

HUMAN SUBJECTS RESEARCH  
AT  
BUCKNELL UNIVERSITY

INSTITUTIONAL REVIEW BOARD

POLICIES AND PROCEDURES

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## I. PRINCIPLES

Bucknell University is committed to safeguarding the welfare, rights and privacy of all persons who participate as subjects in research projects conducted under its auspices, and to ensuring that the subjects of such research are aware of the rights and the protections available to them. Moreover, the University is required to assure the federal government 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.

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 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 to the subjects, 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 participants 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 Bucknell University by its faculty, students or staff, or by outside investigators using Bucknell University students, personnel, facilities, or data collected at the University. "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 thus includes, but is not limited to: pilot studies; class projects aimed for publication; Master's theses; Ph.D. dissertations; co-supervised work; independent research; and senior theses, whether such research takes place on or off the Bucknell University campus, including work done outside of the United States. Note that oral history is generally excluded from IRB review but the investigator must confirm the status of each project through a conversation with the Chair or a member of the IRB. The IRB representative will seek to confirm (1) that the results are not generalizable and thus not true research under the federal definition; and (2) that best practice is followed in the design of oral history projects.

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), and to the Assurances filed by the University with the Office of Human Research Protections (OHRP). In addition, the IRB has consulted *Protecting Human Research Subjects: Institutional Review Board Guidebook* (1993), prepared by the former Office for Protection from Research Risks (OPRR) of the National Institutes of Health; and has adapted sections from the policies of Bryn Mawr and Middlebury Colleges, both of which are based on the same federal standards.

## II. COMPOSITION OF THE INSTITUTIONAL REVIEW BOARD

The IRB consists of seven (7) members appointed by the provost/vice president for academic affairs (Provost/VPAA), plus one *ex officio* member. All appointed and *ex officio* members are voting members of the IRB.

According to 45CFR 46.107, "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."

The membership requirements listed below provide representation from all of the major fields that conduct substantial human subjects research at the University. This

representation ensures that the IRB possesses sufficient knowledge of the local research context.

### Appointed Members

- One member of the community unaffiliated with the University;
- One faculty member from the Department of Psychology;
- One faculty member from the Department of Sociology/Anthropology;
- One faculty member from the Department of Biology or the Program in Biomedical Engineering;
- One faculty member from the Department of Education
- One faculty member selected from the Departments of Management, Geography, Political Science, or Economics;
- One faculty or administrative staff member selected from a non-science discipline.

### Ex Officio Members

- An Associate Dean of Faculty who also serves as IRB Chairperson

The membership of the IRB will appoint a Secretary who will be responsible for the minutes of the IRB meetings.

Each IRB member should be knowledgeable with regard to basic ethical principles related to human subjects research and the function of the IRB. At a minimum each IRB member will complete the same training required of individuals submitting IRB proposals. These requirements are described in Appendix E.

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 (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 Principal Investigator.

Each department that regularly conducts or anticipates human subjects research will appoint a departmental reviewer who will serve as a representative of the IRB with responsibility for the initial review of human subjects research proposals. Each department will also designate an alternate reviewer who will serve (a) if the primary departmental reviewer has a human subjects research proposal that must be reviewed, or (b) if the departmental reviewer anticipates a significant period of absence or unavailability, and delegates responsibility to the alternate reviewer. Departmental reviewers may occasionally be called upon to review research proposals originating outside the department. Examples include: (a) proposals from related departments that do not have a regular reviewer of their own; or (b) proposals from non-Bucknell investigators (forwarded by one of the academic deans) seeking permission to do human subjects research at the University in the reviewer's discipline.

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 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 (PI) who are planning research projects involving human subjects are responsible for initiating the review process by submitting their research proposals and all necessary forms and attachments through the IRB's online submission system (see Sections V, VI and Appendices) to the appropriate individuals designated below.

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. Bucknell's IRB has determined a list of training modules that must be completed by all human subjects investigators. Several additional modules are also required for certain special categories of research (research with children, research with prisoners, etc.). Appendix E provides a list of the training modules that Bucknell requires, with directions for accessing the training website. Investigators must attach a PDF of their completion report as part of the material they submit online. These reports are available after completing the training program.

Electronic Submission. To expedite the management of a large volume of human subjects research proposals, all materials must be submitted for IRB review through the online submission system located at <http://my.bucknell.edu/irb.html>. A list of the questions asked as part of the online submission process for exempt, expedited and full proposals is included in Appendix F.

#### Directing Proposals for Initial Review

- A. Faculty member - Submit proposal through the online submission process. Your proposal will be routed to your departmental reviewer and then to the IRB chair. If there is no departmental reviewer it will be routed directly to the IRB Chair.
- B. Staff member - Submit proposal through the online submission process. Your proposal will be routed directly to the IRB Chair
- C. Student - Submit proposal through the online submission process. The proposal system will route the proposal to the faculty advisor or sponsor, and will then route the proposal to the appropriate departmental reviewer.
- D. Non-Bucknell investigator
  - Secure a Bucknell faculty or staff sponsor and submit your proposal through the online submission process. (See Section XVII)

All research proposals are evaluated by the departmental reviewer, 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):

**Minimal Risk** -- 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 IRB will provide the departmental reviewer with a set of forms to aid in the determination of risk (see Section V and Appendices).

Once the departmental reviewer (or IRB chair) 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 Principal Investigator 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.
- B. Expedited Review - no more than minimal risk to human subjects.
- C. Full IRB Review - greater than minimal risk to human subjects.
- D. Proposals involving no foreseeable risk will be considered exempt, and will require no further review beyond the departmental level before the research can be initiated. The departmental reviewer will notify the IRB Chair of each exemption decision, and forward a copy of the protocol for the IRB files.

Proposals determined by the departmental reviewer to involve minimal or more than minimal risk will be forwarded to the chair of the IRB for review.

- A. If the proposal involves only minimal risk, an expedited review will be conducted by the chair or at least one other member of the IRB designated by the chair (see Section IV(B)).

- B. For proposals judged by the departmental reviewer to involve greater than minimal risk), the chair of the IRB will schedule a full IRB review (see Section IV(C)).

If there is a disagreement between the IRB chair and the departmental reviewer as to the correct category of IRB review, the two individuals will discuss the matter until an agreement is reached. Failing such an agreement, the higher of the two proposed categories of review will prevail.

There are four possible outcomes to an expedited or full review (see Section XV for further information):

1. Approved -- no further action is required before the investigator may initiate the study.
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.
3. Deferred – requires substantial clarification or modification, and must be resubmitted to the IRB.
4. Denied -- the proposed research, because of the level of risk involved, cannot be initiated. NOTE: A research protocol can only be denied after consideration by the full IRB (see Section XV).

Approved research that is continuing must be reviewed at least once a year by the IRB (see Section IX). 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 investigator. 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 scheduled meeting (see Section XVI on Appeals).

## IV. CRITERIA FOR REVIEW CATEGORIES

All research, including that which the investigator believes falls into the exempt category, must be submitted to the departmental reviewer 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

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 (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 (Exception: Research with subjects under the age of 18 may still be considered exempt if the subjects 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.
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, 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). [NOTE: All survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt, whether or not data collection is anonymous.]
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 IV-B).

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

## V. ONLINE SUBMISSION SYSTEM

The online submission system can be found at the following URL:

<http://my.bucknell.edu/irb.html>. This system was designed to facilitate the processing and record keeping associated with IRB proposals.

All IRB proposals must be submitted through the online process. For students the process will route proposals first to the faculty sponsor or project adviser and then to the appropriate departmental level reviewer if one exists (not all departments have departmental reviewers). For faculty the process will route proposals to the appropriate department level reviewer or the IRB Chair.

The following recommendations are helpful in facilitating the completion of the online process:

1. A list of the questions that you will be asked during the online process is available in Appendix F. The questions are different depending on the level of required review (exempt, expedited, full). These questions can be used to help develop your responses for the online application ahead of time. The system will prompt you for your responses and it is possible to then cut and paste responses into the appropriate boxes on the application. Responses to all questions are required before you are able to move on to the next section of the proposal. *Note: Even “exempt” projects must be submitted through this on-line process.*
2. The questions in the on-line application are broken into two main sections. Section I focuses on determining the appropriate level of review. Section II asks specific questions about your study including its purpose, proposed subject sample, sample recruitment, methods/procedures, benefits to subjects, and the relationship of the researcher to study participants.
3. At the end of the process there is an opportunity to append multiple documents to your online submission. These documents may include instruments used in the study, interview protocols, informed consent documents, and associated research proposals. These can be attached either as Word or PDF documents. While you may choose to reference these documents within your responses to the various

prompts, it is most helpful to provide a complete response to each question.

4. In order for your proposal to be considered for review, you must append a PDF of your CITI completion report. CITI training requirements are described in Appendix E. If you cannot locate a copy of your completion report, you can print a new one by logging into the CITI system at [www.citiprogram.org](http://www.citiprogram.org). You can either choose to print as a PDF (under the print menu on your browser) or you can print a hard copy and then scan it.
  
5. The system is designed to save your work. A “save” button is located at the bottom of each page. This is useful if you cannot complete the proposal in a single session.

## VI. PROPOSAL COMPONENTS

Each proposal submitted through the online submission system 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
- A description of the subject population, including the gender and racial/ethnic composition, and criteria for the inclusion or exclusion of any sub-population.

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 all Bucknell students, from which some sample will be recruited for the experiment. Statistics on the race, ethnicity and gender of the Bucknell student body are available from the Institutional Research Office. 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. Studies of populations outside the University setting will require diversity data from other sources.

- A description of the means by which subjects will be recruited
- A discussion of any and all risks to subjects, and how any such risks will be minimized (include copies of all survey instruments , consent forms, assent forms, recruitment flyers, sample recruitment letters and advertisements).

## VII. RECORDS RETENTION

All records must be retained by the PI and the IRB 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.

## VIII. TIMETABLE

The IRB will meet bi-weekly 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 University 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 (see Section XV-C) will be reviewed at the next scheduled meeting. Research proposals in need of expedited review may be submitted through the online submission process at any time. Departmental review timetables are left to the discretion of the departments and their reviewers. The IRB is available as an advisory board if there are any questions regarding the review process and categories of review.

## IX. CONCLUDING AND CONTINUING PROJECTS

### Concluding Projects

Investigators should notify the IRB Chair upon completion of the data-collection phase of their research so that the IRB may close its records on the project.

If the IRB chair receives no confirmation of the status of your project it is assumed that your project is complete.

### 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 request for renewal/continuation, through the online submission system 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.

To avoid interruptions in an ongoing research project, the IRB recommends that requests for continuation be submitted no later than 30 days before the anniversary date of the project.

External Verification – As part of each request for continuation, the IRB will consider whether to require verification from sources other than the PI (“external verification”) that no material changes have occurred since the previous IRB review. Two circumstances may justify this additional requirement:

1. complex projects involving unusual levels of risk;
2. projects by investigators with a history of non-compliance.

## X. 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.

Consent documents must be clearly written and understandable to subjects. The consent form should include language that is non-technical. Scientific, technical, or medical terms should be plainly defined.

The required components of an informed consent document include:

- A statement that this is a Bucknell University research project
- An explanation of the purposes of the research
- The expected duration of the subject's participation
- The anticipated number of subjects participating in the study
- A detailed description of the procedures to be followed
- A description of any foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others (society, student learning) that may reasonably be expected from the research
- A statement regarding anonymity or confidentiality. If records identifying the subject will be maintained, indicate the extent to which these will be kept confidential.
- If deception is involved (see Section XIII), 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."
- 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.”
- Dated signatures for subject and investigator. The use of witness signatures by the Principal Investigator is optional unless specifically required by the IRB .
- The date of IRB approval of the project (date of e-mail notification) and the expiration date of that approval (generally one year from approval unless otherwise specified in the approval notification message). These items must be added as a footer to the consent form as soon as final IRB approval is received.

(See Appendix A-1 (Components of Informed Consent Documentation) and A-2 (Sample Informed Consent Documentation) in the Appendices.)

## XI. PROTECTED CLASSES OF RESEARCH SUBJECTS

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. Although there have been a number of research projects conducted at Bucknell with various protected populations, research with children is by far the most common as a result of the University’s programs in the departments of Education and Psychology. This is the only protected class discussed in detail below. For information on research with other protected groups, you may consult the Federal regulations or a member of the IRB.

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. Whether assent is to be obtained verbally or in writing, a copy of the assent form must be submitted to the IRB with the proposal. (See Appendix B (Sample Assent Form) and Form A-2 (Sample Informed Consent Documentation), in the Appendices).

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.

## **XII. 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; 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.

Note: A waiver of signed consent does not reduce in any way the responsibility of the PI to convey (orally or in writing) all of the elements of informed consent disclosure that are normally found in a signed form.

### XIII. 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.
- The Principal Investigator (PI) should consult first with the departmental representative and/or the chair of the IRB before developing protocols that involve deception that is more severe than incomplete disclosure. (Note: If the PI and the department’s IRB representative are the same person, the PI should consult with the department’s alternate representative, or with the IRB chair.)
- 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.

#### **XIV. GUIDANCE ON CLASSROOM ASSIGNMENTS INVOLVING STUDENT RESEARCH WITH HUMAN SUBJECTS**

In order to help faculty members and students determine whether or not IRB review is necessary for classroom assignments (activities, projects, exercises, etc.), the IRB recommends the following guidelines.

There are three questions that should be considered when determining if a classroom assignment must undergo IRB review:

1. Does the class assignment meet the federal definition of “human participant research” provided by the Department of Health and Human Services in Title 45, Code of Federal Regulations, Part 46

<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html?>

2. Does the class assignment involve more than minimal risk to participants?
3. Does the class assignment involve members of vulnerable populations?

#### Definitions:

##### *Human Participant Research*

In order for research to be considered as human participant research it must involve “a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information” (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). Examples of human participant research include, but are not limited to, observational studies, interview (including those that are open ended) or survey studies, group comparison studies, test development, program evaluation, and interventional research.

Research is defined as any systematic investigation designed to develop or contribute to generalizable knowledge.

Developing or contributing to generalizable knowledge means either that the results of the research activity and any conclusions drawn from it are intended to apply beyond a single individual or classroom and/or are intended to be disseminated in any forum such as professional journals, public presentations or poster sessions. This generally excludes course sponsored presentations. **Those classroom assignments that fall under this definition of research must undergo IRB review.**

##### *Minimal Risk*

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. **Those classroom assignments that pose greater than minimal risk for participants must undergo IRB review.**

### *Vulnerable Populations*

Related to the issue of risk is concern for the wellbeing of individuals who are members of vulnerable populations. These individuals include minors, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons

(<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>). Those classroom assignments that involve members of vulnerable populations as participants must undergo IRB review.

If you anticipate that a planned classroom exercise will involve more than minimal risk or involve members of vulnerable populations, or if there are unique or idiosyncratic elements to your project that do not conform to the descriptions in this document, you should contact Abe Feuerstein, the Chair of the IRB, at 577-1404 ([afeurstn@bucknell.edu](mailto:afeurstn@bucknell.edu)).

If the classroom assignment meets the federal definition of "human participant research" OR the definition of "minimal risk," OR involves individuals who are members of vulnerable populations, then the classroom assignment **must** undergo IRB review.

If the classroom assignment does not meet the federal definition of "human participant research", does not involve more than minimal risk to participants, and does not involve individuals who are members of vulnerable populations as defined above and by 45CFR46, then IRB review is **not** required.

### Examples:

Examples of assignments involving student research with human subjects that must undergo IRB review include but are not limited to the following:

- Undergraduate honor's theses
- Master's theses, case studies, and treatises
- Research exhibitions with audiences that extend beyond members of the Bucknell community
- Presentation at scientific meetings or conferences
- Submission to or publication in professional journals in either paper or electronic format
- Internet postings

Examples of those assignments that do not require IRB review (unless they involve more than minimal risk or members of vulnerable populations) include but are not limited to the following:

- Training activities
- Classroom assignments involving human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods (as in a research methods course)
- Classroom assignments that exist solely to fulfill course requirements to train students in the use of particular methods

### **Best Practices for Assignments that DO NOT Require IRB Review:**

As an extension of Bucknell's policies, the principles of best practice in human subject research apply to all disciplines that use human subjects in classroom assignments, even those that may not normally come under federal review (e.g., artists interviewing passers-by or historians conducting oral history interviews). The IRB Chair and members of the IRB are available for advice and consultation.

The role of the IRB with regard to classroom assignments that don't require IRB review is advisory and consultative. It is the responsibility of each individual faculty member using these types of assignments to:

- A. Complete the Basic Course in human subjects research offered through the CITI website ([www.citi.org](http://www.citi.org)). The Basic Course includes the following 8 modules:
  1. Introduction
  2. History and Ethical Principles -- SBR
  3. Defining Research with Human Subjects -- SBR
  4. The Regulations and the Social and Behavioral Sciences -- SBR
  5. Assessing Risk in Social and Behavioral Sciences -- SBR
  6. Informed Consent -- SBR
  7. Privacy and Confidentiality -- SBR
  8. Research with Protected Populations—Vulnerable Subjects—Overview

- B. Design classroom exercises that are consistent with best practice in human subjects research.
  - The Institutional Review Board can serve as a resource for learning more about methods that ensure the protection of human subjects of research.
- C. Provide consistent oversight of student projects with human subjects.
  - It is the responsibility of the instructor to be sure that student projects meet Bucknell's ethical and scientific standards.
  - It is recommended that all students complete the Basic Course in human subjects research described above.

## XV. OUTCOMES OF IRB REVIEW

For proposals reviewed by the IRB, a letter will be sent to the investigator by the IRB chair, indicating one of four possible actions:

- A. Approved: A protocol that has been approved by the IRB requires no further action from the investigator prior to initiating the study. If the study should extend beyond 12 months, the investigator 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 IX).
- B. Conditionally Approved: A protocol that has been approved on condition may begin as soon as the condition(s) for approval have been met. 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 chair is not completely satisfied that the required conditions have been fully met by the investigator. In that event, the chair will refer the protocol to the full IRB for review.
- C. Deferred: A deferred protocol typically requires substantive clarifications or modifications. 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: 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 (see Section XVI).

## **XVI. 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 Provost/VPAA, 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.

## **XVII. NON-BUCKNELL INVESTIGATORS**

Non-Bucknell investigators should seek out a member of the Bucknell administration, faculty, or staff who would be willing to sponsor their research. Potential research sponsors will need to determine if the proposed research is appropriate for Bucknell. If a willing sponsor is identified, non-Bucknell investigators are also asked to complete the same online process used by Bucknell investigators.

Those individuals unable to identify a sponsor should contact the Chair of Bucknell's IRB.

## **XVIII. RESEARCH CONDUCTED AT OTHER INSTITUTIONS/ OR ABROAD**

If some portion of the research is conducted at another institution, that institution must also review and approve the research protocol. The Bucknell University 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.

In addition, investigators conducting human subjects research abroad should consult <http://www.hhs.gov/ohrp/international/intlcompilation/intlcompilation.html> to determine if there are specific requirements or guidelines that must be followed in the country where the research will take place.

## **XIX. COMMUNICATIONS ---INTERNAL**

### A. IRB Communications to the Campus

1. The IRB will publish an announcement through the Message Center at the beginning of each semester of the schedule of IRB meetings and the lead time required by the IRB for consideration of a research protocol. A schedule of IRB meetings will be made accessible on the IRB website.
2. IRB requirements will be introduced to new faculty each year as part of their orientation.
3. IRB information is included in the Faculty Handbook.
4. The IRB will provide access to policies, procedures and resource material on the Web site and in the file services space of the IRB.

### 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 prior to the expiration date of the previous approval to verify the continuing status of the research project.

### C. Principal Investigator (PI) Communications with the IRB

1. Changes in Ongoing Projects. 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 Chair 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 investigator has taken to respond to the problem. Depending on the nature of the changes and/or adverse events, the chair may require a review by the full IRB.

#### D. IRB Communications with the Administration

1. The IRB will send to the Provost an annual report on IRB activity, including a copy of the IRB activity log.
2. The IRB will report immediately via e-mail to the Provost and to the University Counsel 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.

## **XX. COMMUNICATIONS – EXTERNAL**

1. The IRB will notify OHRP of when there is a change in the members serving on the committee.
2. The IRB will notify OHRP immediately in the event of any adverse or unanticipated occurrences in a research project.
3. The IRB will notify OHRP if there is any persistent or unresolved non-compliance by a Principal Investigator.

## XXI. E-MAIL AND WEB-BASED SURVEY RESEARCH

Currently, the principal media for electronic surveys are e-mail and the Web, but additional possibilities may emerge through the proliferation of ubiquitous handheld devices that combine phones with text messaging, Internet access, GPS and other capabilities.

### E-mail surveys

Although e-mail is often a convenient and effective way to contact and communicate with potential research subjects, the IRB prohibits the use of e-mail as a data collection medium for any true research surveys of human subjects. E-mail is a fundamentally insecure medium. E-mail messages are typically transmitted to a number of different computers, with multiple possibilities for interception, before reaching their final destination. At each intermediary computer, backups can create additional copies of the original message. Messages may thus reside on one or more servers for extended periods, during which time they may be read, subpoenaed, etc.

Theoretically, it is possible for subjects to return surveys through anonymous re-mailers, but interception and duplication remain possible during the initial transmission, and information on re-mailer servers is still subject to subpoena. It is also possible to conduct secure e-mail surveys with encryption technology, but this is rarely used in actual practice.

In short, subjects cannot be assured of the confidentiality of their data in e-mail surveys. E-mail may be safely used as a vehicle only to contact potential subjects, who may then be given the option to (a) print and return an anonymous survey via campus or surface mail, or (b) go to a Web link to complete an online survey (see below).

### Web Surveys

Training Certification: For Web-based surveys that are considered true research under the federal definition, investigators must first complete the online module in the CITI ethics training program: "Internet Research" (SBR—Social Behavioral Research Track). Completion of this module is in addition to the standard modules that all human-

subjects researchers at Bucknell must complete.

Responsibilities of Web Surveyors: In designing protocols for Web-based research, investigators must consider factors at the “front end” (factors related to survey administration that the researchers can control directly) as well as those at the “back end” (the collection, processing and storage of data behind the Web Survey interface). It is the investigator’s responsibility to assure that the survey is implemented in ways that protect the anonymity of the subjects or the confidentiality of their responses.

Front End Considerations: In reviewing the factors under the direct control of the investigator, the IRB will consider the following questions:

- Will the survey be hosted by Bucknell or by another Web site? If hosted using Bucknell’s survey software (WebSurveyor, now marketed as Vovici), the investigator can expect some standardization of human subject protections (see back-end considerations below). If hosted by another site, it is the responsibility of the investigator to document policies and procedures that provide a level of back-end protection for human subjects that is at least equivalent to that which WebSurveyor (Vovici) provides.
- Does the survey require anonymity or confidentiality?
- How will subjects be recruited? (Examples: e-mail, campus mail, surface mail, departmental subject pool, person-to-person, etc.).
- How will subjects access the survey? Will a login be required? If so, will all subjects receive a single login, or will every subject receive a unique login? This decision relates to requirements for anonymity or confidentiality. If the survey promises anonymity, and unique logins (e.g., BUIDs) are required, the researcher must ensure that login information will not be collected and stored in such a way that it can be connected to survey results
- How will informed consent be secured? Since one cannot collect consent form signatures from subjects completing e-mail or Web-based surveys, these instruments must rely on “implied consent”—that is, those subjects who complete the survey instruments have implied that they consent to the terms and conditions of the study. Investigators are still responsible for providing all of the required elements of informed consent (see Section X) in an introductory screen (for Web surveys) or in introductory text (for e-mail). For Web surveys, it has common to employ “electronic signatures” by having subjects “click” on a box that indicates they have read and agree to the terms and conditions of the study. Other examples of consent procedures include signed consent via mail or in person; consent form e-mailed and signed and returned via campus mail.
- Incentives – The use of prizes or other incentives to encourage participation typically requires identifiable personal information about participants. Incentive programs must be designed with care to ensure that subjects’ confidentiality of responses is not compromised.

Back End Considerations: Data collected on a Web site is transmitted directly to a server, and Web surveys are thus not subject to the same interception risks as e-mail. There are, however, a series of steps in the Web data collection process that require informed consideration by the investigator in light of the protections promised to human subjects.

- Logging in – If subjects are promised anonymity, how will the researcher ensure that no identifying information (e.g. unique logins) will be collected and stored with the survey data?
- Informed consent screen (if necessary) – As noted above, a separate screen, which respondents must view before proceeding to the rest of the survey, will be required unless the protocol makes other provisions for securing consent.
- Scripts – These are programs that collect the data entered into forms and transmit the data to a file or a database. Scripts typically have the ability to collect other information when the data is entered: date, time, and IP address of the computer on which the survey was completed. If a study requires anonymity, the highest level of protection is provided if the scripts do not collect IP address data. Because script data can be useful to system administrators, the IRB requires a secondary level of security is to ensure that the investigators/survey-administrators do not have access to script data (see further information, see discussion of Web log, below).
- Server – Files and databases will reside on a server. An important responsibility of the investigator is to ensure that the server is secure, employing various forms of protection including firewalls and encryption (e.g., Secure Sockets Layer [SSL]). Often, servers used for research purposes are also dedicated (used only to collect survey data). It is possible, however, to develop a secure survey on a server that is used for multiple Web applications (e.g., [www.facstaff.bucknell.edu](http://www.facstaff.bucknell.edu)). Servers also have Web-logs that record key information (including IP address) of every visitor or survey participant. For anonymous data collection, turning off the Web log provides the highest level of protection. Web log data, however, is valuable to system administrators in tracking problems. An alternative is to document that Web logs are accessible only to system administrators and will never be shared with the experimenter. In such a case, the survey is not strictly anonymous, but it is anonymous to the investigator.
- When data is received by the server, it should also separate immediately any identifiable personal information from the actual survey data.
- Backups – All servers must be backed up to another location to protect the data. The backup server should have the same protections (described above) as the server that stores the original survey data.
- If you are using Bucknell's WebSurveyor (Vovici) software to conduct online surveys, you can assume that your data is secure. If you use another on-campus Web server, you should treat it like a survey hosted off-campus and document that the data is secure according to the standards described above.

Revision Date:

April 25, 2011

## Appendix A-1: Components of Informed Consent Documentation

The consent form must include:

1. A statement that the study involves research, a readily understood explanation of the purpose(s) of the research and the expected duration of the subject's participation, a simple description of the procedures to be followed, identification of any procedures which are experimental, and if deception will be involved. If deception is involved, there should be an indication that the research cannot be fully described at this time, but that at the conclusion of the subject's participation an explanation will be provided.
2. A description of any risks or discomforts to the subject that can be reasonably foreseen. These include not only physical injury, but also possible psychological, social or economic harm, discomfort or inconvenience.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research (if no direct benefit, this should be stated).
4. A statement concerning costs or compensation to the subject, if any.
5. Identification of the person to contact for answers to pertinent questions about the research and research subject's rights, and who to contact in the event of a research-related injury to the subject. Phone numbers and e-mail addresses should be provided. **NOTE:** If research is related to a federal grant, questions about the research should be directed to the PI; questions about the rights of research subjects or research-related injuries should be addressed to the IRB Chair. This information must be stated in the consent form, together with phone numbers for the PI and the IRB Chair.
6. Description of the extent, if any, to which confidentiality of records identifying the subject will be maintained.
7. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may refuse to answer any questions s/he does not wish to answer and/or may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
8. If deception is used, include a statement to the effect that the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided. (Provide a copy of the debriefing script.)

9. The consent form should conclude with:
10. a statement that the subject has had all questions about the research answered to his or her satisfaction and agrees to participate in this research;
11. an acknowledgement that the subject has received a personal copy of the consent form, signed and dated by the subject.
12. The use of witness signatures in consent or assent forms is optional for the Principal Investigator, unless specifically required by the IRB.

## Appendix A-2: Sample Informed Consent Documentation

1. Project Name:
2. Purpose of the research:
3. General plan of the research:
4. Estimated duration of the research: \_\_\_\_\_
5. Estimated total number of subjects: \_\_\_\_\_
6. The subject is encouraged to ask any questions at any time about the study and its procedures, or his/her rights as a subject.
7. The investigator's name, address, telephone number and e-mail address are included below so that the subject may ask questions and report any study-related problems. The investigators will do everything possible to prevent or reduce discomfort and risk, but it is not possible to predict everything that might occur. If a participant has unexpected discomfort or thinks something unusual or unexpected is occurring s/he should contact \_\_\_\_\_. (Provide the names and telephone numbers of the persons to contact: (a) for answers to pertinent questions about the research and research subject's rights; or (b) in the event of a research-related injury to the subject.) NOTE: If research is related to a federal grant, questions about the research should be directed to the PI; questions about the rights of research subjects or research-related injuries should be addressed to the IRB Chair. **This information must be stated in the consent form, together with phone numbers for the PI and the IRB Chair.**
8. Subject participation is voluntary. Anyone who agrees to participate in this research may change his/her mind at any time. Subjects may refuse to answer any questions and/or withdraw from the study at any time without penalty or loss of benefits to which they are otherwise entitled.
9. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent:
10. The terms of compensation to the subject for study participation:
11. Participation in this research may result in the following benefits either to the subject, others, or the body of knowledge:
12. The information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study

- unless the subject specifically gives permission, in writing, to do otherwise. No reference will be made in oral or written reports which would link the subject to the study.
13. This research may result in the following discomforts
  14. Participation in this research may result in the following risks:
  15. In the unlikely event of physical injury resulting from the subject's participation in the research, emergency medical treatment will be provided at no cost to the subject. The subject should immediately notify the investigator if s/he is injured. If the subject requires additional medical treatment s/he will be responsible for the cost. No other compensation will be provided if s/he sustains an injury resulting from the research.
  16. If subjects are minors, use the following guidelines for obtaining consent:
    - Six years and younger - only parent(s)/guardian/legal representative must sign. Secure oral assent from the subject.
    - Seven and eight years - signature of minor is optional, signature of parent(s)/guardian/legal representative is required. Secure oral assent from the subject.
    - Nine through seventeen years - requires signature of minor on assent form and signature of parent(s)/guardian/legal representative on consent form.
  17. If the subjects are to be audiotaped or videotaped, explain how this material will be used.
  18. If deception is used, include a statement to the effect that the research cannot be fully described at this time, but at the conclusion of participation, an explanation will be provided. Provide a copy of the debriefing script.

I have read the above description of the research. Anything I did not understand was explained to me by \_\_\_\_\_ and I had all of my questions answered to my satisfaction. I agree to participate in this research, and I acknowledge that I have received a personal copy of this signed consent form.

By signing below, I affirm that I am at least 18 years of age or older.

Signature of Subject: \_\_\_\_\_ (Date)

Signature of parent or legal guardian,  
if subject is a minor: \_\_\_\_\_ (Date)

## Appendix B: Sample Assent Form

Name of study: \_\_\_\_\_

\_\_\_\_\_

I understand that I have been asked to participate in a study about:

\_\_\_\_\_

I will be asked to \_\_\_\_\_, which will take about \_\_\_\_\_ minutes. I understand that I do not have to participate. If I do participate, I can quit at any time. I also understand that I do not have to answer any questions I don't want to answer or do anything I don't want to do.

My parents, teachers, or anyone else will not know what I have said or done in the study. No one but the researchers will know.

This study is being done by \_\_\_\_\_ (name of researcher) at Bucknell University. His/her phone number is 570-577-\_\_\_\_ and his/her e-mail address is \_\_\_\_\_.

If I have any questions or concerns about the study, I can call and ask him/her about them.

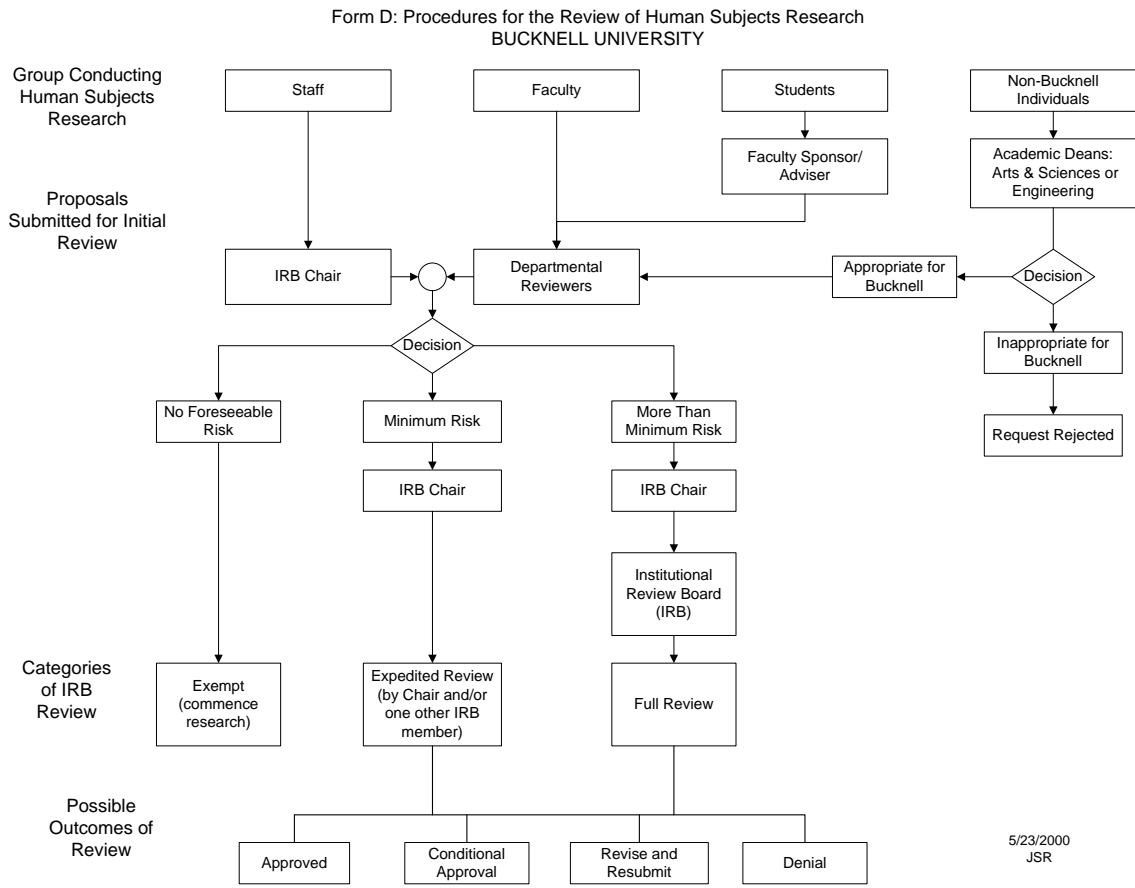
When I sign my name, this means that I agree to participate in the study and that all of my questions have been answered. I have also been given a copy of this form.

Name \_\_\_\_\_

Date \_\_\_\_\_

Signature \_\_\_\_\_

# Appendix C: Flowchart of Procedures for the Review of Humans Subjects Research



## Appendix D: Glossary

**Adverse Effect** – An undesirable and unintended, although not necessarily unexpected, result of experimental interventions.

**Assent** – An agreement by an individual not competent to give legally valid informed consent (e.g., a child or a cognitively impaired adult) to participate in research.

**Assurance** – A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved.

**Autonomy** – Personal capacity to consider alternatives, make choices, and act without undue influence or the interference of others.

**Belmont Report** – A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978. The following is a link to the full text of the Belmont Report:  
<http://ohsr.od.nih.gov/mpa/belmont.php3>

**Best Practice** – The methods and procedures employed by those institutions and/or individuals who are most experienced in a field and are the recognized leaders in terms of the quality of what they do. In terms of human subjects protection, best practice refers to the models which should be emulated in designing research experiments that best protect the rights, privacy and dignity of the subjects or participants.

**Beneficence** – An ethical principle in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do no harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**Benefit** – A valued or desired outcome; an advantage.

**Children** – Persons who have not attained the legal age for consent to the procedures involved in research, as determined under the applicable law of the jurisdiction under which research is conducted.

**Cognitively impaired** – Having either a psychiatric disorder (psychosis, dementia, etc.) or a developmental disorder (retardation) that affects cognitive or emotional functions to the extent that the capacity for judgment and reasoning is significantly diminished. Others, including those under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

**Competence** – Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Deception** – Withholding of information about a research project that might affect the subjects' decision to participate in the study. In its mildest form, deception may involve simply withholding the research hypothesis from the subjects to avoid biasing the results. More severe forms of deception may involve deceiving subjects about the purpose of the study, deceiving them about the status of other individuals who they believe to be subjects (confederates), and deceiving them about the status of individuals supposedly outside of the experiment. In its most extreme form, subjects are not even made aware that they are participating in a research project until the experiment has concluded. All forms of deception violate the fundamental principle of autonomy—the individual's right to self-determination, that is, to freely make a decision to participate or not participate based on full information about the nature of the research. The IRB approves deception research only if its use is carefully justified and when specified conditions are met that restore the autonomy to the individual by the conclusion of the experiment.

**Debriefing** – Giving subjects previously undisclosed information about the research project following completion of their participation in the research. (Note that this usage, which occurs within the behavioral sciences, departs from standard English usage, in which debriefing involves obtaining rather than imparting information.)

**Equitable** – Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed.

**Exempt** -- A project that does not require further review after initial consideration by a member of Bucknell's IRB or a Departmental Representative to the IRB. Exemptions are granted based on criteria specified in the federal regulations: (1) information will not be recorded by investigators in such a manner that subjects can be identified, directly or through identifiers; AND (2) disclosure of subject responses will not reasonably place subjects at risk of criminal or civil liability, or be damaging to the subjects' financial standing, employability, or reputation. Note that the investigator cannot make a judgment of exempt status on her/his own; a member of the IRB or someone designated by the IRB must still conduct an initial review.

**Expedited Review** – Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research.

**Full Board Review** – Review of proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting.

**Guardian** – An individual who is authorized under applicable state or local law to give permission on behalf of a child to participate in research.

**Human Subjects** – Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human

subjects are defined as: living individuals about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information.

**Informed Consent** – A person’s voluntary agreement, based upon an adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.

**Institutional Review Board (IRB)** – A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research.

IRB – See Institutional Review Board.

**Justice** – An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly.

**Legally Authorized Representative** – A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research.

**Minimal Risk** – 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, physiological or psychological examinations or tests.

**OHRP** – Office of Human Research Protections – An office within the U.S. Department of Health and Human Services.

**OPRR** – Office for the Protection from Research Risks – A former office within the U.S. Department of Health and Human Services that was elevated to the Office of Human Research Protections (OHRP) within the Office of Public Health and Science (OPHS) in 2000.

**Principal Investigator** – The scientist or scholar with primary responsibility for the design and conduct of a research project.

**Prisoner** – An individual involuntarily confined in a penal institution, including persons: (1) sentenced under a criminal or civil statute; (2) detained pending arraignment, trial or sentencing; (3) detained in other facilities (e.g., for drug detoxification or treatment of alcoholism) under statutes or commitment procedures providing such alternatives to criminal prosecution or incarceration in a penal institution.

**Privacy** – Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**Protocol** – The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the experimental procedures, and the proposed methods of analysis that will be performed on the collected data.

**Research** – A systematic investigation (i.e., the gathering and analysis of information) designed to develop or contribute to generalizable knowledge.

**Respect for Persons** – An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**Review (of Research)** – The concurrent oversight of research on a periodic basis by an IRB. In addition to reviews at least annually, as mandated by federal regulations, reviews may also, if deemed appropriate, be conducted on a continuous or periodic basis.

**Risk** – The probability of harm or injury (physical, psychological, social or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only “minimal risk.”

**Voluntary** – Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject’s decision to participate (or to continue to participate) in a research activity.

## Appendix E: Training Requirements

Federal regulations 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. Bucknell has contracted with the University of Miami to provide the necessary training. Investigators can register for the training at the following address:

[www.citiprogram.org](http://www.citiprogram.org)

The CITI Course site is best viewed with Internet Explorer version 5.0 or later. Once you complete the registration process, you will receive a username and password. When you log on, you will be taken to a Menu page, where you will click on the link for the “Basic Course.” Bucknell has defined the content of the Basic Course to include the eight modules listed below that are required of all Bucknell investigators. Each module is followed by a few mastery questions. The time to complete the entire program is approximately 2.5 to 3 hours. Upon completion of the eight modules with a minimum score of 80% correct, participants will be able to print a dated certificate of completion, a copy of which must be included with the materials submitted for IRB review. Note that “SBR” refers to the “Social and Behavioral Research” track, which is appropriate for most investigators at Bucknell.

1. Introduction
2. History and Ethical Principles -- SBR
3. Defining Research with Human Subjects -- SBR
4. The Regulations and the Social and Behavioral Sciences -- SBR
5. Assessing Risk in Social and Behavioral Sciences -- SBR
6. Informed Consent -- SBR
7. Privacy and Confidentiality -- SBR
8. Research with Protected Populations—Vulnerable Subjects—Overview

The IRB also requires that investigators conducting certain kinds of research complete additional modules as described below. The IRB will confirm these additional requirements during the review process.

For investigators working with Children or in Schools (e.g., most Education Department investigators):

1. Research with Children - SBR
2. Research in Public Elementary and Secondary Schools -- SBR

For investigators working with Minors, but not in a school setting:

1. Research with Children -- SBR
2. Vulnerable Subjects—Research Involving Minors

For investigators in Anthropology/Sociology:

1. Group Harms: Research with Culturally or Medically Vulnerable Groups

For investigators working with Prisoners:

1. Research with Prisoners -- SBR
2. Vulnerable Subjects – Research with Prisoners

For investigators conducting International research:

1. International Research – SBR

For investigators working with Records rather than live subjects:

1. Records-Based Research

For investigators conducting Internet-based research:

1. Internet Research – SBR

## Appendix F: Overview of Proposal Elements in the Online Submission System

The IRB will no longer accept paper submission of proposals. This appendix is provided as a guide for those who would like to develop responses to the online prompts prior to beginning the online submission process.

### All IRB Proposals (Exempt/Expedited/Full) Need to Complete the Following in the Online Submission System

#### Research Review Status Self-Report

Principal Investigator (PI):

Institutional Sponsor Username:

If Applicable Use the [Directory](#)  to find your sponsor's

Project Title:

Campus Address:

Email:

Phone:

PI Status:

Faculty  Staff  Student  Non-Bucknell

Title is required. Principal Investigator is required.

### (A) PROPOSALS REQUIRING FULL REVIEW WILL COMPLETE THE FOLLOWING:

#### Part I:

1. \_\_\_ The research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects. [NOTE: The accompanying proposal must indicate clearly why the use of subjects in any of these categories is scientifically necessary.]
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. [NOTE: The accompanying proposal must indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.]

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).

[NOTE: The accompanying proposal must indicate clearly why the collection of such information is scientifically necessary and what steps will be taken to preserve subject's anonymity/protect subject's confidentiality.]

4. \_\_\_ The procedures of this research involve more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated 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). [NOTE: The accompanying proposal must identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures, indicate clearly how such risks to subjects are reasonable in relation to anticipated benefits, describe procedures designed to protect against or minimize such risks, and assess their likely effectiveness.]

5. \_\_\_ This research does not fall into any of the categories explicitly identified as qualifying for exempt or expedited status.

#### **Part II:**

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 sample's expected age range. If your research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as subjects, you must indicate clearly why the use of these subjects is scientifically necessary.

3. How will subjects be recruited and selected?

4. Describe fully the following:

a) all research methods and procedures that will be employed in this study.

b) approximately how much time each subject is expected to devote to the research.

c) 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 electronic copies of all written instruments (if you do not have them in electronic form, forward copies via campus mail) and/or describe any apparatus with which subjects will be in direct contact.** Please respond appropriately if any of the following conditions apply.

i) if 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 or be damaging to the subject's financial standing, employability, or reputation or the collection of information regarding sensitive aspects of the subjects' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior), indicate clearly why the collection or recording of such behavior is scientifically necessary and what steps will be taken to preserve subjects' anonymity/protect subjects' confidentiality.

ii) if the research presents more than minimal risk to the subject (where more than minimal risk means that the probability and magnitude of harm or discomfort anticipated 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), you must: a) identify all risks (physical, psychological, financial, social, legal, other) connected with the proposed procedures; b) indicate clearly how such risks to subjects are reasonable in relation to anticipated benefits; c) describe procedures designed to protect against or minimize such risks; and d) and assess the likely effectiveness of any such procedures.

iii) if the research involves any of the following: covert observation, studies of ethnic and group differences, intervention research, invasion of privacy, aversive (noxious) stimulation, induction of mental or physical stress or deprivation (e.g., food, water, sensory, sleep), invasive procedures (e.g., drugs, blood, samples, surgery), potentially embarrassing situations, or other ethical issues concerning the dignity and welfare of the participants, describe these in detail, indicate why they are scientifically necessary, and describe any steps that will be taken to minimize risk and maximize benefit to the subjects.

c) methods for obtaining informed consent and assent in the case of minors. For minors, indicate how their assent and the consent of parents or legal guardians will also be obtained. **Append electronic copies of all materials used to obtain informed consent or assent. Model consent and assent forms can be found in the Appendices (Appendixes A-1, A-2, and B).**

d) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

e) if deception is to be employed, provide a scientific justification for its use and describe debriefing procedures. If, for any reason, it will not be possible to debrief subjects regarding the deception, this must be explained and justified.

5. 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?

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. If the research presents more than minimal risk to subjects, discuss benefits to the subjects, to science, and/or to society that will result from this work in relationship to those risks. [NOTE: You must be able to show that the overall benefits to be gained from the research justify whatever risks subjects are asked to take.]

**(B) PROPOSALS REQUIRING EXPEDITED REVIEW WILL COMPLETE THE FOLLOWING:**

**Part I:**

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 I: Continued**

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; research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required; 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 2:**

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 sample's expected age range.

3. How will subjects be recruited and selected?

4. Describe fully the following:

a) all research methods and procedures that will be employed in this study.

b) approximately how much time each subject is expected to devote to the research.

c) 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 electronic copies of all written instruments (if you do not have them in electronic form, forward copies via campus mail) and/or describe any apparatus with which subjects will be in direct contact.**

d) methods for obtaining informed consent and assent in the case of minors. For minors, indicate how the consent of parents or legal guardians will also be obtained. **Append electronic copies of all materials used to obtain informed consent or assent. Model consent and assent forms can be found in the Appendices (Appendixes A-1, A-2, and B).**

e) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

f) 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.]

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?

**(C) PROPOSALS BELIEVED TO BE EXEMPT FROM FURTHER REVIEW WILL COMPLETE THE FOLLOWING:**

**Part I:**

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 I Continued - below). **Studies under Part I Continued-question 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 I: Continued** (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).  
[NOTE: Survey/interview/observational research in which elected or appointed public officials or candidates for public office serve as subjects is exempt whether or not data collection is anonymous].
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:
  - (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;
  - (iv) 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 II

Please provide the information that is requested below. For exempt research, submission of a formal research proposal is not required. However, if the information requested below is contained in clearly identified fashion in a research proposal, you may append the proposal in lieu of completing some or all of the items below as long as you

indicate where in the proposal (give page, line numbers) the relevant information can be found.

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 fully the following:

a) all research methods and procedures that will be employed in this study.

b) approximately how much time each subject is expected to devote to the research

c) 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.

d) methods for obtaining informed consent or assent in the case of minors. For minors, indicate how the consent of parents or legal guardians will also be obtained. **Append copies of all materials used to obtain informed consent or assent.**

e) methods for preserving confidentiality (including plans for storing/disposing of tapes and other data records at the conclusion of the research).

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?