna Maria College Manual of Policies and Procedures for Conducting Research with Human Subjects.

☐ Exempt- Briefly explain:

☐ Expedited- Briefly explain:

☐ Full Review- Briefly explain:

**Part C: Acknowledgements and Signatures**

☐ This research involves the use of human participants or data governed by other institutions, such as a government agency, private organization (either for profit or non-profit), school, or other entity.

Written approval that permits your use of the participants or data is required by the appropriate authority of that institution. Please note that you may have to request approval from the IRB at that entity, and they may request a written notice of the College IRB approval. In this circumstance, a formal letter stating that research may be conducted pending IRB approval from Anna Maria College and the entity will suffice to submit your proposal for IRB approval. Once the entity has provided an official decision of their board, the principal researcher must submit a copy of the decision to the Anna Maria College IRB.
I, the principal researcher, have completed the ACRP training regarding Research with Human Participants. The certificate of completion is attached to the end of this form.

I, the principal researcher, attest that all information stated in the Proposal Submission Form is true to the best of my knowledge.

Signature of Principal Researcher                        Date

Signature of College Faculty or Staff Sponsor                Date

The information in parts D and E below should also be included as a part of the Informed Consent Form or Information Sheet.

Part D: Details of the Proposed Research

Contextual Background: Provide a brief introduction to the research topic

Research Design: Provide a brief explanation of the research design to be used including why this design was chosen
Sample: Provide an in-depth explanation of the sample for the research proposed. This section should include recruitment and marketing techniques, desired number of participants, and time commitment expectations for participants.

Data Collection: Provide a detailed explanation regarding the procedures and tools to be used for collecting the desired data from the participants. Include the time frame and how are you collecting the data. Include whether the instrument to be used was self-created.

Part E: Protection of Human Subjects

Risk to Participants: Provide an assessment of the physical, emotional and/or psychological risk in your study. Explain how you intend to keep participants from being harmed in these ways.

Benefits to Participants: Please discuss any benefits to participants, such as compensation.
Informed Consent: Explain how you will obtain consent for participations from the people willing to participate. For persons under age 18, provide a brief explanation of how you will gain the child’s permission as well as the parent. Include a copy of the informed consent and, if required, assent form for child participants.

Other: Is there anything else you would like the IRB to know about your research proposal?
IRB Proposal Check List

This form is optional and is for the benefit of the researcher. You may use this form to ensure you have completed your IRB proposal in full. It does not need to be submitted to the IRB with your proposal.

☐ Part A is completed in full, including faculty sponsor for students.

☐ Part B is complete, indicating the type of review being requested.

☐ Part C is complete, including checking all the applicable boxes.

☐ The proposal form is signed by the principal researcher.

☐ For students- the proposal form is signed by the faculty sponsor.

☐ All sections of Part D are complete giving the IRB a clear indication of the research being proposed, the sample to be used and data collection tools.

☐ All sections of Part E are complete giving the IRB a clear indication of the protection of human subjects.

☐ The Informed Consent is attached as an addendum to the proposal form.

☐ A copy of all tools being used for data collection is attached as an addendum to the proposal form.

☐ A copy of the certificate of completion from the ACRP Research with Human Subjects training is attached as an addendum to the proposal form.

☐ For children under the age of 18, an assent form is attached as an addendum to the proposal form.

☐ If needed, a copy of the letter giving permission to conduct research at an agency, organization or school.

☐ If the project has already been approved by an IRB elsewhere, a copy of the approval letter from that entity.
Consent Form for Participation in a Research Project Template

Dear Participants,

I am asking for your participation in a research study titled

This study is being led by

**Study Purpose and Procedures** (*be specific about any experimental procedures*)

**Risks, Benefits, Voluntary Participation** (*include time commitment, compensation or lack thereof*)

You should be aware that the Anna Maria College Institutional Review Board may inspect study records as part of its mission to protect the safety of research participants. If you have any additional questions related to this study, please contact

Should you have any questions related to your rights as a research participant, please contact the Anna Maria Institutional Review Board Chair at IRB@annamaria.edu

I have read this information and have had the study purposes, procedures, risks, and benefits explained to my satisfaction. My signature indicates my informed consent to participate in the study. I acknowledge that I have received a copy of this consent form.

Printed name of participant

Signature of participant

Date

Signature of Principal Researcher or Witness

This form was adopted from the University of Connecticut.
Consent Form for Participation in a Research Project by a Student Template

Dear Participant,

I am asking for your participation in a research study titled

This study is being led by , a student at Anna Maria College.

The faculty sponsor for this research is

Study Purpose and Procedures (be specific about any experimental procedures)

Risks, Benefits, Voluntary Participation (include time commitment, compensation or lack thereof)

You should be aware that the Anna Maria College Institutional Review Board may inspect study records as part of its mission to protect the safety of research participants. If you have any additional questions related to this study, please contact or faculty sponsor at . Should you have any questions related to your rights as a research participant, please contact the Anna Maria Institutional Review Board Chair at IRB@annamaria.edu.

I have read this information and have had the study purposes, procedures, risks, and benefits explained to my satisfaction. My signature indicates my informed consent to participate in the study. I acknowledge that I have received a copy of this consent form.

Printed name of participant

Signature of participant

Date

Witness

This form was adopted from the University of Connecticut.
Dear Participants,

I am asking for your participation in a research study titled

This study is being led by

**Study Purpose and Procedures** *(be specific about any experimental procedures)*

---

**Risks, Benefits, Voluntary Participation** *(include time commitment, compensation or lack thereof)*

You should be aware that the Anna Maria College Institutional Review Board may inspect study records as part of its mission to protect the safety of research participants. If you have any additional questions related to this study, please contact

at . Should you have any questions related to your rights as a research participant, please contact the Anna Maria Institutional Review Board Chair at IRB@annamaria.edu.

---

Signature of primary researcher

Date

This form was adopted from the University of Connecticut.
Dear Participants,

I am asking for your participation in a research study titled .

This study is being led by , a student at Anna Maria College. The faculty sponsor for this research is .

**Study Purpose and Procedures** *(be specific about any experimental procedures)*

**Risks, Benefits, Voluntary Participation** *(include time commitment, compensation or lack thereof)*

You should be aware that the Anna Maria College Institutional Review Board may inspect study records as part of its mission to protect the safety of research participants. If you have any additional questions related to this study, please contact 
at or the faculty sponsor at

Should you have any questions related to your rights as a research participant, please contact the Anna Maria Institutional Review Board Chair at IRB@annamaria.edu.

Signature of primary researcher
Date
This form was adopted from the University of Connecticut.
Institutional Review Board Review of Continuing Research Form

This form should be completed by any principal researcher who has been approved to conduct a study with human subjects as affiliated with Anna Maria College, and that project will be continuing for more than one year. Please complete all aspects of the form and submit it along with supporting documentation via email to IRB@annamaria.edu by the date stated in the letter received by the IRB Chair.

Note: Students conducting research should do so in consultation with their faculty sponsor. Both the student and faculty sponsor must sign the submission form. The faculty sponsor will submit the form via email to IRB@annamaria.edu. If this proposal has not yet been approved by the research committee of your program or school (as determined by the college department), please do not submit it for IRB review. It will not be reviewed until this requirement has been met.

Part A: Researcher and Basic Project Information

Project title:

Principal researcher:

Street address:

City, state, zip:

Anna Maria College Email:

School or program:

The principal researcher is (check one):

☐ Anna Maria College faculty member

☐ Anna Maria College staff member

☐ Anna Maria College student

☐ Other (please explain): Names and email addresses of other researchers, as applicable:
If an Anna Maria College student is the principal researcher, provide the following information regarding the faculty sponsor:

Name:

Campus Address:

Campus Telephone:

Anna Maria College email:

**Part B: Type of Review Initially Approved**

The continued review will follow the same classification as the previous review, unless there has been a major change in the study’s risk to participants. Depending on the level of risk associated with the research, a proposal may be classified as exempt from review, eligible for expedited review, or requiring a full review. Definitions for the types of review are in accordance with federal regulations [45 CFR 46.110] and can be found in the Anna Maria College Manual of Policies and Procedures for Conducting Research with Human Subjects.

☐ Exempt
☐ Expedited
☐ Full Review

**Part C: Acknowledgments and Signatures**

☐ This research involves the use of human participants or data governed by other institutions, such as a government agency, private organization (either for profit or non-profit), school, or other entity.

Written approval that permits your continued use of the participants or data is required by the appropriate authority of that institution. Please note that you may have to request approval from the IRB at that entity, and they may request a written notice of the Anna Maria College IRB approval. In this circumstance a formal letter stating that research may be conducted pending IRB approval from Anna Maria College and the entity will suffice to submit your proposal for IRB approval. Once the entity has provided an official decision of their board, the principal researcher must submit a copy of the decision to the Anna Maria College IRB.

☐ I, the principal researcher, have completed the ACRP training regarding Research with Human Participants. The certificate of completion is attached to the end of this form.
I, the principal researcher, attest that all information stated in the Review of Continuing Research Form is true to the best of my knowledge.

Signature of Principal Researcher

Date

Signature of Faculty Sponsor (for students only)

Date

Part D: Summary of the Research Conducted

Provide a brief summary of the study conducted since the study began: Include information regarding the study design, participants and data collection techniques. Discuss any changes to recruitment or data collection tools, or the time frame initially reported in the original IRB Proposal.

Part E: Continued Protection of Human Subjects

Risk to Participants: Provide an assessment of the physical, emotional and/or psychological risk in your study. Explain how you intend to keep participants from being harmed in these ways. Explain any changes in risk to participants.
IRB Continued Review Check List

This form is optional and is for the benefit of the researcher. You may use this form to ensure you have completed your IRB proposal in full. It does not need to be submitted to the IRB with your proposal.

☐ Part A is completed in full, including faculty sponsor for students.

☐ Part B is complete, indicating the type of review being requested.

☐ Part C is complete, including checking all the applicable boxes.

☐ The proposal form is signed by the principal researcher.

☐ For students- the proposal form is signed by the faculty sponsor.

☐ All sections of Part D are complete giving the IRB a clear indication of the research being conducted and any changes to the research initially approved.

☐ All sections of Part E are complete giving the IRB a clear indication of the protection of human subjects and continued efforts to keep risk at a minimum.

☐ Only if there are changes: The Informed Consent is attached as an addendum to the proposal form.

☐ Only if there are changes: For children under the age of 18, an assent form is attached as an addendum to the proposal form.

☐ Only if there are changes: A copy of all tools being used for data collection is attached as an addendum to the proposal form.

☐ If needed, a copy of the letter giving permission to conduct research at an agency, organization or school.

☐ If a continued review has already been approved by an IRB elsewhere, a copy of the approval letter from that IRB.
RE:

Dear

Thank you for submitting your research proposal to the Institutional Review Board (IRB) at Anna Maria College. We have reviewed all materials related to the proposal and have voted to approve your research project as submitted via:

☐ Exempt Review ☐ Expedited Review ☐ Full Review

This approval is valid for one year and will expire on . If a continued review is needed, all materials are due to the IRB no later than .

If you wish to make changes to the project an IRB review will be required. Please contact the IRB chair via IRB@annamaria.edu for information regarding what materials will be needed for the IRB to complete a comprehensive review of the changes prior to their implementation. However, at this time there is no further action required.

Congratulations and good luck with your research project.

Sincerely,

Institutional Review Board Chair Signature

Date

Cc: IRB file
Template Approval with Restrictions/Limitations

RE:

Dear

Thank you for submitting your research proposal to the Institutional Review Board (IRB) at Anna Maria College. We have reviewed all materials related to the proposal and have voted to approve your research project with restrictions/limitations as submitted via:

☐ Exempt Review  ☐ Expedited Review  ☐ Full Review

The restrictions/limitations for your project are as follows:

This approval is valid for one year and will expire on . If a continued review is needed, all materials are due to the IRB no later than .

If you wish to make changes to the project an IRB review will be required. Please contact the IRB chair via IRB@annamaria.edu for information regarding what materials will be needed for the IRB to complete a comprehensive review of the changes prior to their implementation. However, at this time there is no further action required.

Congratulations and good luck with your research project.

Sincerely,

Institutional Review Board Chair

Date

Cc: IRB file
Template Decline Research Letter

RE:

Dear

Thank you for submitting your research proposal to the Institutional Review Board (IRB) at Anna Maria College. We have reviewed all materials related to the proposal and have voted to decline your proposal at this time. You may resubmit a full proposal at a future date, ensuring that all of the below have been corrected.

The reason(s) for the decline is/are:

Should you have questions regarding this decision please contact the Anna Maria College Institutional Review Board Chair via IRB@annamaria.edu.

Sincerely,

Institutional Review Board Chair

Date

CC: IRB File
RE:

Dear

Thank you for submitting your research proposal to the Institutional Review Board (IRB) at Anna Maria College. We have reviewed all materials related to the proposal and have determined additional information is required. The information needed is listed below. Your response should be submitted within 2 weeks of this notice. The information needed is as follows:

Once submitted the IRB will review and provide a response within 2 weeks. Please be advised that the project may not begin until the IRB has provided approval of the study. If no response is submitted within 90 days of this notice, the proposal will be administratively closed. After this time, a complete initial proposal will need to be resubmitted for review.

The IRB appreciates your time and commitment to conducting research with human subjects. Should you have further questions, please do not hesitate to contact the IRB Chair via IRB@annamaria.edu.

Sincerely,

Institutional Review Board Chair

Date

CC: IRB File