Original 2002
Amended 2014
Amended 2016 v.5
Amended and Revised May 2017 v.6

LINCOLN COLLEGE

INSTITUTIONAL REVIEW BOARD GUIDEBOOK

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I. Introduction

Lincoln College is committed to protecting the rights, welfare, and privacy of all human subjects involved in research studies conducted under the auspices of the college. It is the responsibility of the Institutional Review Board (IRB) to protect human subjects and to insure that academic research is conducted in an ethical manner. The IRB has the authority to review, approve, modify, or deny academic research proposals, as well as ongoing research, submitted by faculty, staff, and student researchers that involves human subjects. IRB approval will be determined by the level to which the proposal satisfies the following requirements:

A) Minimal potential risk to subjects,
B) Informed, voluntary consent of the subjects, and
C) Fair selection of subjects.

These safeguards derive from the following ethical principles, which were first articulated in the Belmont Report issued by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979.

Respect for persons: recognition of the personal dignity and autonomy of individuals and special protection of those persons with diminished autonomy or particular vulnerabilities, including prisoners, children, fetuses, those who are mentally or cognitively disabled, pregnant women, or economically or educationally disadvantaged persons. Human subjects should enter into research voluntarily and with adequate information.

Beneficence: the obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks. Possible risks to human subjects should be weighed against possible benefits of the research, as well as against the possible improvement of knowledge.

Justice: fairness in the distribution of research benefits and burdens. In selecting human subjects for research, investigators should ensure that no group of subjects is either consistently selected to participate in research, or consistently deprived of the opportunity to do so.

The Institutional Review Board (IRB) is the body charged with reviewing and approving all proposed research involving human subjects, whether funded or not, conducted under the auspices of Lincoln College by its faculty, students or staff, or by outside investigators using Lincoln College students, personnel, facilities, or data collected at the College. "Research" is defined as "systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge" (45 CFR 46.102d).

Research subject to review by the Institutional Review Board thus includes, but is not limited to:

- pilot studies;
- class projects aimed for publication or presentation; and
- independent research, whether such research takes place on or off the Lincoln College campus or sites.

The procedures for review described below adhere to the regulations of the Department of Health and Human Services (45CFR 46, as amended and published in the Federal Register on June 18, 1991 and any subsequent amendments).

II. Composition of the Institutional Review Board

The Federal guidelines (45CFR46.110) specify that each IRB shall have at least five 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.

(a) Per the federal regulations, every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender.
(b) No IRB may consist entirely of members of one profession.
(c) Each IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.
(d) 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.
(e) No IRB may have a member 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.
(f) An IRB may, in its 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

At Lincoln College, Appointed Members (through faculty vote) include:

- •One member of the community unaffiliated with the College
- •One social science faculty member;
- •One non-science faculty member from the Languages, Humanities or Fine Arts disciplines;
- •One science faculty member; and
- •One “at-large” faculty member

Ex Officio, Non-Voting Member

- •The Vice President for Academic Affairs

The Vice President for Academic Affairs will designate one of the members listed above as the chairperson of the IRB. The membership of the IRB will appoint a Secretary who will be responsible for the minutes of the IRB meetings.

IRB functions and operations

In order to fulfill the federal requirements, each IRB shall:

(a) Follow written procedures in the same detail as described in §46.103(b)(4) (Written procedures which the IRB will follow (i) for conducting its initial and continuing review of research and for reporting its findings and actions to the investigator and the institution; (ii) for determining which projects require review more often than annually and which projects need verification from sources other than the investigators that no material changes have occurred since previous IRB review; and (iii) for ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject) and, to the extent required by, §46.103(b)(5) (Written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval.).

(b) Except when an expedited or exempt review procedure is used (see §46.110), review proposed research at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. In order for the research to be approved, it shall receive the approval of a majority of those members present at the meeting.

Each IRB member will absent her/himself from deliberations on any protocol in which s/he has a conflicting interest (i.e., s/he is the Principal Investigator, Co - PI, has some financial interest, etc.); this action will be noted in the minutes. All Principal Investigators (PI), however, may meet with the IRB in advance of its review to provide information or answer questions about the project. Such an advance meeting may occur either at the request of the IRB or the PI.

The presence of a majority of the voting members (including the chair or acting chair and one member whose primary concerns are in non - scientific areas) will constitute a quorum for the conduct of business at regular meetings of the IRB. All decisions will be reached by a simple majority of the voting members present. The Secretary of the IRB will record in the minutes all votes pertaining to research protocols in the following format: “Total Votes”; number of votes “For;” number of votes “Opposed;” number of votes “Abstained.”

III. The Review Process

Principal Investigators who are planning research projects involving human subjects are responsible for initiating the review process by submitting their research proposals and all necessary forms (see Section X and Appendices) to the IRB chairperson. All forms and the proposal must be submitted as a packet. Please do NOT send multiple individual files.

The IRB does require faculty members to submit an application form to the IRB for class projects that require students to perform research using human participants, including research which is not used in any publication or presentation of generalizable results. Research conducted without any intention of using the results for something outside of class assignment purposes is considered research with human participants under the IRB rules and Exempt or Expedited application to the IRB is needed from the faculty member.

Training Requirements. Federal regulations also require that all faculty, students and staff who are engaged in human subjects research certify to the IRB that they have completed a program of training in the ethics and best practice of human subjects research before their research protocol can be approved. Students enrolled in and attending PSY 101 (Introduction to Psychology), CHS 210 (Techniques in Interviewing and Intervention), CRT 353 (Research Methods in the Social Sciences), CRT 401 (Qualitative Research Methods in the Social Sciences), EXS 353 (Research Methods in Exercise Science), SIT 402 (Senior Research Project), or CJS 490 (Research Project) receive their training in this class. Others can receive training through the online training available on Lincoln College's web site at https://lincolncollege.edu/irb/.

Directing Proposals for Initial Review. A directory of the Institutional Review Board membership is available online at https://lincolncollege.edu/irb/.

(A) Faculty member - Submit proposal to the IRB chairperson.
(B) Class Research assignments – Faculty member submit proposal to IRB Chairperson.
The IRB does require faculty members to submit an application form to the IRB for class projects that require students to perform research using human participants, including research which is not used in any publication or presentation of generalizable results. Research conducted without any intention of using the results for something outside of class assignment purposes is considered research with human participants under the IRB rules and Exempt or Expedited application to the IRB is needed from the faculty member.
(B) Staff member - Submit proposal to the IRB chairperson.
(C) Student - Submit proposal to the faculty advisor or sponsor, who will in turn submit it to the IRB chairperson.
(D) Non Lincoln College investigator – submit proposal to the Vice President for Academic Affairs who will in turn submit it to the IRB chairperson.

Risk: All research proposals are evaluated by the chair of the IRB, or the full IRB with regard to the degree of "risk," if any, to human subjects. Risk is conceived broadly to include the probability of harm or injury of any sort (physical, psychological, social or economic). The degree of risk can vary from "minimal" to "significant." The concept of "minimal risk" is very important in risk assessment and is the only category of risk defined in federal regulations (Code of Federal Regulations: 45CFR46): A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed 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. The forms, submitted with the research proposal, were designed to aid in the determination of risk (see Section XII and Appendices).

Once the IRB chairperson has completed a preliminary assessment of risk, s/he will assign the proposal to one of three categories of IRB review listed below. (As part of the required package of information, the PI must also include her/his own opinion as to the project's category of IRB review.) Categories of IRB Review:

(A) Exempt - no foreseeable risk to human subjects. Proposals involving no foreseeable risk will be considered exempt, and will require no further review beyond the review of the IRB chairperson before the research can be initiated.
(B) Expedited Review - no more than minimal risk to human subjects. If the proposal involves only minimal risk, an expedited review will be conducted by the IRB chairperson and at least one other member of the IRB designated by the chair.
(C) Full IRB Review - greater than minimal risk to human subjects. Proposals judged by the IRB chairperson and/or one other designated member of the IRB to involve greater than minimal risk will undergo a full IRB review at the next regularly scheduled meeting of the IRB.

There are four possible outcomes to an expedited or full review:

1. Approved -- no further action is required before the investigator may initiate the study. If the study should extend beyond 12 months, the PI should send a letter to the IRB chair, informing her/him of the current status of the project, any changes in the protocol, and whether any adverse events have occurred (see Section VIII).

2. Conditionally Approved – requires changes that generally involve only simple concurrence by the PI. Research may commence as soon as the conditions for approval have been satisfied. These conditions typically require only simple concurrence by the PI, who must submit appropriate documentation to the chair of the IRB before the project is initiated. No additional meeting of the full IRB is required unless the chairperson is not completely satisfied that the required conditions have been fully met by the investigator. In that event, the chairperson will refer the protocol to the full IRB for review.

3. Deferred – requires substantial clarification or modification, and must be resubmitted to the IRB. A revised application must be submitted to the IRB clarifying the issues involved or providing the requested documentation. The IRB will review the revised application at its next meeting.

4. Denied -- the proposed research, because of the level of risk involved, cannot be initiated. Projects may be denied approval only by action of the full IRB, which will provide in writing the reasons for denial. An investigator is prohibited from conducting any project that has been denied approval; however, s/he may request a reconsideration of the decision at the next regular meeting of the IRB Approved research that is continuing must be reviewed at least once a year by the IRB. Shorter periods of review may be required by the IRB for research that has a high degree of risk. An e-mail message describing the decision of the IRB will be sent to the PI. If the e-mail signifies approval, it will specify the one-year time period during which the approval remains valid. If the IRB requires revisions or denies approval of the proposed research, the PI may request that the IRB reconsider its decision at the next regularly schedule d meeting (see Section IV).

IV. Appeals

If the Principal Investigator disputes a decision of the IRB (e.g., a denial), s/he may request in writing that the IRB review its decision at its next regularly scheduled meeting. The PI may provide the IRB with written arguments and supporting materials in advance of the meeting, and/or may choose to appear before the IRB in person to discuss the issue. If the PI remains unsatisfied with the outcome of the IRB's reconsideration, s/he may consult with the Vice President for Academic Affairs, who may choose to mediate further discussion

between the PI and the IRB. Once any mediation has concluded, the decision of the IRB is final; there is no further appeal.

V. Records Retention

All records must be retained by the IRB chairperson for three (3) years after the completion of the research. Applicable records include, but are not limited to, research proposals, informed consent documents, progress reports, reports of any injuries to subjects, and all related correspondence concerning the use of human subjects.

VI. Timetable

The IRB will meet monthly throughout the academic year as required by the volume of proposals submitted for review. The first meeting of each year will be scheduled in late August to accommodate researchers preparing proposals for the forthcoming academic year. The chair will designate meeting dates and communicate them to all members of the Lincoln College community before the beginning of each semester. Research proposals requiring full review should be submitted at least seven (7) days before the committee meeting. Any proposal in need of full review that does not meet this deadline will be reviewed during the next scheduled meeting. Research proposals that have been conditionally approved will be dealt with by the chair or the IRB on a case by case basis. The chair may approve the proposal if s/he feels that the conditions have been satisfied, or s/he may refer it to the full IRB if there are unresolved risks to human subjects. Deferred projects will be reviewed at the next scheduled meeting. Research proposals in need of expedited or exempt review may be sent to the chair of the IRB at any time. The IRB is available as an advisory board if there are any questions regarding the review process and categories of review. Generally, Exempt Reviews will be decided within one calendar week of receipt of the application and Expedited Reviews will be decided within two calendar weeks of the receipt of the application. (Investigators should note that decisions may take longer than normal in the summer sessions of an academic year.)

VII. Changes to Ongoing Projects

1. <u>Proposed Changes.</u>

The PI will request approval in advance of any proposed changes of the following types:

a. Changes in research methodology, procedures for collecting data, or research focus. Note: The PI may make changes unilaterally only to mitigate an immediate hazard to subjects. These changes must be reported promptly to the IRB Chair.

b. Changes in the subject pool that were not anticipated as part of the methodology outlined in the original research proposal. NOTE: The IRB recognizes that in some fields of research (e.g., sociology/ anthropology), the recruitment of new research subjects is normally expected in the course of a typical research project. Such anticipated changes should be clearly outlined in the initial proposal, along with assurances that a standardized methodology will be applied to old and new groups to provide uniform protection from any risks of the study.

Each revision in research methodology, including changes in consent forms, must be incorporated into a new, written document, so that there is only one complete protocol with revision dates noted on each revised page and on the cover page. Minor changes may be approved by the IRB chariperson or her/his designate via

expedited review. Changes will be considered minor if they (a) do not result in a significant increase in the risk profile of the project, or (b) do not change significantly the composition of the subject pool.

2. Unanticipated Problems.

The PI will notify the IRB immediately in writing of the occurrence of any adverse events or unanticipated problems involving risks to human subjects. This communication will include a description of the actions that investigators have taken to respond to the problem. Depending on the nature of the changes and/or adverse events, the IRB chairperson may require a review by the full IRB.

VIII. Concluding and Continuing Projects

1. Concluding Projects

Investigators should notify the IRB Chairperson upon completion of the data - collection phase of their research so that the IRB may close its records on the project. Review of Continuing Projects Data collection involving human subjects that extends beyond one year must be reviewed and re - approved annually. The PI must submit a complete new protocol summary, including:

- a status report on the progress of the research;
- the number of subjects processed;
- any adverse effects or unanticipated problems;
- amendments or modifications to the research;
- a copy of the current informed consent document; and
- a summary of any new literature on the research topic that is relevant to the assessment of risks and benefits and the choice of research methodology.

2. Continuing Projects

To avoid interruptions in an ongoing research project, the IRB recommends that this protocol package be forwarded to the IRB chairperson no later than 30 days before the anniversary date of the project:

- Expedited – The IRB chair is empowered to re-approve expedited research projects unless s/he finds changes or issues that merit consideration by the full IRB.
- Full IRB review – A continuation review will be conducted at the next regularly scheduled meeting of the full IRB. All IRB members will receive in advance of the meeting a full copy of the new protocol and all attachments.

IX. IRB Communications

A. IRB Communications to the Campus

1. The IRB will send an annual email to division chairpersons to estimate the number human subjects research efforts during the current year. This email and the discussion that must occur among faculty and division chairpersons will serve as a reminder of the review process.
2. IRB requirements will be introduced to new faculty each year as part of their orientation.

3. IRB information will be included on the Lincoln College web site.

B. IRB Communications with Principal Investigator

1. The IRB will send the PI an e-mail message communicating its findings and its action on each proposal submitted for review. IRB actions are effective as of the date of the e-mail message, and normally remain valid for a period of one year (unless a shorter term of review is specified in the e-mail message due to an unusual degree of risk). The PI should print and retain a copy of the e-mail notification with other important papers pertaining to the research project.
2. The IRB will contact the PI at the end of each academic year to verify the continuing status of the research project.

C. IRB Communications with the Administration

1. The IRB will send to the Vice President for Academic Affairs an annual report on IRB activity.
2. The IRB will report immediately via e-mail to the Vice President for Academic Affairs in the event of (a) any unanticipated problems involving risks to human subjects, (b) any serious non-compliance by a Principal Investigator, or (c) any suspension or termination of IRB approval.

X. Proposal Components

Each research proposal must include the following:

- A clear and concise statement of the research hypothesis or hypotheses, written in terms that are understandable to non-scientist members of the IRB.
- The purpose of the project
- A full description of all procedures, including debrief procedures.
- A description of the subject population, including the gender and racial/ethnic composition, and criteria for the inclusion or exclusion of any sub-population.
- The subject recruitment method and materials (include copies of all survey instruments, consent forms, assent forms, recruitment flyers, sample recruitment letters and advertisements). If subjects will be offered an inducement, such as extra credit, for participating the IRB needs to ensure the reward is not coercive.
- A discussion of any and all risks to subjects including how any such risks will be minimized.
- Forms indicating PI opinion of exempt, expedited or full review (See Appendices).

This provision is meant to assure that the benefits and burdens of research are distributed equitably. For many research projects, the "subject population" will be Lincoln College students, from which some sample will be recruited for the experiment. If the subject population is to be more narrowly defined, investigators should provide a scientific justification for including or excluding any sub-population on campus.

XI. Research Conducted at Other Institutions

If some portion of the research is conducted at another institution, that institution must also review and approve the research protocol. The Lincoln College IRB will normally request some evidence of review and agreement from the host institution's IRB. If the host institution does not have an Institutional Review Board, a letter on institutional letterhead signed by an official of the host institution agreeing to permit access to the study population will be required.

XII. Criteria for Review Categories

All research, including that which the investigator believes falls into the exempt category, must be submitted to the IRB chairperson for confirmation of the relevant review category as defined by federal regulations. The criteria used to determine the categories of review are described below.

(A) Exempt

Some class-based and/or laboratory demonstrations are exempt from the IRB review process. For a research project to be exempt from human subjects review, all items in Part A, AND at least one item in Part B, MUST apply.

Part A concerns criteria to help determine the risk to the participants. Part B concerns the research methodology.

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.
2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The research does not involve subjects under the age of 18.
5. The research does not involve deception.
6. The procedures of this research are generally free of foreseeable risk to the subject.
7. The research does not require a waiver from informed consent procedures.

Part B (at least one item must apply)

1. Research conducted in established or commonly accepted educational settings and involving normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, oral histories, interview procedures or observation of public behavior, where information is recorded anonymously (i.e., so that the human subject cannot be identified, directly or indirectly through identifiers linked to the subject).
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources must be either publicly available or the information must be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4. Research (including demonstration projects) conducted by or subject to the approval of federal department or agency heads, and designed to study, evaluate, or otherwise examine (i) public benefit or service programs (e.g., social security, welfare, etc.); (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.
5. Research involving taste or food quality evaluations or consumer acceptance studies, where the tested products are wholesome foods without additives, or foods which contain additives at or below levels found to be safe by the Food and Drug Administration (FDA) or approved by the Environmental Protection Administration (EPA) or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(B) Expedited Review

For a research project to be eligible for expedited review, all items in Part A, AND at least one item in Part B MUST apply.

Part A (all items must apply)

1. The research does not involve as subjects prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults.
2. The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of this research present no more than minimal risk to the subject. ("Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.)

Part B (at least one item must apply)

1. Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. [NOTE: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously(e.g., use will be made of audio- or -video-tapes, names will be recorded, even if they are not directly associated with the data).]
2. Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) 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; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise,

muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight and health of the individual.

3. Collection of data from voice, video, digital or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
4. Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies).
5. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [NOTE: Although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio- or videotapes, names will be recorded, even if they are not directly associated with the data).]
6. Research that involves mild deception. [NOTE: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review. See description of Full IRB Review in Part C, below.]
7. Prospective collection for research purposes of biological specimens; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; collection of blood samples by finger stick or venipuncture.
8. 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 the research remains active only for the purposes of data analysis; or (c) where the IRB has determined that the research involves no greater than minimal risk and no additional risks have been identified; or (d) where no new subjects have been enrolled and no additional risks have been identified.

(C) Full IRB Review

Full IRB review is required if ANY of these apply to the proposed research:

1. The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.
3. The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. The procedures of the research involve more than minimal risk to the subject. The risk may be actual or perceived. “More than minimal risk" means that the probability and magnitude of physical or psychological harm or discomfort likely to be experienced in the proposed research is greater than that that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
5. Any research which does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

6. The research involves deception, and the nature of the deception is considered of sufficient consequence to require consideration by the full IRB. (Deception of lesser consequence may be eligible for expedited review (see Section XIV).

XIII. Components of Informed Consent

Subjects must have sufficient information to make an informed decision to participate in the research study. If subjects cannot give informed consent, it must be obtained from their legal representatives. For example, when subjects are minors (under 18) or when they are mentally incapacitated, the consent of legal representatives is required.

Investigators are required to use the standard Lincoln College consent form (See Appendices).

The consent form requires the PI to provide a description of the research. This description should include:

- A statement that this is a research project
- The purpose of the research or if deception is involved (see Section XIV), a statement to the effect that "We cannot explain all of the details of the experiment to you at this time, but they will be explained fully at the conclusion of the experiment."
- The expected duration of the subject's participation
- The anticipated number of subjects participating in the study
- A description of the research procedures that allows subjects to understand what they are volunteering to perform.
- A description of any foreseeable risks or discomforts to the subject.

The consent form also includes standard wording that shall not be modified. The standard wording includes the following:

- A statement regarding anonymity or confidentiality. If records identifying the subject will be maintained, indicate the extent to which these will be kept confidential.
- An explanation of whom to contact for pertinent questions about the research (generally the PI), and whom to contact about research subjects' rights and research-related injury (the current Chair of the IRB).
- 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.
- A statement preceding the signature block guaranteeing the legal age of subjects: "In signing below, I affirm that I am 18 years of age or older" or if an online survey, "By clicking on the link to the survey below, I affirm that I am 18 years of age or older and voluntarily consent to participate in this study."
- Dated signatures for subject and investigator.
- The witness signature may be the investigator unless otherwise specified by the IRB.

<u>Children and other protected classes of research subjects</u>

Federal regulations provide higher standards of protection for individuals belonging to certain classes of research subjects, such as prisoners, the seriously ill, mentally or cognitively compromised adults, and minors (children under the age of 18). In the case of prisoners, there is concern that the coercive environment of a prison may compromise the inmate's voluntary participation. With other protected classes, the issue is the

ability of the subjects to provide adequate, informed consent, either because of physical/cognitive limitations or because of age. Therefore, there are additional informed consent requirements.

Excluding exempt research (e.g., naturalistic observation), all research with children requires signed consent forms from the parents or legal guardians. In addition, the child, if of sufficient age to be verbal, must give her/his own assent, or agreement to participate. Such assent must follow an explanation--at a level appropriate to the individual's age, maturity, experience, and condition--of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. Children should be asked if they wish to participate in the research or not. Mere failure to object on the part of the child should not, in the absence of affirmative agreement, be construed as assent. In the proposal, the investigator should indicate: 1) how assent will be obtained (what the investigator will say to the child and whether or not the child's parent(s) or guardian(s) will be present); and 2) how assent will be documented. The child may either sign a very brief assent form or verbally indicate a willingness to participate.

If the research is to be conducted in an institutional setting, the IRB also requires permission from an appropriate institutional official. Within a school system, the permission of a school superintendent or principal will be sufficient for research conducted in a public assembly or similar venue; research in a classroom, however, requires the additional permission of the classroom teacher.

Waiver of signed informed consent

There are some situations where a signed consent form may not be required:

(1) if the principal risks are those associated with a breach of confidentiality concerning the subject's mere participation in the research (e.g., studies on potentially sensitive topics such as illegal drug use, other illegal conduct, or sexual behavior); AND if the consent document is the only record linking the subject with the research; OR
(2) if the research presents no more than minimal risk and involves procedures that do not require written consent when they are performed outside of a research setting (for example, in conducting online survey research); OR
(3) in the case of certain kinds of research (e.g., anthropological or sociological), if the objectives of the research would be compromised by signed consent forms given the nature of the culture under investigation.

If the PI believes a research project meets the above guidelines, s/he must petition the IRB for a waiver of informed consent as part of the proposal review package. The specific justification for each waiver of informed consent will be documented in the IRB minutes.

XIV. Deception

Deception involves withholding information from subjects that might affect their decision to participate in the study. The IRB regards very seriously any use of deception, since withholding information violates the fundamental ethical principle of autonomy. If we have respect for subjects as autonomous individuals, we also respect their right to a make a decision about their participation based on full information. Nonetheless, there are certain types of research that would be impossible without deception (e.g., fields such as social psychology), and deception is acceptable under federal regulations as long as appropriate protections are provided.

Deception occurs in varying degrees of severity. In its most benign form--incomplete disclosure--subjects are told the truth but not the whole truth. The only information that is typically withheld is the experimental hypothesis to ensure that subjects provide unbiased responses.

Progressively more severe examples include (a) deceiving subjects about the purpose of the experiment, (b) deceiving them about the status of other individuals who they believe to be subjects (confederates), and (c) deceiving them about the status of individuals supposedly outside of the experiment (e.g., persons allegedly needing help in a study of helping behavior).

The most extreme form of deception occurs when participants are not even aware that they are subjects until after the experiment has concluded.

The IRB endorses the following principles of best practice in studies involving deception:
•Deception should never be employed if there is an alternate way of studying the research question without deception.
•Incomplete disclosure (to protect the research hypothesis) is acceptable as long as the project follows the practices outlined below.
•Every experiment involving deception must include the following provisions:

- The consent form must advise subjects that they are not receiving all of the relevant information prior to the experiment, but they will be fully informed at its conclusion. The IRB recommends the following language: "We cannot explain all of the details of the experiment to you at this time, but they will be explained fully at the conclusion of the experiment."
- Subjects must receive a thorough debriefing at the conclusion of the experiment, including a disclosure of the deception and an explanation of why it was necessary for the experiment. A complete debriefing script should be approved in advance as part of the methodology of the study.
- To restore subjects' autonomy and control (that is, to restore the right to decide on participation based on full information), experimenters must, at the conclusion of the debriefing, offer subjects the opportunity to withhold the use of their data if they are unhappy with the deception.

References

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education and Welfare. Office for Human Research Protections (OHRP) IRB Guidebook, U.S. Department of Health and Human Services.

IRB Procedures for Approval of Human Subjects Research, Eureka College

Policies and Procedures for Reviewing Research Involving Human Subjects, Bucknell University.

Protection of Human Subjects, Title 45 Code of Federal Regulations Part 46, Department of Health and Human Services, National Institutes of Health, Office for Protection from Research Risks.

TEMPLATE: Signed Consent Form in a Research Setting

Purpose of Research
(To be completed by research team)

Provide to the participant of the purpose, risks, benefits and expected duration of the participation and the procedures of the study.

Consent

I, _____, state that I am over 18 years of age and that I agree to participate in a research study being conducted by _____. I acknowledge that _____ has informed me that my participation in this study is voluntary, that I may refuse to participate or withdraw my participation at any time without penalty or loss of benefits, and that all data that I contribute will remain confidential. The purpose, risks, benefits and expected duration of my participation, and the procedures of the study (including the identification of any procedures that are experimental) have been explained to me, and I am competent to understand them. I understand that this study involves minimal risk. This consent is being signed prior to participation in the study.

_____ _____
Signature of participant Date

_____ _____
Signature of witness Date

Please contact _____ at _____ if you have any questions about the research.

Please contact _____ at _____ if you have any questions about your rights as a participant, or in the event of a research-related injury. If you would like to receive a summary of the results at the conclusion of the study, please write your email address here:
_____

TEMPLATE: Informed Consent/Recruitment Letter for Electronic Survey Research

Greetings!

I am a (*insert role: researcher, student, faculty member, etc.)*. I am asking for your participation in my research study through the completion of a brief online survey. The purpose of my study is to *(indicate purpose of the study in laymen terms).* This survey will gather information regarding participant's (*insert general information intending to be collected from participants).*

Participation in this survey is completely voluntary. At any time you may decide not to participate. You may answer only the questions you choose to. This survey, should take approximately *(indicate estimated time for completion)* minutes to complete.

Participation in this survey is completely anonymous. Any data gathered will be kept confidential and no participant information will be noted, other than the relationship of being part of the general population of *(insert general population).*

There are no anticipated risks associated with completion of this survey. Your participation will assist researchers in determining *(insert the principle hypothesis/hypotheses of the study)*. Your participation will also *(indicate general benefits of participation in the research study, including any direct benefits such as inducements for participation and/or any indirect benefits to participation). (If there are no direct benefits to the study, indicate that here with a general statement such as: "There are no direct benefits for you as a participant, though your assistance is appreciated.*")

If at any time you have any questions about the research process or your participation, you may address the questions to *(indicate name of PI and contact information).*

By clicking on the link to the survey below, I affirm that I am 18 years of age or older and voluntarily consent to participate in this study.

Thank you for your assistance.

Insert Survey Link

Signature of Co-PI or PI

FORM
Checklist for Research Qualifying as Exempt with Guidelines for Protocol Preparation

Directions: If you believe that your project qualifies for Exempt Review, please submit the following materials to the IRB: (a) a completed copy of this form; (b) an indication of the date of completion of the IRB training program in Part I General Information (Note: faculty members submit an indication of the date of completion of IRB training certification and students submit the date of completion of the course serving as training certification); (c) a research proposal or thorough document of your procedures and materials. a research proposal or thorough documentation of your procedures and materials indicated in Part C and D. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Either complete or attach a complete research proposal that addresses the items outlined in Part D.

Research activities will only be considered for exemption from further review when all items in Part A and at least one item in Part B apply.

I. General Information

A. Protocol Information	
Protocol Title:	
Is this research part of a thesis or dissertation proposal? ☐ No ☐ Yes If yes, has the thesis or dissertation proposal been approved? ☐ No ☐ Yes	
B. **Principal Investigator Information**	
Principal Investigator	Department
Telephone Number	Email Address
Date of Completion of IRB Training Certification:	Mailing Address
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	

II. Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

1. The information provided for this project is correct
2. No other procedures will be used in this protocol
3. I agree to conduct this research as described in the attached supporting documents
4. I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators or any changes in procedures).
5. I will comply with IRB and LINCOLN COLLEGE policies for conducting ethical research.
6. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.
7. Any unexpected or otherwise significant events in the course of this study will be promptly reported to the IRB.
8. In the case of student research, I assume responsibility for ensuring that any student will comply with College and Federal regulations regarding the use of human subjects in research.
9. In the case of externally funded research, I will request a modification to my approved protocol if any relative changes to the project's scope of work are requested by the agency.

_____ _____
Principal Investigator Signature **Date**

Part A:

1._____ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.

2._____ The research does not involve the collection or recording of behavior which, if known 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._____ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).

4._____ The research does not involve subjects under the age of 18 (Exception: research with subjects under the age of 18 may still be subject to exempt review if they are participating in projects that fall under categories 1, 3, 4 and/or 5 in Part B). Studies under Part B-2 that include minors should be submitted for expedited review.

5._____ The research does not involve deception.

6._____ The procedures of this research are generally free of foreseeable risk to the subject.

Part B

(Check all categories that apply to your research project):

1._____ The research will be conducted in established or commonly accepted educational settings and will involve normal educational practices (e.g., research on regular and special education instructional strategies, research on instructional techniques, curricula, or classroom management methods).

2._____ The research will involve any of the following (indicate the letter of all that apply):

(a) the use of educational tests (cognitive, diagnostic, aptitude, achievement),

(b) survey procedures,

(c) interview procedures or observation of public behavior in which information will be recorded anonymously (i.e., so that the human subject cannot be identified, directly or through identifiers linked to the subject).

3._____ The research will involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. These sources are either publicly available or the information will be recorded anonymously (i.e., in such a manner that subjects cannot be identified, directly or through identifiers linked to the subject).

4.____ The research (including demonstration projects) will be conducted by or subject to the approval of federal department or agency heads, and is designed to study, evaluate, or otherwise examine:

a. public benefit or service programs (e.g., social security, welfare, etc.);

b. procedures for obtaining benefits or services under those programs;

c. possible changes in or alternatives to those programs or procedures;

d. possible changes in methods or levels of payment for benefits or services under those programs.

5. ____ The research involves taste or food quality evaluations or consumer acceptance studies and the tested products are wholesome foods without additives or foods which contain additives at or below levels found to be safe by the FDA or approved by the EPA of the Food Safety and Inspection Service of the US Department of Agriculture.

Part C

1. Describe approximately how much time each subject is expected to devote to the research.

2. How data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio-or videotapes be employed in data collection?). Append copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.
3. Describe the methods for obtaining informed consent (or assent in the case of minors).
4. Describe the methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records.
5. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.
6. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Principal Investigator handle it?

Part D
Please provide the information that is requested below. A research proposal may be attached.
1. What is the purpose of the proposed study (the research question) and what is the research hypothesis?
2. Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples.
3. How will subjects be recruited and selected?
4. Describe all research methods and procedures that will be employed in this study.

FORM
Checklist for Research Qualifying for Expedited Review with Guidelines for Protocol Preparation

Directions: If you believe that your project qualifies for Expedited Review, please submit the following materials to the IRB: (a) a completed copy of this form; (b) an indication of the date of completion of the IRB training program in Part I General Information (Note: faculty members submit an indication of the date of completion of IRB training certification and students submit the date of completion of the course serving as training certification); (c) a research proposal or thorough document of your procedures and materials. a research proposal or thorough documentation of your procedures and materials indicated in Part C and D. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Either complete or attach a complete research proposal that addresses the items outlined in Part D.

Research activities will only be considered for Expedited Review when all items in Part A and at least one item in Part B apply.

I. General Information

A. Protocol Information	
Protocol Title:	
Is this research part of a thesis or dissertation proposal? ☐ No ☐ Yes If yes, has the thesis or dissertation proposal been approved? ☐ No ☐ Yes	
B. **Principal Investigator Information**	
Principal Investigator	Department
Telephone Number	Email Address
Date of Completion of IRB Training Certification:	Mailing Address
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	

II. Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

1. The information provided for this project is correct
2. No other procedures will be used in this protocol
3. I agree to conduct this research as described in the attached supporting documents
4. I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators or any changes in procedures).
5. I will comply with IRB and LINCOLN COLLEGE policies for conducting ethical research.
6. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.
7. Any unexpected or otherwise significant events in the course of this study will be promptly reported to the IRB.
8. In the case of student research, I assume responsibility for ensuring that any student will comply with College and Federal regulations regarding the use of human subjects in research.
9. In the case of externally funded research, I will request a modification to my approved protocol if any relative changes to the project's scope of work are requested by the agency.

_____ _____
Principal Investigator Signature **Date**

Part A:
1. _____ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. _____ The research does not involve the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. _____ The research does not involve the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. _____ The procedures of this research present no more than minimal risk to the subject (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests).

Part B (at least one item should apply)
1. ____ Research involving existing identifiable data, documents, records, or biological specimens (including pathological or diagnostic specimens), where these materials, in their entirety, have been collected or will be collected solely for non-research purposes. [NOTE: These sources are not publicly available and, although confidentiality will be strictly maintained, information will not be recorded anonymously (e.g., use will be made of audio-or videotapes, names will be recorded, even if they are not directly associated with the data.]
2. ____ Collection of data through use of the following procedures: a) non-invasive procedures routinely employed in clinical practice excluding procedures involving x-rays or microwaves; b) 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; c) weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, echography, sonography, ultrasound, magnetic resonance imaging (MRI), diagnostic infrared imaging, doppler blood flow, and echocardiography; d) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
3. ____ Collection of data from voice, video, digital or image recordings made for research purposes where identification of the subjects and/or their responses would not reasonably place them at risk of criminal or civil liability, be stigmatizing, or be damaging to the subjects' financial standing, employability, insurability, or reputation.
4. ____ Research on individual or group characteristics or behavior (including but not limited to research involving perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior, or research employing surveys, interviews, oral history, focus groups, program evaluation, human factors evaluation, or quality assurance methodologies).
5. ____ Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. [Although confidentiality will be strictly maintained, information will not be recorded anonymously, e.g., use will be made of audio-or videotapes, names will be recorded, even if they are not directly associated with the data).]
6. ____ Research that involves deception [NOTE: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review.]

7. ____ Prospective collection for research purposes of biological specimens and collection of blood samples by finger stick or venipuncture.
8. ____ 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 the research remains active only for the purposes of data analysis; or
    c. where the IRB has determined at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified; or
    d. where no subjects have been enrolled and no additional risks have been identified.

Part C

1. Describe approximately how much time each subject is expected to devote to the research.
2. How data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio-or videotapes be employed in data collection?). Append copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.
3. Describe the methods for obtaining informed consent (or assent in the case of minors).
4. Describe the methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records.
5. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]
6. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.
7. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Principal Investigator handle it?

Part D

Please provide the information that is requested below. A research proposal may be attached.

1. What is the purpose of the proposed study (the research question) and what is the research hypothesis?
2. Describe the proposed subject sample. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples.
3. How will subjects be recruited and selected?
4. Describe all research methods and procedures that will be employed in this study.

FORM
Checklist for Research Qualifying for Full Review with Guidelines for Protocol Preparation

Directions: If you believe that your project qualifies for Full Review, please submit the following materials to the IRB: (a) a completed copy of this form; (b) an indication of the date of completion of the IRB training program in Part I General Information (Note: faculty members submit an indication of the date of completion of IRB training certification and students submit the date of completion of the course serving as training certification); (c) a research proposal or thorough document of your procedures and materials. a research proposal or thorough documentation of your procedures and materials indicated in Part C and D. Please check all applicable items in Parts A and B and provide all relevant information in Part C. Either complete or attach a complete research proposal that addresses the items outlined in Part D.

Research activities will be considered for Full Review when at least one of the items in Part A applies.

I. General Information

A. Protocol Information	
Protocol Title:	
Is this research part of a thesis or dissertation proposal? ☐ No ☐ Yes If yes, has the thesis or dissertation proposal been approved? ☐ No ☐ Yes	
B. **Principal Investigator Information**	
Principal Investigator	Department
Telephone Number	Email Address
Date of Completion of IRB Training Certification:	Mailing Address
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	
Co-Principal Investigator Information	
Co- Principal Investigator	Department
Telephone Number	Email Address
☐ Faculty ☐ Staff ☐ Grad. Student ☐ Undergrad. Student	Mailing Address
Course Number and date of completion certifying training or Date of IRB Training Certification:	

II. Principal Investigator Assurance

As Principal Investigator, I certify that to the best of my knowledge:

1. The information provided for this project is correct
2. No other procedures will be used in this protocol
3. I agree to conduct this research as described in the attached supporting documents
4. I will request and receive approval from the IRB for changes prior to implementing changes (including but not limited to changes in cooperating investigators or any changes in procedures).
5. I will comply with IRB and LINCOLN COLLEGE policies for conducting ethical research.
6. I will be responsible for ensuring that the work of my co-investigator(s)/student researcher(s) complies with this protocol.
7. Any unexpected or otherwise significant events in the course of this study will be promptly reported to the IRB.
8. In the case of student research, I assume responsibility for ensuring that any student will comply with College and Federal regulations regarding the use of human subjects in research.
9. In the case of externally funded research, I will request a modification to my approved protocol if any relative changes to the project's scope of work are requested by the agency.

_____ _____
Principal Investigator Signature **Date**

Part A:

1. _____ The research targets as participants: prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
2. _____ The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the subjects at risk of criminal or civil liability, be stigmatizing, or be damaging to the subject's financial standing, employability, insurability, or reputation.
3. _____ The research involves the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
4. _____ The procedures of this research present more than a minimal risk to the subject (where minimal risk means that the probability and magnitude of harm or discomfort anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical/psychological examinations or tests).
5. _____ Research that involves deception [NOTE: Deception must be scientifically justified and de-briefing procedures must be outlined in detail. Based upon the judgment of the reviewers, some protocols involving deception may qualify for expedited review. In other cases, the deception will be of sufficient consequence to require full IRB review.]
6. ____ Collection of data through the use of invasive biomedical procedures including: a) invasive procedures routinely employed in clinical practice; b) physical sensors that are applied either to the surface of the body or at a distance and involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; c) excessive exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

Part B

1. Describe approximately how much time each subject is expected to devote to the research.
2. How data will be collected and recorded (with or without identifiers? what instruments, materials, or equipment will be used? will audio-or videotapes be employed in data collection?). Append copies of all written instruments and/or describe any apparatus with which subjects will be in direct contact.
3. Describe the methods for obtaining informed consent (or assent in the case of minors).
4. Describe the methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records).
5. If deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. [NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]
6. If biomedical procedures are to be employed, provide a scientific justification for their use and describe debriefing procedures. [NOTE: If the research is such that debriefing cannot be carried out, the project must be submitted for full committee review.]
7. Indicate any benefits that are expected to accrue to subjects as a result of their participation in the research. In the event that subjects will be paid, describe all payment arrangements, including how much subjects will be paid should they choose to withdraw from the study prior to completion of the research.
8. Describe any relationship between researcher and subjects, such as: teacher/student; superintendent/principal/teacher, employer/employee. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the Principal Investigator handle it?

Part C

Please provide the information that is requested below. A research proposal may be attached.

1. What is the purpose of the proposed study (the research question) and what is the research hypothesis?
2. Describe the proposed subject sample and a justification of the need for recruiting that subject sample for the study. If subjects under the age of 18 will participate in your research, indicate the expected age range of the samples. If subjects are members of another protected class of participants, provide a justification for the recruitment of those subjects.
3. How will subjects be recruited and selected?
4. Describe all research methods and procedures that will be employed in this study including proposed data analysis.

Appendix A

URL Address for the Code of Federal Regulations: 45 CFR 46

http://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/