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SAINT ANSELM COLLEGE
Assurance of Compliance with HHS regulations
For Protection of Human Research Subjects

Part I

Saint Anselm College (hereafter noted as the “College”) hereby gives assurance that it will comply with the Department of Health and Human Services (“HHS”) regulations for the protection of Human Research Subjects (45 C.F.R. Part 46, as amended) as specified below.

I. Statement of Applicability and Principles

A. Ethical Principles

Research personnel at the College are guided by and reaffirm their commitment to the ethical principles regarding all research involving human subjects as set forth in the report of 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”).

B. The College’s Policy

1. The College acknowledges and accepts responsibility for protecting the rights and welfare of human subjects of research covered by this Assurance.
2. The College bears full responsibility for complying with federal, state, and local laws as they relate to research covered by this Assurance.
3. All research covered by this Assurance will be reviewed by an Institutional Review Board (“IRB”) established pursuant to HHS regulations found at 45 C.F.R. Part 46.
4. No research covered by this assurance will be permitted until the IRB has approved or exempted the research protocol pursuant to HHS

regulations found at 45 C.F.R. Part 46, and informed consent has been obtained in accord with 46 C.F.R. §46.116.

5. The College will comply with the policies and additional projections set forth in 45 C.F.R. Subparts B (Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research) C (Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) and D (Additional Protections for Children Involved as Subjects in Research)
6. The Chair of the IRB shall make available to each individual conducting or reviewing human subject research a copy of this “Assurance of Compliance” and a copy of any future modification, with the exception of changes in IRB membership, which may be made to this Assurance.
7. The President of the College encourages and promotes constructive communication among the faculty, research administrators, department chairs, research investigators, clinical care staff, IRB members, other College officials and human subjects as a means of maintaining high levels of awareness regarding the rights and welfare of human subjects.

C. Applicability

This Assurance is applicable to all activities related to research with human subjects and subject to the HHS under its regulations found at 45 C.F.R. Part 46. This includes,

- a. research sponsored by the College;
- b. Research conducted by or under the direction of any employee or agent of the College in connection with his or her College responsibilities;
- c. Research conducted by or under the direction of any employee or agent of the College using any property or facility of the College;
- d. Use of the College’s nonpublic information to identify or contact human research subjects or prospective subjects; and
- e. Any other research involving the College in any capacity, (e.g., use of data, facilities, or equipment).
- f. Please see Attachment D which includes the federal definition of research and the permitted exceptions, as designated in Code of Federal Regulations, TITLE 45, PUBLIC WELFARE,

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
PART 46, PROTECTION OF HUMAN SUBJECTS, Revised
June 23, 2005.

II. Designation of the IRB

1. The President of the College has established and will maintain one IRB in accordance with 45 C.F.R. Part 46.
2. The IRB has the responsibility to review and the authority, in accordance with the policies contained in this Assurance, to approve, disapprove, require modification of, or to find exempt research activities involving human subjects. It functions under the general oversight of the President of Saint Anselm College.
3. IRB membership possesses the professional competence and cultural diversity necessary to appropriately review the specific research activities that will be assigned for review to the IRB.
4. Research investigators will be responsible for complying with all IRB decisions, conditions, and requirements.
5. Research investigators covered by this Assurance are responsible for having a working knowledge of the HHS regulations found at 45 C.F.R. Part 46.
6. The President of the College will provide for meeting space and sufficient staff to support all IRB activities, including review and record keeping duties.

III. IRB Membership and Structure

A. IRB Members

A list of IRB members is attached to this Assurance as Attachment C. It includes each members' name; earned degrees; representative capacity; indications of experience such as board certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to IRB deliberations; and any employment or other relationship between each member and the institution; for example: full-time employee, part-time employee, member of governing panel or board, stockholder, paid or unpaid consultant.

B. IRB Structure

1. Membership composition.

- a. The IRB will be composed of members from diverse disciplines.
- b. The IRB will be racially and culturally diverse so as to promote sensitivity to community attitudes and respect within the community for its advice and decisions.
- c. The IRB will include both male and female members.
- d. The IRB will include at least one member whose primary expertise is in a non-scientific area and at least one member whose primary expertise is in a scientific area.
- e. The IRB will include at least one member who is not otherwise affiliated with the College and who is not a part of the immediate family of a person affiliated with the College.
- f. “No IRB...member [may] participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.”
- g. “[The Chair] of the IRB may, at [his or her] discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.”
- h. Students may be appointed to the IRB at the discretion of the President of the College. Neither students nor consultants may vote with the IRB.

2. Appointments to membership.

- a. The College President will appoint the members of the IRB.
- b. Each member shall serve for a term of three years, or until such member resigns or is removed.
- c. The term of membership shall begin on August 15th of each year.
- d. Members may be reappointed without limit to the number of terms and without interruption of continuity of service.

- e. A chair shall be appointed by the College President in the same manner as members are appointed. The Chair shall preside at all meetings of the members. The Chair may appoint a member of the IRB to serve as Chair in his or her absence.
3. Vacancies in membership.
- a. Vacancies that occur among the membership of the IRB, such as those caused by the death, resignation, or removal of a member, shall be filled by the President in accordance with the provision for appointment of members to full terms.
 - b. Persons appointed to fill vacancies shall serve only until August 14th.
4. Resignations and removals.
- a. An IRB member may resign by delivering a letter of resignation to the Chair of the IRB. Such resignation shall be effective upon receipt, unless specified to take effect at some other designated time. An acceptance of the resignation shall not be necessary to make it effective unless it so states.
 - b. An individual serving as the Chair of the IRB may resign from IRB membership and/or the role of Chair by delivering a letter of resignation to the College President. Such resignation shall be effective upon receipt, unless specified to take effect at some other designated time. An acceptance of the resignation shall not be necessary to make it effective unless it so states.
 - c. The College President may remove members from the IRB following consultation with the Chair of the IRB. Causes for removal will include, but need not be limited to: nonfeasance; knowing participation in an IRB decision involving a conflict of interest; and a violation of the confidentiality of IRB activities.
 - d. The College President may remove the Chair of the IRB for the same causes as the removal of members.
 - e. Members shall not be compensated but may be reimbursed for reasonable expenses for travel, meals, or other expenses incurred as a result of carrying out their designated duties.
5. Frequency of meetings.

Convened meetings of the College's IRB will occur,

- a. as scheduled by the IRB, during at least ten (10) months of the year;
 - b. at the call of the Chair when he/she judges the meeting to be necessary or advantageous;
 - c. at the call of the Chair upon receipt of a joint written request of three or more members;
 - d. at the call of the Chair upon request of the College President.
 - e. Meetings may be cancelled if no new business or research comes before the committee in a given month.
6. Internal policies of the IRB.

The IRB may establish such internal operating policies as seem appropriate and necessary, and which do not otherwise conflict with this Assurance or 45 C.F.R. Part 46. Lacking such policies, IRB procedures (unless decided otherwise by a majority vote of the IRB) will be in accordance with procedures for boards as described in the most recent edition of Robert's Rules of Order.

IV. Initial Review

A. Preparations by the Research Investigators

1. Determination of human subject involvement.
 - a. Research investigators are responsible for making an initial determination whether research will involve human subjects as defined in the HHS regulation.
 - b. When it is unclear whether research involves human subjects, the investigator will seek assistance from the College's IRB in making this determination.
2. Submission of application and protocol.
 - a. Researchers are responsible for submitting to the IRB an application and protocol, providing a comprehensive description of the proposed research.

- b. In the application and protocol, research investigators will describe provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.
- c. Applications for human subjects research can be obtained from the Saint Anselm College IRB website (see section IX) or by contacting the current chair of the IRB.
- d. College policy requires that all investigators listed on the application undergo research ethics training for human subjects research.
- e. Research investigators seeking exemptions should use the appropriate application. In such cases the researcher will document the request with appropriate information and references to 45 C.F.R. §46.101.
- f. Research investigators should include samples of their proposed informed consent form (and appropriate assent forms for studies involving children) as part of the application materials submitted for IRB review.

B. Informed Consent

1. Obtaining informed consent.

- a. Research investigators are responsible for obtaining informed consent in accordance with the HHS regulations. No human subject will be involved in the research prior to the investigators having obtained informed consent. (cf. 45 C.F.R. 46 § 46.116 “General Requirements for Informed Consent”.)
- b. Unless otherwise authorized by the IRB, research investigators are responsible for ensuring that informed consent,
 - 1. is obtained from the subject or the subject’s legally authorized representative;
 - 2. is stated in language understandable to the subject or representative;
 - 3. is obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate;

4. does not include 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 research investigator, the sponsor, the College or its agents from liability for negligence; and
5. is documented by use of a written consent form that has been approved by the IRB and signed by the subject or the subject's representative.

2. The basic elements of informed consent.

Unless otherwise authorized by the IRB, research investigators, at a minimum, shall provide the information listed in the "Basic Elements for Informed Consent" policy, attached at the back of this Assurance (cf. Attachment A). This list is consistent with the HHS basic elements of informed consent found at 45 C.F.R. §46.116 (a. 1-8).

3. Additional elements of informed consent.

When appropriate, the research investigator will provide appropriate additional elements of information to each subject, including but not limited to the times enumerated in the "Additional [b2] [b3] Informed Consent" policy, attached at the back of this Assurance. This list is consistent with the HHS additional elements of informed consent found at 45 C.F.R. §46.116 (b. 1-6).

4. Waiving informed consent.

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB find and documents that:

1. The research or demonstration project is to be conducted by or subject to the approval of the state or local government officials and is 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; (iv) possible changes in methods or levels of payment for benefits or services under those programs; and
2. The research could not practicably be carried out without the waiver or alteration.

5. Approval of the waiver of informed consent.

An IRB may approve or consent to a procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver of alteration will not adversely affect the rights and welfare of the subject;
3. The research could not practicably be carried out without the waiver or alternation; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

C. IRB Procedures

1. Receipt of application and protocol.

The IRB Chair or designee will receive all applications and protocols from the principal investigators. Applications must be received at least 14 days prior to the next scheduled committee meeting in order to be eligible for a convened committee review. Applications eligible for expedited review may be received anytime during the month.

2. Expedited review.

- a. The IRB Chair (or his/her designee) will determine whether the application and protocol qualify for expedited review under 45 C.F.R. §46.110.
- b. Expedited review does not negate or modify the policies of the College or the HHS regulations. It allows a review to be carried out by the Chair or by one or more experienced members of the IRB.
- c. The IRB member(s) conducting the expedited review may exercise all of the authority of the IRB, except that the reviewer(s) may not disapprove the research.
- d. The reviewer(s) shall refer to the full IRB any research protocol that the reviewer(s) would have disapproved. The

reviewer(s) may refer to the full IRB any research protocol the reviewer(s) believes should be reviewed by the full board.

- e. The reviewer(s) will inform IRB members of their action.

3. Full committee review.

- a. Applications, including protocol descriptions and copies of informed consent forms, will be distributed to all members of the IRB prior to meeting. The complete protocol will be distributed to the designated reviewer prior to meeting and to any other member upon request.
- b. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the application and protocol will also be distributed to the appropriate consultants or experts prior to meeting.
- c. All IRB initial reviews and continuing reviews of research will be conducted at convened meetings and at timely intervals.
- d. A majority of voting membership of the IRB constitutes a quorum, and a quorum is required in order to convene a meeting for the review of research applications.
- e. An IRB member whose concerns are primarily in nonscientific areas must be present at a convened meeting before the IRB can conduct its review of research.
- f. Official IRB approval of a research protocol requires the approval of a majority of those voting members present at a convened meeting.
- g. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a perceived conflicting interest, except to provide information requested by the IRB.
- h. To facilitate the review of research, investigators responsible for submitting the application may be invited to attend IRB meetings.

4. Exempt research.

If the IRB determines that such research falls within one or more of the categories exempted or waived under 45 C.F.R. §46.101, then it may exempt such research from further review.

D. IRB Review

1. Criteria.

The IRB's approval of the use of human subjects in proposed research shall be based on a determination that the criteria listed in the HHS regulations at 45 C.F.R. §46.111 have been satisfied. These criteria are summarized as follows:

- a. Risks to subjects are minimized.
- b. Risks to subjects are reasonable in relation to anticipated benefit to subjects and the importance of the knowledge reasonably expected to result.
- c. Selection of subjects is equitable, with consideration given to the purposes and context of the research.
- d. Informed consent will be sought from each prospective subject or subject's representative, and such consent will be properly documented.
- e. When appropriate, research data will be monitored so as to ensure the safety of subjects.
- f. When appropriate, the subject's privacy and confidential data will be properly protected.
- g. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards will be included in the study.

2. Failure to meet criteria.

When the IRB reviews an activity that fails to meet the criteria listed above, it will disapprove the activity or will require modification as a condition of approval.

3. Assessment of risk.

- a. The IRB will, upon initial review of an application or activity that passes the above described criteria, assess the relative risk of the activity for purposes of determining which projects require review more often than annually.
- b. The IRB will assess risk systematically, assigning activities with similar levels of risks similar frequencies of review.
- c. Reviews of activities shall be performed annually, semi-annually, quarterly, or monthly, depending upon whether the activity is determined to pose no risk, a very low risk, a low risk, or moderate risk, respectively.

E. Institutional Review

Research covered by this Assurance that has been approved or exempted by the IRB may be subject to further appropriate review by College officials. The officials may approve or disapprove such research, but may not approve research not approved by the IRB.

V. Continuing Review

A. Submission of Progress Reports on the Research

Research investigators are responsible for providing a summary report on the progress of their research upon completion of the project or no later than one year after their approval. Continuation of a research study beyond the approval period (1 year maximum) requires submission of a request for continuance to the IRB. A request for continuance form can be obtained from the Saint Anselm College IRB website (see section IX) or by contacting the current chair of the IRB.

B. Suspension or Termination of Approval

The IRB may suspend or terminate its approval of research in the event that it determines that research is not being conducted in accordance with requirements of the IRB, or has been associated with unexpected serious harm to human subjects.

C. Third Parties

1. The IRB may directly observe, or request a third party to observe, the process of obtaining informed consent.
2. The IRB will determine which projects will require verification from sources other than the involved research investigators that no significant

changes relevant to IRB issues have occurred since previous IRB review of research activities.

D. Changes and Problems in Research Activity

1. Reporting changes in research.

- a. Research investigators are responsible for reporting promptly to the IRB proposed changes in a research activity.
- b. No research investigator will initiate a change in research during a period for which IRB approval has been given without submission of a supplemental application. Such submission is unnecessary when the change seeks to eliminate apparent immediate hazards to the subject.

2. Submission to the IRB of a supplement to an original application or protocol.

Research investigators will be responsible for submitting to the IRB a supplement to their original application or protocol when,

- a. involvement of human subjects is expected, and prior proposals or activities had no plans, or indefinite plans, for the involvement of human subjects; or
- b. a change in the nature of the involvement of human subjects is expected, and such involvement is significantly different from that which was initially described in a previous application (proposal) approved by the IRB.

3. Reporting injury and unanticipated problems involving risks.

Research investigators are responsible for reporting promptly to the department chairs and the IRB any,

- a. injuries to human subjects;
- b. unanticipated problems in the application or protocol that involve increased risks to the human research subjects or others.

Injuries and risks include, without limitation, physical, psychological, social or economic harm.

4. Reporting noncompliance.

Both research investigators and department chairs are responsible for reporting promptly to the IRB any serious or continuing noncompliance with the requirements of this Assurance or the determinations of the IRB.

VI. Reporting and Documentation

A. IRB Notification to Research Investigators

1. The IRB will notify the research investigator(s) in writing of its decisions, conditions and requirements.
2. The IRB will also provide to the research investigator(s) reasons substantiating its decisions to disapprove research protocols and opportunities for the research investigator(s) to respond.

B. Documentation of Informed Consent

In accord with 45 C.F.R. §46.117, informed consent will be documented by use of a written consent form.

1. Documenting the consent.
 - a. Research investigators will ensure that each subject, or the subject's representative, signs the consent form and that each person so signing a form is given a copy of the form.
 - b. The research investigators is responsible for ensuring that all other documentation required by the IRB, such as assent of a child, is properly obtained.
 - c. The research investigator may use one of two forms for documenting consent:
 1. An IRB approved, written consent document embodying the basic elements of informed consent, as well as any additional elements required by the IRB. This form may be read to the subject or the subject's representative, but in any event, the research investigator must provide adequate opportunity for the party to read the form before the party signs it.
 2. A "short-form" written consent document stating that basic and applicable additional elements of consent have been

presented orally to the subject or the subject's legally authorized representative.

When the "short form is used, research investigators shall ensure that,

- a. a witness is present at the oral presentation,
- b. the short form is signed by the subject or the representatives,
- c. the witness signs both the short form and a copy of the written summary of the oral presentation,
- d. the person obtaining consent signs a copy of the summary,
- e. a copy of both the short form and summary is given to the subject or the representative, and
- f. the IRB gives prior approval to the written summary of the oral presentation.

2. Waiver of alteration.

- a. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent, only if the IRB acts in accordance with 45 C.F.R. §45.116 (c) and (d).
- b. The IRB may waive the requirement for the research investigator to obtain a signed consent form from some or all subjects only if the IRB acts in accordance with 45 C.F.R. §46.117 (c).
- c. In cases where elements of consent documentation requirements have been waived or altered, the IRB may still require the research investigator to provide subjects with written statements regarding the research.

3. Consent record retention.

Research investigators are responsible for retaining copies of the consent documents. Documents will be maintained in an IRB approved manner for at least six (6) years after

completion of the research project. Such documents are deemed to be the property of the College.

C. IRB Records

1. The IRB will prepare and maintain adequate documentation of IRB activities, including those listed in 45 C.F.R. §46.115, which are summarized as follows:
 - a. Copies of all applications, proposals, and supporting information.
 - b. Minutes of IRB meetings.
 - c. Records of continuing activities.
 - d. Copies of all correspondence between the IRB and research investigators, the College President, and grant-funding agencies.
 - e. A list of IRB members.
 - f. Written IRB procedures.
 - g. Statements of significant new findings provided to subjects.
 - h. Any other relevant correspondence.
2. The IRB will provide for the maintenance of records relating to a specific research activity for at least 3 years after termination of the last IRB approval period for the activity

VII. Special Situations

The College will comply with the requirements set forth in 45 C.F.R. §46.114, regarding cooperative research projects. When research covered by this Assurance is conducted at a location other than the Saint Anselm campus or in cooperation with another entity, all provisions of this Assurance remain in effect for that research.

VIII. Confidentiality

Deliberations and decisions of the IRB and substantive information associated with specific projects or research activities acquired by IRB members in the course of IRB business shall be considered confidential, except insofar as where the dissemination of information regarding research projects or activities and IRB deliberations,

decision, and recommendations to appropriate College officials is required to effectuate or support the policies or interests of the College.

- IX. Stable URL for Saint Anselm College IRB website: www.anselm.edu/x4285.xml

Attachment A

Basic Elements for Informed Consent

The following information shall be provided to each subject in seeking informed consent. Information should be presented in a language understandable to the subject. The form must be printed on Saint Anselm College letterhead, paginated, and contain the title of the study, the P.I.'s name, telephone number, and date at the top of each page. A statement should be included indicating the subject will receive a copy of the form. Please note that this process represents the minimum information to be given a potential subject; the IRB may request that additional information be provided. The IRB may waive the requirements to obtain informed consent in some circumstances. If a waiver of any requirement for informed consent is requested, please consult with the Chair of the College's Institutional Review Board. This information includes:

1. A statement that the study involves research, an explanation of the purpose of the research, the expected duration of the subjects' participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject;
8. 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.

Attachment B

Additional Elements of Informed Consent

Additional elements of informed consent are best included with the basic elements. If inappropriate, then the form must be on Saint Anselm letterhead, numbered, with the title of the study, the P.I.'s name telephone number, and date at the top of each page. A statement should be included that the subject will receive a copy of the form.

The list is not exhaustive. The IRB may request that additional information be provided. The IRB may waive the requirements to obtain informed consent in some circumstances. If a waiver of any requirement for informed consent is requested, please consult with the IRB Chair.

When appropriate, the research investigator will provide one or more of the following types of information to each subject in seeking informed consent. Information should be presented in a language understandable to the subject.

1. 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) that are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;
3. Any additional cost to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that any significant new finding 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
6. The approximate number of subjects involved in the study.

Attachment C
Institutional Review Board (IRB) Membership

IRB Name: Saint Anselm College

Member Name	Highest Degree Earned	Professional Affiliation	Address and Phone Number of Chairperson Only
*R. Janet Romaine	Ph.D.	Associate Professor / Chair of Economics & Business	Saint Anselm College 100 Saint Anselm Drive #1710 Manchester, NH 03102 603-641-7125
Hui-Ling Chen	Ph.D.	Director Institutional Research	
Rev. Benedict M. Guevin, O.S.B.	Ph.D.	Professor of Theology / Ethicist	
^{a,b} Kathleen Thies	Ph.D.	Senior Nurse Researcher Elliot Health System	
Matthew Gonzales	Ph.D.	Associate Professor of Classics	
Jennifer Thorn	Ph.D.	Assistant Professor of English	
Michael W. Smith	Ph.D.	Director NHIOP, Professor / Professor of Sociology	
Bill Ploog	Ph.D.	Director of Sponsored Programs and Research	
*R. Janet Romaine	Ph.D.	Associate Professor / Chair of Economics & Business	
^a Antonia M. Nelson	Ph.D.	Associate Professor of Nursing	

^{*}Denotes Chairperson

^aDenotes Scientist. A scientist is defined as someone whose occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline.

^bDenotes Outside Member. Each 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.

Attachment D: Federal Guidelines for when IRB policies apply and acceptable exceptions

“§46.101 To what does this policy apply?”

Research on human subjects that might incur more than minimal risk. Note definitions and exceptions below.

§46.102 Definitions.

(d) Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

(f) Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

(i) 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.

46.101

Exceptions (b) Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(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 which are conducted by or subject to the approval of department or agency heads, and which are 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 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.”