GANNON UNIVERSITY

INSTITUTIONAL REVIEW BOARD

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

POLICY MANUAL

Submitted by Faculty Committee

to Gannon University Provost

Approved: Fall 1995

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Office Location:
The Central Office of the IRB is located in Main 101 (MS01; 871-5800).

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MISSION STATEMENT

Mission Statement of Gannon University Institutional Review Board: For research involving human subjects, Gannon University is guided by the ethical principles found in the report by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research: the Belmont Report*. <http://ohsr.od.nih.guidelines/Belmont.html>. Gannon University is in compliance with the requirements contained in federal guidelines in *Title 45 Public Welfare, Part 46, Protection of Human Subjects* of the *Code of Federal Regulations* (*CFR*) <http://ohsr.od.nih.gov/guidelines/45cfr46.htm>. These guidelines will be followed for all research without regard to source of funding.

INTRODUCTION

When human beings are used as subjects in research projects, safeguards must be established to protect their health, well-being, and rights. Gannon University's special identity recognizes the dignity and sacredness of all human beings and thus endorses such safeguards and protection. Under the policies established by the Department of Health and Human Services (HHS), this protection was extended to all human subjects regardless of the nature of the research being performed. This protection required that an Institutional Review Board (IRB) be established at colleges and universities to review and act on all research proposals involving human subjects.

On June 23, 2005, HHS revised *Code of Federal Regulations (CFR), Title 45 Public Welfare; Part 46 Protection of Human Subjects*. Those exemptions notwithstanding, all university research is subject to these rules and regulations. Therefore, in those cases where research involves human beings as research subjects, the investigator must submit the proposed project to the Gannon University IRB Committee for the Protection of Human Subjects for review of the proposal. Approval of projects involving human subjects by this IRB is a prerequisite for the approval of any grant that may be recommended to the Provost for funding by the University or for seeking or using research or grant funds from external agencies.

This document establishes policies and procedures as it relates to IRB membership, procedures for IRB review, maintenance of IRB records, and an overview of the types of research requiring IRB review.

RESEARCH REQUIRING REVIEW BY GANNON UNIVERSITY IRB

All research involving human subjects that is conducted under the auspices of Gannon University must have approval of the Gannon University IRB before it is initiated. A review of research activities will be made by the IRB for studies sponsored by students, faculty, staff, or administration of Gannon University. In those instances where individuals not affiliated with Gannon University wish to conduct research on its campus, a faculty or staff member of the University must sponsor the application to the IRB. Students are bound by the same procedures and policies as the faculty and staff. Moreover, no proposals to the IRB from either an undergraduate or a graduate student will be reviewed unless sponsored by a faculty member. The Gannon University IRB, which has been duly constituted in accordance with HHS guidelines, is the Committee for the Protection of Human Subjects.

To approve a research project the IRB shall determine that all of the following requirements are satisfied (*CFR Title 45 Part 46.111*):

1. Risks to the subjects are minimized.

2. Risks to the subjects are reasonable in relation to anticipated benefits, if any, to the subjects, and the importance of the knowledge that may be reasonably expected.

3. Selection of subjects is equitable.

4. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.

5. Informed consent will be appropriately documented.

6. Where appropriate, the research plan makes adequate provision for monitoring the data collected to insure the safety of the subjects.

7. Where appropriate, there are adequate provisions to protect privacy of subjects and to maintain the confidentiality of data.

8. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, or persons who are economically or educationally disadvantaged, appropriate additional safeguards have been included in the research to protect the rights and welfare of these subjects.

9. The design of the study is consistent with sound scientific principles, ethical norms, and regulatory requirements.

Gannon University IRB has authority to (a) approve, (b) require modifications in or (c) disapprove all research proposals that include the use of human subjects for research. 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 serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator and appropriate University officials.

The IRB reserves the right to consult with subject matter, medical, or legal experts concerning any project submitted for review. If expert review of a proposal is deemed necessary by the IRB, a substantial delay in IRB action should be anticipated. .*CFR* requires that research involving any level of deception be followed by appropriate debriefing of all subjects. Debriefing procedures should be specified in the IRB application forms.

Research Not Subject to IRB Review:

Specific research activities **NOT** subject to IRB review are (a) samples from deceased individuals; (b) samples collected for diagnostic purposes only; (c) Samples or data that are available from commercial or public repositories or registries; (d) established cell lines that are publicly available to qualified scientific investigators; and (e)self-sustaining, cell-free derivative preparations including viral isolates, cloned DNA or RNA.

MEMBERSHIP OF GANNON UNIVERSITY IRB

In compliance with *CFR Title 45 46:107:*

1. The IRB shall consist of members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects. The *CFR* requires at least five members on an IRB. Gannon University IRB consists of 11 members.

2. Every nondiscriminatory effort will be made to ensure that the IRB does not consist entirely of men or women. Consideration of qualified persons of both sexes shall occur, so long as no selection is made to the IRB on the basis of gender.

3. No IRB may consist entirely of members of one profession.

4. The IRB shall include at least one member whose primary concerns are in nonscientific areas: for example: lawyers, ethicists, members of the clergy; and at least one member whose primary concerns are in scientific areas:

5. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

6. The IRB shall not have a member participating in the initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

7. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

Selection and Term of IRB Members:

Faculty membership of the IRB shall comply with the existing regulations of the Department of Health and Human Services, HHS, as set forth in the *CFR.*

Gannon University Institutional Policy Manual [**link**] recommends that membership of the Gannon University IRB shall include three members from the College of Humanities, Education, and Social Sciences, three members from the College of Health Professions and Sciences, three members from the

College of Engineering and Business who are appointed at the discretion of the College Dean, one community member, and one at-large member—a total of 11 members

Members of the IRB who are not faculty or staff of Gannon University, and who meet the requirements of *CFR,* shall be recommended for appointment by the IRB members to the Provost. The Provost shall have final authority to appoint such members to the IRB.

Gannon University Institutional Policy Manual states term of service shall be three years without prejudice to re-appointment. The IRB Chairperson is to be elected by the members of the IRB for a two-year term.

Maintaining Membership List:

A list of the members of the IRB shall be on file in the Offices of the President and the Provost of Gannon University and shall be updated annually. The list of the IRB members who shall be identified by name will include the following information:

- Earned degrees;
- Representative capacity;
- Indications of experience such as IRB certifications, licenses, professional credentials that are sufficient to describe each member's chief anticipated contribution to IRB deliberations;
- Employment or other relationship between each member and the institution; for example: Full-time employee, part-time employee, member of the governing IRB, paid or unpaid consultant.

This list shall be made available to the Secretary of HHS as required when the University seeks federal funding for research that involves human subjects in compliance with existing federal regulations.

FUNCTIONS OF THE IRB

In accordance with requirements set forth in the *CFR, Gannon University Institutional Policy Manual* Section I page 3.17 states. The functions of the IRB Committee for the Protection of Human Subjects shall be to:

1. Review and approve all faculty and student research proposals involving human subjects.

2. Establish, monitor, and periodically evaluate all criteria for such review in compliance with federal laws and regulations for Institutional Review Boards.

3. Serve as Gannon University's IRB for external grant certification purposes.

4. Implement the IRB policies of Gannon University as they relate to human subjects for research.

5. Annually, report findings and recommendations to the Office of the Provost of Gannon University. Any changes in federal regulations and resultant policy updates should also be included in the annual report.

IRB approval of a project constitutes only a statement by the Gannon University IRB that it believes the rights of human beings will be adequately protected. All research projects that have been approved by the IRB may be subject to further review or disapproval by appropriate officials of the University. Projects

that have been disapproved by the IRB may not subsequently be approved by any other University Administrator or official.

Meeting Schedule:

CFR requires annual IRB meetings. The Gannon University IRB meets monthly September through April (when there is business to conduct) on the last Tuesday of the month that Gannon University is in session. Standard Reviews will not be conducted in May, June, July, or August. The IRB meeting Schedule is available in the IRB Office and is posted online at Gannon University's web site. Standard reviews are conducted at scheduled IRB meetings. Other reviews are conducted on an individual basis.

PLEASE NOTE: For Standard Review, applications must be submitted to the IRB Office no later than noon, ten working days (10) prior to a scheduled IRB meeting. Applications for Standard Reviews submitted fewer than 10 working days before a scheduled meeting will be held until the next monthly meeting.

MAINTENANCE OF IRB RECORDS

In accordance with requirements set forth in the *CFR*, the chairperson of the Gannon University IRB shall prepare and maintain adequate documentation of IRB activities including the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent/assent documents, questionnaires and surveys, progress reports submitted by investigators and reports of injuries to subjects.

2. Minutes of IRB meetings, which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.

3. Records of continuing review activities.

4. Copies of all correspondence between the IRB and investigators.

5. A list of IRB members as required by *Title 45 CFR 46.103 (b) (3).*

6. Written procedures for the IRB as required by *Title 45 CFR 46.103 (b) (5)*.

7. Statements of significant, new findings provided to subjects, as required by *Title 45 CFR 46.116 (b) (5)*. The records required to be maintained by the IRB shall be retained for at least three (3) years after completion of the research, and the records shall be accessible for inspection and copying by authorized representatives of the Department of Health and Human Services at reasonable times and in a reasonable manner as required by *Title 45 CFR 46.115 (b).*

TYPES OF IRB REVIEW

Although all forms of research involving human subjects must be reviewed by the IRB, there are three types of IRB reviews: (1) Exempted from standard review, (2) Expedited, and (3) Standard. Standard

reviews are conducted at a meeting of a majority of IRB members. Questions concerning application procedures and guidelines should be referred to the Chairperson of the Gannon University IRB. The criteria used to determine if a proposed research qualifies as exempted from standard review, expedited review, or standard review is detailed below.

Exempted From Standard Review:

Certain studies may be exempted from standard review which is a review by a majority of IRB members. Reviews of research that is exempted from standard review are conducted by a single IRB member. The review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after Standard Review. However, a single reviewer may recommend a standard review be conducted. The categories of research that may be exempt from Standard Review according to federal regulations include:

- Research involving common educational practices
- Research involving standard educational tests or assessment instruments
- Survey research
- Observational research
- Research involving existing data
- Research involving programs of the Department of Health and Human Services.

PLEASE NOTE: No Exempted from standard review criteria apply to research involving prisoners or pregnant women. See also the section below entitled "Vulnerable Populations", subsection "Exemption from Standard Review for research Involving Children".

Anything exempted from standard review in *CFR Title 45 Part 46.101b* <http://ohsr.od.nih.gov/guidelines/45cfr46.htm> will be exempted from standard review here. The specific categories for exempted from standard review are described below:

1. **Common Educational Practices:** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special educational instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. **Educational Testing I:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior. The exemption does NOT apply if the information is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects, and disclosure of a subject's responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

3. **Educational Testing II:** Research involving the use of educational tests (cognitive, diagnostic, aptitude, or achievement), survey procedures, interview procedures, or observation of public behavior that is NOT exempt in #2 above is exempt under theses conditions; (a) the human subjects are elected or appointed officials or candidates for public office, or (b) federal statutes require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. **Existing Data:** Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. **Public Benefit or Service.** Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine (a) public benefit or service programs, (b) procedures for obtaining benefits or services under these programs, (c) possible changes in or alternatives to those programs or procedures, or (d) possible changes in methods or levels of payment for benefits or services under those programs

6. **Taste and Food Quality.** Research that involves taste or food quality evaluation and consumer acceptance studies if (a) wholesome foods without additives are consumed or (b) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempted from standard review may be provided for a single research or for a group of related studies. Claims for exempted from standard review are evaluated by the IRB representative within the appropriate academic unit.

Expedited Review:

Certain studies may qualify for expedited review. Expedited reviews are conducted by a single IRB member rather than a majority of the IRB members. The review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after Standard Review. However, a single reviewer may recommend a standard review be conducted.

An IRB may use the expedited review procedure to review either or both of the following: (a) some or all of the research appearing on the list and found by the reviewer(s) to involve no more than minimal risk or (b) minor changes in previously approved research during the period (of one year or less) for which approval is authorized (*CFR Title 45, 46.110*).

Other categories of research which federal regulations permit expedited reviews include:

- Research involving no manipulation of the subjects' behavior and involving no stress to the subjects—such as studies or perceptual or cognitive processes or studies for developing or evaluating tests
- Study of existing data, documents, records, pathological specimens or diagnostic specimens
- Moderate exercise by healthy volunteers
- Voice recording for research purposes, such as for research of speech defects.

Expedited review may be provided only if the research involves (a) no more than minimal risk, that is, risk that is no greater in probability and severity than that ordinarily encountered in daily life during the

performance of routine physical or psychological examinations or tests *(Title 45 CFR 46.102.g)* and (b) if the research falls into one of the following categories:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

   (a) Research on drugs for which an investigational new drug application (*21 CFR Part 312*) is not required. Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

   (b) Research on medical devices for which (i) an investigational device exemption application (*21 CFR Part 812*) is not required; or (ii) the medical device is cleared for marketing and is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from adults and children under restrictions.

   (a) From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week, or

   (b) From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of the blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by non-invasive means, such as hair and nail clippings, sweat, and saliva. Examples:

   (a) Prospective collection of biological specimens for research purposes by non-invasive means, such as hair and nail clippings, sweat, and saliva. Examples: hair and nail clippings in a non-disfiguring manner;

   (b) Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

   (c) Permanent teeth if routine patient care indicates a need for extraction;

   (d) Excreta and external secretion (including sweat);

   (e) Uncannulated saliva collected either in an unstimulated fashion or stimulated by (chewing gum base or wax or by applying a dilute citric solution to the tongue;

   (f) Placenta removed at delivery;

   (g) Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

(h) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

(i) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(j) Sputum collected after saline mist nebulization.

4. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. When medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

(a) 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;

(b) Weighing or testing sensory acuity;

(c) Magnetic resonance imaging;

(d) Electrocardiography, electroencephalography, thermography, detection of naturally infrared imaging, Doppler blood flow, and echocardiography;

(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects [*Title 45 CFR, 46.101(b) (4)*]. This listing refers only to research that is not exempt.

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects [*Title 45 CFR 46.101(b) (2) and (b) (3)*]. This listing refers only to research that is not exempt.

8. Continuing review of research previously approved by the convened IRB as follows:

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

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where data analysis poses ongoing risk to participants (e.g., privacy or confidentiality issues).

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Standard Review:

Except in those cases that qualify for exempted from standard review or expedited review as detailed above, a Standard review is conducted at a meeting of the full IRB membership that has a majority of members present and includes at least one member whose primary concerns are in nonscientific areas. Approved research shall receive the approval of a majority of those members present at the meeting.

For Standard review, applications must be submitted to the IRB Office no later than noon, ten days (10) prior to a scheduled IRB meeting to allow time for members to thoroughly examine proposals. Applications for Standard Reviews submitted fewer than 10 days before a scheduled meeting will be held until the next monthly meeting.

The Gannon University IRB meets monthly September through April, when there is business to conduct, on the last Tuesday of the month that Gannon University is in session. Standard Reviews will not be conducted in May, June, July, or August.

IRB DISPOSITIONS

Four dispositions are possible from the IRB review: (1) Full Approval, (2) Approval with Recommendations, (3) Approval with Conditions, or (4) Disapproval.

Full Approval:

Upon notification of Full Approval the investigator may begin the proposed research immediately. The investigator is required to immediately notify the IRB for further review of the research in the event that any of the following should occur:

- A major change in the method of collection of data
- Unanticipated adverse effects on the human subjects
- Unanticipated difficulties in obtaining informed consent or maintaining confidentiality
- The research is not completed within 12 months of the notice of approval from the IRB.

Approval with Recommendations:

Upon notification of Approval with Recommendations the investigator may begin the proposed research immediately. Note however, that while the IRB has approved the research, the IRB has chosen to make

recommendations to the investigator regarding possible improvements to the research plan or appearance of written materials to be used in the research. The investigator is required to immediately notify the IRB for further review of the research in the event that any of the following should occur:

- A major change in the method of collection of data
- Unanticipated adverse effects on the human subjects
- Unanticipated difficulties in obtaining informed consent or maintaining confidentiality
- The research is not completed within 12 months of the notice of approval from the IRB.

Approval with Conditions:

If Approval with Conditions is granted, the IRB will specify what conditions must be met before research may begin. In this case, the investigator in consultation with the thesis chair and IRB chair, if applicable, must address each of the conditions and report in memo format back to the IRB Chair. Upon subsequent favorable review the application is granted either Full Approval or Approval with Recommendations at which time the proposed research may begin

Disapproval:

If the IRB disapproves of the research, the investigator is notified of the specific reasons for Disapproval. The investigator should schedule a meeting with the IRB Chair to discuss the research and what actions need to be taken to remedy the problems. When an application receives a disposition of Disapproval, the investigator must submit a new application with supporting materials to the IRB for the application to be reviewed again. The proposed research may not begin until Full Approval or Approval with Recommendations has been granted by the IRB.

REQUIREMENTS FOR INFORMED CONSENT

No investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate. These circumstances must also minimize the possibility of coercion or undue influence. The information given to the subject or the representative shall be in language understandable to the subject or the representative. **No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.**

Informed consent requirements are not intended to preempt applicable federal, state, or local laws which require additional information to be disclosed in order for informed consent to be legally effective. Nothing in these regulations is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state, or local law.

Title 45 CFR 46.116 states informed consent documents shall include the following:

- A statement that the research involves research
- An explanation of the purposes of the research
- Notification of the expected duration of the subject's participation

- A description of the procedures to be followed
- Identification of any procedures which are experimental;
- A description of any reasonably foreseeable risks or discomforts to the subjects;
- A description of any benefits to the subject or to others which may be reasonably expected from the research (PLEASE NOTE: Money or other compensation for participation is **NOT** considered to be a benefit, but rather a compensation for research-related inconveniences.);
- A disclosure of appropriate alternative procedures or course of treatment, if any, that might be advantageous to the subject;
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- An explanation of contact procedures, including a name and phone number, for answers to pertinent questions about the research:
- An explanation of contact procedures, including a name and phone number, for answers to pertinent questions about the research subject's rights;
- An explanation of contact procedures, including a name and phone number, in the event of a research related injury to the subject;
- A statement that participation is voluntary;
- A statement that that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled;
- A statement that the subject may discontinue participation at any time without penalty or loss of benefits;
- A dated signature of the subject or the subject's legal representative.

If more than minimal risk is involved informed consent documents shall include:

- An explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

Where appropriate, the following elements of informed consent must also be included:

- A statement that the particular treatment or procedure may involve risks to the subject which are currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- Disclosure of the approximate number of subjects involved in the research.

The IRB has the authority to approve a consent procedure which does not include or which alters some or all of the previously mentioned elements of informed consent or waive the requirements for informed consent if, either:

1. (a) The research involves no more than minimal risk;
   (b) The waiver or alteration does not adversely affect the rights and welfare of the subjects;
   (c) The research could not practically be carried out without the waiver or alteration; and
   (d) Wherever applicable, the subjects will be provided with additional pertinent information: or

2. The research is to be conducted for the purpose of demonstrating or evaluating
(a) Federal, state, or local benefit or service programs which are not themselves research programs;
(b) Procedures for obtaining benefits or services under these programs; or
(c) Possible changes in or alternatives to these programs or procedures; and
the research could not practicably be carried out without the waiver or alteration.

Documentation of Informed Consent:

Informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either of the following:

1. A written consent document that embodies the elements of informed consent. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed; or

2. A "short form" written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. However, the witness shall sign both the short form and a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the "short form."

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

1. That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or,

2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases where the documentation requirement is waived the IRB may require the investigator to provide subjects with a written statement regarding the research.

VULNERABLE POPULATIONS

CFR provides additional protections for vulnerable populations including (a) pregnant women, human fetuses, and neonates; (b) prisoners; and (c) children. Gannon University IRB will refer to *CFR* as needed regarding all vulnerable populations. Since many researchers at Gannon University recruit children as the subject of research, those regulations are detailed below.

Additional Protections for Children Involved as Subjects in Research

Children are those persons who have not attained the legal age for consent to treatments or procedures involved in research, under the applicable law of the jurisdiction in which the research is conducted. *CFR* states that IRBs may approve only those research proposals which satisfy the following conditions:

1. Research not involving greater than minimal risk to children, provided adequate provisions for soliciting the assent of the children and the informed consent of their parents or guardians is proposed.

2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects only if (a) the risk is justified by the anticipated benefit to the subjects; (b) the relation of the anticipated benefit to the risk is at least as favorable as that presented by available alternatives and (c) adequate provisions for soliciting the assent of the children and the informed consent of their parents or guardians is proposed.

3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition provided adequate provisions for soliciting the assent of the children and the informed consent of their parents or guardians is proposed.

4. Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children.

Exemptions from Standard Review for Research Involving Children:

Some exemptions from Standard Review are applicable to children as subjects. Exemption #1 Common Educational Practice, #3 Educational Testing, #4 Existing Data, # 5 Public Benefit or Service and #6 Taste and Food Quality as listed previously in the *Policy and Procedure Manual* are applicable. The part of Exemption #2 regarding educational tests is applicable. However, Exemption #2 regarding survey procedures, interview procedures, or observation of public behavior are not exempt. Research involving participant observation is exempt only if the investigator does not participate in the activities being observed.

RESPONSIBILITIES OF INVESTIGATORS

Investigators are responsible for applying for IRB approval when their proposal meets the definitions of (a) research and (b) involvement of human subjects. Proposals involving non-human subjects may require approval of a different Review Board. Investigators responsibilities include:

1. Waiting to receive notification from the IRB as to the disposition of the application before beginning research activities. Depending on the disposition, the research project may either (a) proceed or (b) be held until approval is granted after conditions are satisfied or additional information is supplied to the IRB. The *CFR* requires IRB approval prior to beginning any research involving human subjects

2. Familiarizing themselves thoroughly with these guidelines and *CFR* resolving any questions regarding proposed research activities by consulting with IRB members.

3. Notifying the IRB and the Department Chairperson/Supervisor of any injury—physical, psychological, or social—that is suffered by subjects because of their participation in a research activity.

4. Requesting a continuing review if the research is judged by the IRB to involve more than minimal risk.

5. Reporting the status of their research annually on the anniversary of the original IRB approval in cases where research is not complete within 12 months. Research is considered to be ongoing as long as intervention is occurring, data is being collected, or analysis of identifiable data is being conducted.

6. Informing the IRB in writing when (a) the investigator has terminated the research project or (b) the following criteria have been met:
   (i) The data have been de-identified. That is, when personal identifiers have been removed from the data, and
   (ii) No further investigation, intervention, or data collection is ongoing, and
   (iii) No further analysis of identifiable data is ongoing.

7. Developing and implementing a plan to keep records, documents (including informed consent forms), and data securely and confidentially stored for at least three years following the completion of the study, or for a longer period if judged necessary.

8. Providing a written explanation of these plans and a plan for the destruction of the records, documents, and data within the application for IRB review.

9. Maintaining contact with faculty sponsor and faculty advisors and notifying them of IRB dispositions and of any conditions which require notification of IRB.

10. Submitting a completed IRB application packet and preparing the necessary copies for review by the IRB.

    For Exemption from Standard Review. Submit (a) an original application that includes original signatures, supporting documents, and one copy of the research proposal and (b) one photocopy of the original application including signatures, supporting documents, and research proposal. The original will be retained in IRB records. The photocopy will be forwarded from the IRB Office to the departmental representative for review.

    For Expedited Review. Submit (a) an original application that includes original signatures, supporting documents, and one copy of the research proposal and (b) one photocopy of the original application including signatures, supporting documents, and research proposal. The original will be retained in IRB records. The photocopy will be forwarded from the IRB Office to the departmental representative for review.

    For a Standard Review. Submit (a) an original application that includes original signatures, supporting documents, and one copy of the research proposal and (b) thirteen (13) photocopies of the original application including signatures, supporting documents, and research proposal. The

original will be retained in IRB records. The photocopies will be forwarded from the IRB Office to the members of the IRB for review.

DEFINITIONS

To comply with existing federal regulations the following definitions are applicable:

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Guardian means an individual who is authorized under applicable state or local law to consent on behalf of a child to general medical care.

Human subject means a living individual about whom an investigator conducting research obtains (a) data through intervention or interaction with the individual or (b) identifiable private information.

IRB means an Institutional Review Board established in accord with and for the purpose expressed in this policy.

Minimal risk means that 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.

Parent means a child's biological or adoptive parent.

Permission means the agreement of parent(s) or guardian(s) to the participation of their child or ward in research.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to general knowledge. Research is completed when the following criteria have been met:

(i) The data have been de-identified. That is, when personal identifiers have been removed from the data, and
(ii) No further investigation, intervention, or data collection is ongoing, and
(iii) No further analysis of identifiable data is ongoing.

Also research is completed when the investigator has terminated the research project.