Eureka College

Institutional Review Board (IRB)

Procedures for Approval of Human Participants Research

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I. Introduction

Eureka College is committed to safeguarding the welfare, rights, and privacy of all persons who volunteer as participants in research projects conducted under its auspices, and to ensuring that the participants of such research are aware of the rights and the protections available to them. Moreover, Eureka College is required to assure the Federal Government of the United States of America that such safeguards are being provided and enforced for all federally-funded grants. 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.

A. **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, those who are mentally or cognitively disabled, pregnant persons, or economically or educationally disadvantaged persons. Human participants should enter into research voluntarily and with adequate information.

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

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

The Eureka College Institutional Review Board (IRB) is the body charged with reviewing and approving all proposed research involving human participants, whether funded or not, conducted under the auspices of Eureka College by its faculty, students, staff, or by outside investigators using Eureka 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 46.1021). Research subject to review thus includes, but is not limited to: pilot studies, class projects aimed for publication or presentation, Honors theses, and independent research, whether such research takes place on or off the Eureka College campus.

The procedures for review described below adheres to the regulations of the Department of Health and Human Services (45 CFR 46, as amended and published in the Federal Register on January 17, 2017, and any subsequent amendments). In addition, the author has consulted policies of Bucknell University, Swarthmore College, Bryn Mawr, and Middlebury Colleges, all of which are based on the same federal standards.

II. Composition of the Institutional Review Board (IRB)

The Federal guidelines (45 CFR 46.107) specify members of the IRB must fit into 3 categories:

1. a member from the community,

2. a non-scientist, and
3. members qualified to discuss the research under consideration.

These guidelines must be met for federally funded research. The IRB consists of five (5) members appointed by the Provost of the College. All appointed members are voting members of the IRB. The membership requirements listed below provide representation from the 3 categories specified in the Federal guidelines.

Appointed Members

- ◊ One member of the community unaffiliated with the college;
- ◊ One social science faculty member from the Business and Social Sciences Division;
- ◊ One non-science faculty or staff member;
- ◊ The Chaplain of the College; and
- ◊ The Provost of the College

The Provost will designate one of the members listed above as the Chairperson of the IRB. The membership of the IRB will appoint a Secretary Pro-tem at each meeting who will be responsible for the minutes of the IRB meetings.

Each IRB member will recuse themselves from deliberations on any protocol in which they have a conflicting interest (e.g., is the Principal Investigator (PI), Co-PI, has some financial interest, etc.); this action will be noted in the minutes. All Principal Investigators, 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.

Operation of the IRB

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 Pro-tem 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 participants are responsible for initiating the review process by submitting their research proposals and all necessary forms (see Appendices or https://www.eureka.edu/academics/institutional-review-board) to the IRB Chairperson. All forms and the proposal must be submitted as a packet. Please do NOT send multiple individual files.

A. Training Requirements

Federal regulations also require that all faculty, students, and staff who are engaged in human participants research certify to the IRB that they have completed a program of training in the ethics and best practice of

human participants research before their research protocol can be approved. Students enrolled in and attending PSY280 Psychological Statistics and Methods I receive their training in this class. Others can receive training through the online training materials available on Eureka College's IRB website.

B. Directing Proposals for Initial Review

A. Faculty: Submit proposal to the IRB Chairperson.
B. Staff: Submit proposal to the IRB Chairperson.
C. Students: Submit proposal to the faculty advisor or sponsor, who will in turn submit it to the IRB Chairperson.
D. Non-Eureka College Investigators: Submit proposal to the Provost, who will in turn submit it to the IRB Chairperson.

All research proposals are evaluated by the Chair of the IRB, the IRB Chair and one other member of the Board, or the full IRB with regard to the degree of "risk," if any, to human participants. 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 (Common Rule 45 CFR 46):

> 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 Appendices).

Once the IRB Chairperson has completed a preliminary assessment of risk, they 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 their own opinion as to the project's category of IRB review.

C. Categories of IRB Review

1. *Exempt Review*: No foreseeable risk to human participants.
2. *Expedited Review*: No more than minimal risk to human participants.
3. *Full IRB Review*: Greater than minimal risk to human participants.

1. 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.
2. If the proposal involves only minimal risk, an *expedited review* will be conducted by at least one other member of the IRB designated by the Chair.
3. Proposals judged by the IRB Chair to involve greater than minimal risk will undergo a full IRB review at the next scheduled IRB meeting. There are four possible outcomes to an *expedited* or *full review*:
    a. Approved: No further action is required before the investigator may initiate the study.

Approval of 12 months is granted to complete the research, from the date of approval. If the study should extend beyond 12 months, the PI should send a letter to the IRB Chair, informing them of the current status of the project, any changes in the protocol, and whether any adverse events have occurred (see Section VIII).

b. Conditionally Approved: Requires changes that generally involves only simple correspondence by the PI. Research may commence as soon as the conditions for approval have been satisfied. These conditions typically require only simple correspondence 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 revised protocol to the full IRB for review.
c. 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.
d. 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, the PI may request that the IRB reconsider its decision at the next meeting (see Section IV).

An email message describing the decision of the IRB will be sent to the PI notifying them of the decision. If the email signifies approval, it will specify the one-year time period on the protocol application page, during which the approval remains valid.

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.

IV. Appeals

If the Principal Investigator disputes a decision of the IRB (e.g., a denial), they may request, in writing, that the IRB review and reconsider its decision at its next meeting. The PI may provide the IRB with written arguments and supporting materials in advance of the meeting and 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, they may consult with the Provost, 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 participants, and all related correspondence concerning the use of human participants.

VI. Timeline for Review

The IRB will meet on an ad-hoc basis throughout the academic year as required by the volume of proposals submitted for review. The Chair will designate meeting dates and communicate them to all members of the Eureka College community at least two (2) weeks before the meeting date. Research proposals requiring full review should be submitted at least seven (7) days before the committee meeting, in consultation with the IRB Chair. *Any proposal in need of full review that does not meet this deadline will be reviewed during a follow-up meeting* at the earliest convenience of the full Board. 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 they feel that the conditions have been satisfied, or they may refer it to the full IRB if there are unresolved risks to human participants. Deferred projects will be reviewed at the next scheduled meeting. Research proposals in need of *Exempt* or *Expedited Review* may be sent to the Chair of the IRB at any time. The IRB Chair or Board is available at any time as an advisory board if there are any questions regarding the review process, categories of review, or whether a project must be reviewed by the Board.

VII. Changes to Ongoing Projects

A. Proposed Changes

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 participants. These changes must be reported promptly to the IRB Chair.
b. Changes in the participant 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 or anthropology), the recruitment of new research participants 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 in 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 Chairperson or their designate via *Exempt 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 participant pool.

B. Unanticipated Problems

The PI will notify the IRB immediately in writing the occurrence of any adverse events or unanticipated problems involving risks to human participants. 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

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 participants that extends beyond one (1) year must be reviewed and re-approved annually. The PI must submit a complete new protocol summary, including the following details:

- ◊ a status report on the progress of the research;
- ◊ the number of participants 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.

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 Approval end-date of the project:

- ◊ *Exempt and Expedited Review*: The IRB Chair is empowered to re-approve expedited research projects unless they find changes or issues that merit consideration by an additional member of the IRB or the full IRB.
- ◊ *Full IRB Review*: A continuation review will be conducted at the next 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 may send an annual email to Division Chairpersons to estimate the number human participants research efforts during the current year, if necessary.
2. The IRB will publish meetings times and locations on the Eureka College website calendar, when available.
3. IRB requirements will be introduced to new faculty each year as part of their orientation.

4. IRB information will be included on the internal Eureka College website.
5. At any time, a faculty or staff member, student, or other member of the Campus Community may reach directly out to the IRB Chairperson for specific guidance and instruction of the policies and procedures for Human Participant Research at the College.

B. IRB Communications with Principal Investigator(s)

1. The IRB will send the PI(s) an email message communicating its findings and its action on each proposal submitted for review. IRB actions are effective as of the date of the Approved Protocol Page, and normally remain valid for a period of one (1) year (unless a shorter term of review is specified in the email message due to an unusual degree of risk). The PI(s) 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(s) at the end of each academic year to verify the continuing status of the research project.

C. IRB Communications with the College Administration

1. The IRB will send to the Provost an annual report on IRB activity.
2. The IRB will report immediately via email to the Provost and in the event of (a) any unanticipated problems involving risks to human participants, (b) any serious non-compliance by a Principal Investigator, or (c) any suspension or termination of IRB approval.

X. IRB Proposal Components

Each 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 consent and debrief procedures.
- ◊ A description of the participant population, including the age, gender, racial/ethnic composition, and class standing of the potential participants, as well as the criteria for inclusion or exclusion of any subpopulation.
- ◊ The participant recruitment method and materials (include copies of all survey instruments, consent forms, assent forms, recruitment flyers, sample recruitment letters, and advertisements). If participants will be offered an inducement or compensation (e.g., extra credit) for participating, the IRB needs to ensure the reward is not coercive.
    - o This provision is meant to assure that the benefits and burdens of research are distributed equitably. For many research projects, the "participant population" will be Eureka College students, from which some sample will be recruited for the experiment. If the participant population is to be more narrowly defined, investigators should provide a scientific justification for including or excluding any subpopulation on campus.
- ◊ A discussion of any and all risks to participants and how any such risks will be minimized.
- ◊ Forms indicating PI opinion of *Exempt, Expedited,* or *Full Review* (See Appendices).

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 Eureka 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 is required.

XII. Criteria for Review Categories

All research, including what the Principal Investigator(s) 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 Review

Class-based (conducted within the classroom) or laboratory demonstrations are exempt from the IRB review process. For a research project to be *Exempt* from Human Participants review, all items in Part A, AND at least one item in Part B, MUST apply. Part A criteria help to determine the overall risk to the participants. Part B criteria consist of the possible research methodologies.

Part A (all items must apply):

- ◊ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
- ◊ 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.
- ◊ 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).
- ◊ 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.
- ◊ The research does not involve deception.
- ◊ The procedures of this research are generally free of foreseeable risk to the subject.

Part B (at least one item must apply):

- ◊ 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).
- ◊ The research will involve the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. Information will be

recorded anonymously (i.e., so that the human subject cannot be identified, directly or through identifiers linked to the subject).

- ◊ 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).
- ◊ 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:
    - public benefit or service programs (e.g., social security, welfare, etc.);
    - procedures for obtaining benefits or services under those programs;
    - possible changes in or alternatives to those programs or procedures; or
    - possible changes in methods or levels of payment for benefits or services under those programs.
- ◊ 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.

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 must apply):

- ◊ The research does not involve prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects.
- ◊ 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.
- ◊ 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).
- ◊ 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 must apply):

- ◊ 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 recordings or names will be recorded, even if they are not directly associated with the data.]

- ◊ 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.
- ◊ 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.
- ◊ 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).
- ◊ 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 video recordings, names will be recorded, even if they are not directly associated with the data.]
- ◊ Research that involves deception [NOTE: Deception must be scientifically justified and debriefing procedures must be outlined in detail. Based on 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.]
- ◊ Prospective collection for research purposes of biological specimens and collection of blood samples by finger stick or venipuncture.
- ◊ Research previously approved by the convened IRB as follows:
    - o 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 remain active only for long-term follow-up of subjects; or
    - o where the research remains active only for the purposes of data analysis; or
    - o 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
    - o where no 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:

- ◊ The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as participants.

- ◊ The research involves the collection or recording of behavior which, if known outside the research, could reasonably place the participants at risk of criminal or civil liability, be stigmatizing, or be damaging to the participants' financial standing, employability, insurability, or reputation.
- ◊ The research involves the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior).
- ◊ 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 ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- ◊ Any research which does not fall into any of the categories explicitly identified as qualifying for *Exempt* or *Expedited* status.
- ◊ 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).

During each full IRB review, the committee members will consider whether the degree of risk to human participants requires IRB review more frequently than once per year.

XIII. Components of Informed Consent

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

Investigators are required to use the standard Eureka College Informed Consent Form (See Appendices). The Informed 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 participants volunteering for the study.
- ◊ A description of the research procedures that allows participants to understand what they are volunteering to perform.
- ◊ A description of any foreseeable risks or discomforts to the participant.

The Informed 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 participant 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 participants' rights and research-related injury (the current Chair of the IRB).
- ◊ A statement that participation is voluntary and refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- ◊ A statement preceding consent (via electronic signature or handwritten signature) guaranteeing the legal age of participants: "In consenting/signing below, I affirm that I am 18 years of age or older."
- ◊ Dated signatures for subject and investigator, if handwritten.
    - o A witness signature may be the investigator unless otherwise specified by the IRB.

Children and Other Protected Classes of Research Participants

Federal regulations provide higher standards of protection for individuals belonging to certain classes of research participants, 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 participants 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 Informed Consent Forms from the parents or legal guardians. In addition, the child, if of sufficient age to be verbal, must give their 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 participant'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; 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 a PI believes a research project meets the above guidelines, they 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 participants 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 participants as autonomous individuals, we also respect their right to a make a decision about their participation based on full information. Nevertheless, 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 — participants are told the truth but not the whole truth. The only information that is typically withheld is the experimental hypothesis to ensure that participants provide unbiased responses. Progressively more severe examples include: (a) deceiving participants about the purpose of the experiment, (b) deceiving them about the status of other individuals who they believe to be participants (confederates), or (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 participants 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 or problem 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 Informed Consent Form must advise participants 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.”

- Participants 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 participants' autonomy and control (that is, to restore the right to decide on participation based on full information), investigators must, at the conclusion of the debriefing, offer participants 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 Participants in Research, Report of the National Commission for the Protection of Human Participants 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.

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

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

Swarthmore College IRB Procedures for Approval of Human Participants Research, Swarthmore College

Appendices

Appendix A. Informed Consent Form Template

Eureka College: Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Eureka College Institutional Review Board (IRB) has reviewed and approved for conduct by the investigators named here. This form is designed to provide you - as a human subject - with information about this study. The Investigator or his/her representatives will describe this study to you and answer any of your questions. You are entitled to an Experimental Research Subject's Bill of Rights and a copy of this form (you may copy/paste this form into a word processor). Please contact **[names]**, Principal Investigator at **[email address]** or **[phone number]** if you have any questions about the research. Please contact Alexander Swan, IRB Chairperson at aswan@eureka.edu or 309-467-6418 if you have any questions about your rights as a participant, or in the event of a research-related injury.

Protocol Title:

Protocol Number:

PURPOSE:

PROCEDURE:

RISKS/BENEFITS:

VOLUNTARY PARTICIPATION: You must be 18 years of age or older to participate in this study. Participation in this study is voluntary, and you can withdraw at any time without penalty.

CONFIDENTIALITY: Any information that you provide will be kept confidential. Your responses will be combined with those of others and will be reported as a whole. Data may be reported in publications or in conference presentations. Your personal information will not be linked to any of the reported results.

If you have any further questions about the survey, or would like a printed version of this form, please contact Alexander Swan, IRB Chair (aswan@eureka.edu). Thank you for your time and willingness to help us.

Have you read the above information and do you agree to be a participant in this study? By signed you also agree that you are 18 years old or older. Remember that you can withdraw from the study at any time without penalty.

Please circle one.

Yes No

_____ _____

Signature Date

Appendix B. Exempt Review Protocol Application

For Institutional Review Board Use Only
Date Received: _____ Approved: __ Yes __ No
IRB Protocol # _____ Approval Expiration: _____
_____ IRB Chair Signature
The signature of the IRB Chair indicates that the activity described in the attached pages has been reviewed and approved.

Checklist for Research Qualifying as Exempt with Guidelines for Protocol Preparation
Researcher(s) _____
Researcher Email _____
Course #/Grant _____
Name of Project _____

Directions: If you believe that your project qualifies for exemption, please submit the following materials to the IRB: (a) a completed copy of this form; (b) a copy of your IRB Training Quiz; (c) a research proposal or thorough document of your procedures and materials. 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.

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 the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. 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 (e.g., with or without identifiers? what instruments, materials, or equipment will be used? will audio or video recording 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/compensation 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 Researcher(s) 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 and indicate. 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.

RESEARCHER: READ THIS CERTIFICATION CAREFULLY. YOU ARE MAKING AN IMPORTANT COMMITMENT.

I understand that I am responsible for the safe conduct of this project. I will conduct this study in the manner described in this form. I will notify the Eureka College Institutional Review Board ***immediately*** to:

• _Request review and approval of all proposed changes prior to implementation;

• _Report any problem(s) that may put subjects at risk, including but not limited to adverse events (e.g., mental or physical adverse events/reactions, breach of confidentiality safeguards); and,

• _Report any other problems associated with the conduct of this research (e.g., compliance).

I agree to comply with all copyright and record retention requirements designated by Eureka College Institutional Review Board (IRB), Federal and State governments, and other organizations/institutions associated with this research, including funding organizations and sponsors.
I have completed or will complete the IRB Ethics Training Quiz before this research commences as will all individuals who interact with human subjects or have access to their identifiable data.

_____	_____	_____
Researcher Signature	Researcher Name	Date

Appendix C. Expedited/Full Review Protocol Application

For Institutional Review Board Use Only
Date Received: _____ Approved: __ Yes __ No
IRB Protocol # _____ Approval Expiration: _____
_____ IRB Chair Signature
The signature of the IRB Chair indicates that the activity described in the attached pages has been reviewed and approved.

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

Researcher(s) _____
Researcher Email _____
Course #/Grant _____
Name of Project _____

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) a copy of your IRB Training quiz; (c) a research proposal or thorough document of your procedures and materials. 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. If one item cannot be checked in Part A, the research will require a full IRB Committee review.

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 video recordings or 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 video recordings, 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 debriefing procedures must be outlined in detail.** Based on 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:

1. 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

2. where the research remains active only for the purposes of data analysis; or

3. 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

4. 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 video recordings 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 digital files 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/compensation 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 Researcher(s) 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 and indicate the size of the 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.

RESEARCHER: READ THIS CERTIFICATION CAREFULLY. YOU ARE MAKING AN IMPORTANT COMMITMENT.

I understand that I am responsible for the safe conduct of this project. I will conduct this study in the manner described in this form. I will notify the Eureka College Institutional Review Board ***immediately*** to:

• _Request review and approval of all proposed changes prior to implementation;
• _Report any problem(s) that may put subjects at risk, including but not limited to adverse events (e.g., mental or physical adverse events/reactions, breach of confidentiality safeguards); and,
• _Report any other problems associated with the conduct of this research (e.g., compliance).

I agree to comply with all copyright and record retention requirements designated by Eureka College Institutional Review Board (IRB), Federal and State governments, and other organizations/institutions associated with this research, including funding organizations and sponsors.

I have completed or will complete the IRB Ethics Training Quiz before this research commences as will all individuals who interact with human subjects or have access to their identifiable data.

_____	_____	_____
Researcher Signature	Researcher Name	Date