Policy #:	**IR 1.00 (2 pages)**
Classification:	General Administration
Category:	Institutional Research
Topic:	**Institutional Review Board Policies**
Approved by:	President
Signature:	Rosalie M. Murenda
Title:	President
Original Date:	January 1994
Review/Revision:	July 2015

Neumann University Institutional Research Board Policy Statement

The following policies serve as a general framework for the protection of the rights and welfare of human subjects involved in research conducted at Neumann University or by its employees and/or students.

1) The University shall establish and maintain an Institutional Review Board (IRB) to ensure the protection of the rights and welfare of human research subjects pursuant to the federal regulations (45CFR Part 46 and 21CFR Part 56).

2) The President in consultation with the Executive Team shall appoint members to the IRB and its Chair. Members shall be appointed in conformity with the IRB's Standard Operating Procedures.

3) The IRB will report to the President. The President will provide sufficient resources for the efficient conduct of IRB business, including an administrative liaison to serve as IRB coordinator.

4) The IRB will not apply any review standard that exceeds the standards set by the Code of Federal Regulations (45CFR Part 46 and 21CFR Part 56).

5) Decisions to not approve a research protocol by the IRB may not be appealed. The IRB will provide written explanations for its decisions and investigators may choose to revise and resubmit their protocols.

6) Approval of research by the IRB does not preclude the review of such research by other divisions within the University.

7) Research that does not fall within the scope of the federal Code of Regulations shall be exempt from IRB review. The IRB, however, shall be the sole interpreter of when research falls outside its purview and what research is exempt per the federal regulations. All exempt research will be reported to the IRB as a matter of record.

8) The IRB will maintain and publish a set of "Standard Operating Procedures" detailing the IRB policies, procedures, and protocols to be followed by investigators.

9) Principal Investigators may contact the IRB for clarification and advice relative to their research and submission of proposals.

10) Research that originates from outside the University must be submitted for review to the IRB and the Investigator must have a liaison at Neumann University. The IRB may choose to accept an external IRB's review as sufficient or, at its discretion, it may require that the research be reviewed and approved by the Neumann University IRB.

11) Employees of the University who engage in research activities involving human subjects must seek prospective approval of their research. This includes all research activities conducted at Neumann University or all research activities conducted outside the University but in one's capacity as an employee of the University.

12) All research activities involving human subjects conducted by students at Neumann University or outside the University are subject to prospective IRB review and approval if the research is conducted as part of their curriculum or under the auspices of a Neumann University program. Procedures for students to submit their research for review to the IRB are detailed in the Standard Operating Procedures document.

13) All student research protocols submitted to the IRB must have a University faculty member as a co-investigator. The University faculty co-investigator should have experience in the area of research being conducted by the student and the University faculty co-investigator is responsible for protecting the rights and welfare of the human subjects involved in the research.

14) All members of the IRB and individuals conducting research at the University are expected to complete the Human Subject Assurance Training from the Office for Human Research Protections (OHRP), every three years, and submit their training certificate to the administrative liaison upon completion.

Policy #:	**IR 1.00 (19 pages)**
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Category:	Institutional Research
Topic:	**Institutional Review Board Policies**
Approved by:	President
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Title:	President
Original Date:	January 1994
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Neumann University Institutional Research Board Standard Operating Procedures

I. Institutional Review Board's Mandate to Protect Human Subjects

A. Neumann University hereby establishes and maintains an Institutional Review Board (IRB) to ensure the protection of the rights and welfare of human research subjects pursuant to the federal regulations (45CFR Part 46 and 21CFR Part 56).

B. The IRB will:
1. Perform prospective and continuing review of protocols;
2. Determine the informed consent process and the procedures utilized to enroll subjects;
3. Ensure that the human subject research is conducted ethically and in compliance with the *Belmont Report*, and with all applicable federal, state, local and institutional requirements.

II. The IRB Administration

A. Reports to the President, who will provide sufficient resources for the efficient conduct of IRB business;

B. Employs a staff person who serves as Administrative Liaison and reports to the IRB Chairperson;

C. The duties of the Administrative Liaison include:
1. Assisting in the development and implementation of procedures to ensure the efficient flow of all IRB records
2. Maintaining documentation and records in accordance with federal regulatory requirements
3. Tracking records and the progress of all studies
4. Ensuring meetings are conducted in accordance with federal regulations, i.e., recording attendance, as well as preparing and distributing materials for meetings and;
5. Attendance at all IRB meetings.

III. IRB Membership

A. Membership
1. Will have sufficient expertise to review the broad variety of research in which the University becomes involved;
2. Will be knowledgeable about all relevant regulatory requirements and;
3. Will make every effort to be impartial and objective in its review (45 CFR 46.107(a) and 21 CFR 56.107(a)).

B. IRB Chairperson – Appointment, Length of Service, and Duties:
   1. Appointed by the President
   2. Responsible for the IRB membership
   3. Conducts IRB meetings;
   4. Directs the IRB staff to ensure operation of the IRB within all applicable regulatory requirements;
   5. Works with IRB members and investigators to ensure that the rights and welfare of research subjects are adequately protected;
   6. Signs all official IRB correspondence and;
   7. Reports directly to the President.

C. IRB Members – Appointment and Duties:
   1. Appointed by the President in consultation with members of the executive team and current and past appointed members;
   2. Responsible for ensuring the rights and welfare of research subjects are protected;
   3. Vote to approve, require modifications in, disapprove, or table proposals;
   4. Are expected to attend IRB meetings on a regular basis;
   5. Serve as primary reviewers for research within their expertise;
   6. Serve as general reviewers on all research discussed at convened meetings and;
   7. May be designated by Chair to review non-research, exempt, and expedited review protocols.

D. Membership will:
   1. Be composed of at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at Neumann University (46.107 of 45 CFR 46);
   2. include at least one member whose primary concerns are in nonscientific areas;
   3. include one person who is not currently affiliated with Neumann University and is not part of the immediate family of a person who is currently affiliated with Neumann University;
   4. Be drawn from diverse backgrounds; and
   5. Exercise sensitivity with regard to such diversity and community attitudes in order to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

E. When reviewed research involves a category of vulnerable subjects (e.g. prisoners, pregnant women, children, individuals institutionalized as mentally disabled), the IRB shall include in its reviewing body one or more individuals who have a primary concern with the welfare of vulnerable subjects (see: http://grants2.nih.gov/grants/policy/hs/populations.htm).

F. Specific Duties of Membership include:
   1. Responsibility in the development of procedures for submitting research protocols for review;
   2. Making the determination if research protocols are in conformity with federal regulations regarding use of human subjects in research;
   3. Reviewing approved research projects on a continuing basis (at a minimum of once a year);
   4. Reporting to the President of the University any serious or continuing noncompliance by University investigators with the conditions outlined in the project as approved; and
   5. Reporting to the Secretary of Health and Human Services any serious or continuing noncompliance by University investigators who are funded by the Department of Health and Human Services.

G. Conflict of interest is prohibited and exists where:
   1. A member participates in the IRB's initial or continuing review of any project in which that member has a conflicting interest;
   2. Information requested by the IRB is provided by a member with a conflicting interest; or
   3. An IRB member is a Principal Investigator for a study being reviewed by the IRB.

H. Initial Training, Continuing Education, and Professional Development of IRB Members:
   1. IRB members
      a. Will receive a copy of these IRB standard operation procedures to enable each to review research from an ethical and regulatory perspective; and
      b. Must complete the **Human Subject Assurance Training** from the Office for Human Research Protections (OHRP).
   2. IRB members will become familiar with:
      a. Federal regulations; and
      b. The Belmont Report
      c. Availability of specific information will come from the Administrative Liaison.
   3. IRB members will have available specific information provided by the Administrative Liaison.

I. Compensation
   1. No monetary compensation is provided for service on the IRB

IV. IRB Meetings

A. Schedule
   1. Convene at the call of the chairperson when the chairperson judges the meeting to be necessary or advantageous;
   2. Convene at joint written request of three or more members;

3. Meet once each semester;
4. Cancel or add a meeting with the discretion of the IRB chair in the event
   a. There is no business; or
   b. There is additional business to conduct.

B. Procedures
1. Convened meetings conducted under and pursuant to Roberts' Rules of Order;
2. Members must have received all pertinent information prior to the meeting and be able to actively and equally participate in all discussions;
3. A quorum is required for review of research protocols and recommendations (e.g., exempt and expedited studies) and conducting the business of the committee;
4. A simple majority of members present at the convened meeting must approve a research protocol for non-expedited procedures
5. Any member may request at a convened IRB meeting that an activity that has been approved under the exempt or expedited procedure be reviewed by IRB in accordance with non-expedited procedures;
6. All committee decisions requiring vote are decided by majority;
7. Research studies previously approved under exempt or expedited protocols and subsequently reviewed by non-expedited procedures at the request of the committee member/s) will be determined at the convened meeting. Decisions made at this time will supersede any previous decisions.

V. Substance of IRB Review

A. Principal Investigators' (PI) Submission to IRB.
1. All research studies involving human subjects should be submitted for IRB review;
2. Submissions should be sent to the chair of the IRB electronically and should use the IRB submission template form;
3. Form includes all submission requirements (see Appendix A for submission requirements);
4. Principal Investigator may request either:
   a. exemption from IRB review
   b. expedited review; or
   c. full board review.

VI. IRB Review and Approval of Research

A. Initial Review and Categorization of Study
1. Chair or the Chair's designee
   a. Will review the submitted protocol;
   b. Determine its status for IRB review
      1. Non-research
      2. Quality improvement
      3. Exempt
      4. Expedited review

5. Full board review

c. All human subjects research must be prospectively reviewed and approved by IRB except:
    1. If exempt from IRB review under 45 CFR 46.101(b); (and described in Appendix C); or
    2. Does not meet the criteria for human subjects research (45 CFR 46.102(d) and (f));
d. Studies that qualify as exempt or do not meet the criteria for human subjects research will be designated by the Chair and notify the PI.
e. IRB Chair may deem a protocol exempt after obtaining enough information from the investigator to determine whether the claimed exemption applies;
f. IRB members are given a list of all recently verified exempt protocols before the next scheduled meeting. No action is required on their part, though they can read exempt proposals and raise concerns. (No continuing reviews or renewals are required for exempt or non-research protocols).

B. Expedited Review Procedure
1. Eligible studies determined for expedited review will be reviewed by the Chair or the Chair's designee from the IRB membership
    a. Will determine the criteria for expedited review as described in the federal regulations ([56 FR 28012, 28022 June 18, 1991, as amended at 70 FR36328, June 23, 2005] and included in Appendix D) have been met;
    b. Administrative Liaison will ensure that the Principal Investigator has submitted all the required materials.
2. Chair will review proposed research and assess whether the study should be approved by expedited review according to the criteria for IRB approval of research (section V-C).
3. Decision is communicated to the PI and IRB committee members
    a. IRB members review protocol and approval decision
    b. Alert Chair if there is a question or potential issue of concern before or at the next scheduled meeting
4. Approved protocols are approved for a period of up to one year as determined by the IRB at the time of approval
5. Consent Form(s) are approved for a period of up to one ear as determined by the IRB at the time of approval
6. Approved protocols require submission of a continuing review report at the completion of the study or within one year of approval date, whichever comes first (described in Appendix B, and reviewed in section V-B4)
7. Forms of advertisement for recruitment must be submitted to and approved by the

IRB prior to distribution or publication of the material if they contain more than the:
a. Title
b. Purpose of the study
c. Protocol summary
d. Basic eligibility criteria
e. Study site location(s) and
f. How to contact the study site for further information

C. Full Review Procedure
1. Non-exempt studies not meeting the criteria for Expedited Review must have full board review
2. Administrative Liaison ensures that the PI has submitted all the required materials and will add this protocol to the agenda of the next meeting
3. IRB committee members will review proposed research in preparation for next meeting
4. Proposal discussed at the meeting; majority vote from all present members is required for approval
5. PI is notified by Chair of
   a. Approval
   b. Conditional approval pending minor changes
   c. Need for major changes before review
   d. Tabling
   e. Disapproval (with explanation)
6. Approved protocols are approved for a period of up to one year as determined by the IRB
7. Consent Form(s) are approved for a period of up to one ear as determined by the IRB at the time of approval
8. Approved protocols will also require submission of continuing review at the completion of the study or within one year of approval date, whichever comes first (described in Appendix B, and reviewed in section V-B4*)*
9. Forms of advertisement for recruitment must be submitted to and approved by the IRB prior to distribution or publication of the material if they contain more than the:
   a. Title
   b. Purpose of the study
   c. Protocol summary
   d. Basic eligibility criteria
   e. Study site location(s) and
   f. How study site can be contacted for further information

D. Continuing Review
1. The IRB is required to conduct substantive and meaningful continuing review of research
2. Reviews shall be conducted at intervals appropriate to the degree of risk of the

project, but not less than once per year. (See Appendix B.)

3. PI must submit a continuing review report within the time period approved
   a. Indication on the continuing review report if proposal is to be continued for up to one more year or
   b. Proposal is to be terminated before approval has expired
4. IRB Chair shall review the protocol file in the time of the continuing review
5. The Chair can approve continuation of research originally approved by expedited review
6. Approval is discussed at the next meeting and can be affirmed or rescinded.
7. All other continuing reviews must be reviewed by the full board.

VII. Criteria for IRB Approval of Research

A. Initial Review and Categorization of Study
   1. Any proposed research to be conducted at Neumann University must be approved by the IRB determining that all of the following requirements (46.111(a)(1-7)) are satisfied:
      a. Using procedures which are consistent with sound research design and
      b. Using procedures which do not unnecessarily expose subjects to risk, and
      c. Whenever appropriate, using procedures already performed on the subjects for diagnostic or treatment purposes.
   2. Risks to subjects are reasonable in relation to anticipated benefits, if any,
      a. To the subjects
      b. To the importance of the knowledge that may reasonably be expect to result;
      c. IRB, in evaluating risks and benefits, shall consider only those risks and benefits that may result from the research that
         1. Does not distinguish from the risks and benefits of therapies subjects would receive even if not participating in research,
         2. Should not consider possible long-range effects of applying knowledge gained in the research (e.g., the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.
   3. Selection of subjects is equitable; the IRB should take into account
      a. The purposes of the research,
      b. The setting in which the research will be conducted.
      c. IRB should be particularly cognizant of the special problems of research involving vulnerable populations such as
         1. Children,
         2. Prisoners,
         3. Pregnant women,
         4. Mentally disabled persons,
         5. Economically disadvantaged persons,
         6. Educationally disadvantaged persons,

7. Other protected or vulnerable populations.

4. Informed consent shall be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by 45 CFR 46.116. The following information will be provided to each subject:
   a. A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental;
   b. A description of any reasonably foreseeable risks or discomforts to the subject;
   c. A description of any benefits to the subject or to others which may reasonably be expected from the research;
   d. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
   e. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
   f. For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
   g. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights and whom to contact in the event of a research-related injury to the subject; and
   h. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled.
5. When appropriate, one or more of the following elements of information shall also be provided to each subject:
   a. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
   b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
   c. Any additional costs to the subject that may result from participation in the research;
   d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
   e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
   f. The approximate number of subjects involved in the study.
6. The IRB may approve a consent procedure that does not include or alters some or all of the elements of informed consent set forth in this section. The IRB may waive the requirements to obtain informed consent, provided the IRB finds and documents that:
   a. The research involves no more than minimal risk to the subjects;

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
c. The research could not practicably be carried out with the waiver or alteration; and
d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

7. Informed consent (electronic or hard copy) will be appropriately documented in accordance with and to the extent required by 45 CFR 46.117. The consent form may be either of the following:
   a. A written consent document that embodies the elements of informed consent stated above
      1. This consent form may be read to the subject or the subject's legally authorized representative,
      2. The investigator should give either the subject or the representative adequate opportunity to read the document before it is signed.
   b. A short form written consent document stating that the elements of informed consent as noted above have been presented orally to the subject or the subject's legally authorized representative.
   c. When above method is used,
      1. There shall be a witness to the oral presentation.
      2. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative.
      3. Only the short form itself is to be signed by the subject or the representative.
      4. However, the witness shall sign both the short form and a copy of the summary, and
      5. The person actually obtaining consent shall sign a copy of the summary.
      6. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.
8. An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

   a. That the only record linking the subject and the research would be the consent document, and
      1. The principal risk would be potential harm resulting from a breach of confidentiality.
      2. Each subject will be asked whether the subject wants documentation linking the subject with the research, and
      3. The subject's wishes will govern; or
   b. 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.
   c. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

9. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
   a. A general description of the data and safety-monitoring plan shall be submitted to the IRB as part of the research proposal.
   b. The plan must include procedures for reporting adverse events.
   c. When appropriate, the research study provides adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.
   d. If, when some or all of the subjects are likely to be vulnerable to
      1. Coercion or Undue influence, for example
         a. Children,
         b. Prisoners,
         c. Pregnant women,
         d. Mentally disabled persons,
         e. Economically or educationally disadvantaged persons,
         f. Educationally disadvantaged persons, or
         g. Other protected or vulnerable populations; additional safeguards should be included in the study to protect the rights and welfare of these subjects.
   e. Following conclusion of Review Process. IRB actions for initial or continuing review of research will include one of the following:
      1. *Approved* with no changes or no additional changes. The research may proceed.
      2. *Approved with minor changes* that are clearly delineated by the IRB so the investigator may simply concur with the IRB's revisions. The research may proceed **after** the required changes are made and verified by the IRB Chair.
      3. *Tabled.* Tabled research applications are approvable but require substantive changes or additional substantive information that must be reviewed at a subsequent convened subsequent meeting of the IRB. The research may proceed only **after** the convened IRB meeting has reviewed and approved the required changes to the research or the information provided.
      4. *Disapproved.* The IRB has determined that the research, as submitted, may not be conducted by the investigator(s). If the IRB disapproves a research protocol, it shall include in its written notification a statement of the reasons for its decision and afford the investigator an opportunity to respond in person or in writing.

VIII. IRB Record Keeping and Required Documentation

A. IRB Records. Federal regulations require:
   1. IRB retains records for at least three years after the termination of the research protocol.
      a. All IRB records shall be kept in a secure place.
      b. Access to IRB records shall be limited to the President and Chairperson of the IRB, the administrative staff of the IRB, the IRB members, and officials of federal and state agencies.

c. All records shall be accessible for inspection and by authorized representatives of applicable Federal agencies at reasonable times and in a reasonable manner.*

2. IRB records will include the following:
   a. IRB Policy Statements,
   b. IRB Standard Operating Procedures (SOP),
   c. IRB membership roster,
   d. Curriculum Vitae for IRB members.
3. In addition to above:
   a. Record of certification of *human subjects training* for IRB members, Principal Investigators and co-investigators every three years.
   b. IRB research application files for all submitted protocols, including:
      1. All required documentation,
      2. Continuing review reports, and
      3. Correspondence.
   c. Minutes of the convened IRB meetings
   d. A current IRB membership roster record by the Administrative Liaison is to be maintained pursuant to 45 CFR 46.103(b)(3).

B. Contents of Minutes. The minutes of IRB meetings shall be compiled by the Administrative Liaison and approved by the IRB. The following specific information shall be included in the minutes:
   1. Attendees by name, absent members, in addition:
      a. Consultants,
      b. Invited investigators and
      c. Guests, and
      d. Members present via teleconference shall be noted as such in the meeting minutes.
      e. Whether quorum requirements have been met.

2. Actions taken by the IRB on
    1. New and continuation applications;
    2. Review of protocol and informed consent modifications or amendments;
    3. Protocol deviations;
    4. Adverse event reports;
    5. Reports from sponsors;
    6. Waiver or alteration of elements of informed consent;
    7. Suspensions or terminations of research; and,
    8. Other actions.
3. Votes on these actions categorized as "for, against and abstain."
4. Basis for requiring changes in or disapproving research.
5. A list of research approved since the last meeting utilizing
    a. Expedited review procedures and specific citation for the category of expedited review of the individual protocol,
    b. Exempt review and non-research protocols.
6. Report of other business.
7. Members who recuse themselves by name, name of protocol and reason for the recusal or conflict.

IX. Additional Considerations

A. Certificates of Confidentiality. The IRB may determine that special protections are needed to protect subjects from the risks of investigative or judicial processes in research projects that include the collection of highly sensitive information about individually identifiable subjects necessary to achieve the research objectives. Research will be considered sensitive if it involves the collection of information in any of the following categories:
    1. Information relating to sexual attitudes, preferences or practices;
    2. Information relating to the use of alcohol, drugs or other addictive products/practices;
    3. Information relating to illegal conduct;
    4. Information that if released could reasonably be damaging to an individual's financial standing, employability or reputation within the community;
    5. Information that would normally be recorded in a patient's medical record and the disclosure of which could reasonably lead to social stigmatization or discrimination;
    6. Information pertaining to an individual's psychological well-being or mental health.
    7. The IRB may require that the investigator obtain a Certificate of Confidentiality from the Department of Health and Human Services.
        a. Federal funding is not a prerequisite to such a determination that a Certificate of Confidentiality is necessary.
        b. The purpose of the Certificate of Confidentiality is to protect against any

involuntary release of sensitive information about individual subjects for use in federal, state or local civil, criminal, administrative or other legal proceedings.

c. The Certificate does not prohibit the disclosure of information that is imminently harmful to others and/or the public by an investigator including, but not limited to, child abuse or a communicable disease.

d. The investigator must detail in the informed consent document what information will and will not be protected by the Certificate of Confidentiality.

B. Reporting Unanticipated Problems and Adverse Events.

1. Any adverse events or unanticipated problems involving subjects of any IRB-approved study must be:
   a. Reported to the IRB as soon as possible, but no later than five days from the event's occurrence.
   b. Deaths or other serious adverse events should be reported to the IRB as soon as possible, but no later than five days after the event's occurrence.
   c. If an adverse event occurs at a study site other than the University, the Principal Investigator must promptly notify all IRBs governing the protocol.
2. Protocol Amendments: If a Principal Investigator would like to make a change to an already approved protocol or exempt protocol, he or she can submit an amendment to the protocol. Minor changes can be reviewed and approved by the Chair, and discussed at the next meeting. Major changes are typically referred to the full IRB committee for discussion and action at the next meeting.

Review of Standard Operating Procedures (SOP).

The IRB shall review the IRB SOP at a minimum of every five years.

Recommended revisions to the SOP will be discussed and decided on by the full IRB.

X. Acknowledgements

A. University of Florida IRB. (June 2007). *IRB Policies and Procedures Manual.* Retrieved from http://irb.ufl.edu/irb02/

B. Research with Children FAQ's: http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf

C. Code of Federal Regulations: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101

APPENDIX A – Protocol Submission Requirements

The IRB will provide forms for submission of new protocols: Requested information includes the following:

1. Certificate of Completing Training for all investigators
2. Name of P.I. and co-P.I.s
3. Project title
4. Purpose of study
5. Background
6. Location of study
7. Duration of project
8. Research plan
9. Statistical considerations
10. Incentives for subjects
11. Subject population
12. Potential risks & benefits to subjects
13. Description of informed consent
14. Funding source
15. Requested review type
16. Copies of all data collection tools, questionnaires, interview/survey forms, assessment materials, and descriptions of materials that subjects will encounter.
17. Advertisement(s) for subject recruitment.
18. Curriculum vitae for the PI listed on the application.
19. If applicable, a Conflict of Interest form for each investigator listed on the application.
20. If applicable, a Request for Access to Protected Health Information for a Research Purpose and/or Research Authorization Form.
21. If applicable, IRB approval form from additional sites; at discretion of IRB Committee.

APPENDIX B – Continuing Review Submission Requirements

(Request for Termination or Continuation)

All protocols approved by Expedited or Full IRB review are required to have a continuing review submitted by the PI four weeks prior to the end of the one-year approval period. Requested information includes:

1. Request for permission and reason to continue, or termination

APPENDIX C– Criteria for Exemption Status

Exemption Criteria: All research that is potentially exempt from IRB review shall be submitted to the IRB Chairperson with a request for exemption status. Research activities in which the only involvement of human subjects will be in one or more of the categories listed below are exempt from IRB review pursuant as quoted from 45 CFR 46.101:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) 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 use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources 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. Research and demonstration projects conducted by or subject to the approval of department or agency heads designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed, or (ii) if a food is consumed that contains a food ingredient at or below the level found to be safe, or an 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.

APPENDIX D –Criteria for Expedited Review

Expedited Approval: Federal regulations permit the IRB Chairperson to review and approve proposed research through an expedited procedure if the proposed research activities (a) present no more than minimal risk to human subjects, and (b) involve only procedures listed in one or more of the categories in 45 CFR 46.110 and 21 CFR 56.110 (as quoted below).

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/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. from healthy, nonpregnant 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[2], considering the age, weight, and health of the subjects, the collection procedure, the amount of 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 noninvasive means. Examples: (a) hair and nail clippings in a nondisfiguring 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 secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase 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 noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where 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 occurring radioactivity, electroretinography, ultrasound, diagnostic 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 nonresearch 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. 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 the HHS regulations for the protection of human subjects. 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 the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (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.