Institutional Review Board
Sponsored Programs Office, Buckham Hall B-206
1300 Elmwood Avenue, Buffalo, NY 14222
Federalwide Assurance ID#: 00007126

AN INVESTIGATOR'S GUIDE TO RESEARCH WITH HUMAN PARTICIPANTS

The purpose of this guide is to assist investigators planning to conduct research involving human participants in designing their research and submitting it for approval. The review of human participants research at Buffalo State is intended to result in mutually acceptable research procedures which accomplish the investigator's objectives while protecting the rights and welfare of the participants. **These guidelines do not cover every research possibility. Please contact the Research Compliance Manager for questions you may have regarding specific human participants research procedures. For additional guidance an "Investigator's Checklist for Human Participants Compliance" is available on the Sponsored Programs website (sponsoredprograms.buffalostate.edu).**

I. FREQUENTLY ASKED QUESTIONS

WHAT is human participants research?

Human participants research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge, which involves the collection of data from or about living human beings. In addition, all student research involving participants outside their own classroom would be considered in this category.

WHY must it be reviewed?

It is College policy to ensure that the rights and welfare of human participants are protected in research conducted under its auspices. Both Federal and State laws require this protection. In order for the College to fulfill its responsibility, **all** human participants research conducted under its auspices - **funded or unfunded** - must receive appropriate approval.

WHO must submit it?

Human participants research must be reviewed if it is conducted by any faculty, staff, or student under the auspices of the College.

HOW is it submitted?
Human participants research protocols are submitted via the SUNY RF PACS IRB module. This system is a new online administrative tool designed to help researchers and administrators better manage grants. The link to the portal can be found on Sponsored Programs website (**sponsoredprograms.buffalostate.edu**).

WHO reviews it?
The College has named a Research Compliance Manager who determines Exempt research, and it has authorized the Institutional Review Board (IRB) to review and approve all other human participants research. The IRB is a campus-wide committee made up of faculty, administrators, and an off-campus representative. Certain categories of research may be eligible for less intensive review procedures (**Expedited Review**) than review by the entire IRB. Some student research may be reviewed at the **Department Level**.

WHEN does it have to be submitted?
According to College policy, all research on campus must be approved prior to conducting the research. When submitting protocols, allow a minimum of two weeks for adequate review. If you are submitting a **grant proposal** for your project, you are required to submit the human participants protocol after the initial peer review**. A copy of the grant submission must also be included with your human participants protocol unless it is already on file in the Sponsored Programs Office**.

WHAT if I disagree with the decision of the IRB?
The investigator is given the opportunity to respond to the review. The response will be discussed under the full review process, in which the investigator will be asked to attend the IRB meeting to discuss the study with the IRB, and explain their reasons for the disagreement.

WHERE can I get additional assistance?
The Research Compliance Manager is available in the Sponsored Programs Office at 716-878-5723 or gameg@buffalostate.edu and can assist faculty, staff and students in submitting their protocols for review. You can also access information on Sponsored Programs website (sponsoredprograms.buffalostate.edu).

II. APPROVAL AND REVIEW PROCEDURES

A. Planning a Research Project
Investigators conducting research involving human participants are advised to contact the Research Compliance Manager as early as possible with any questions regarding their research. Problematic aspects of a project will be discussed and alternative procedures suggested.

B. Determining Human Participants Involvement
The initial determination as to whether a research project should be considered human participants research is made by the investigator. He/she should consult the Research Compliance Manager for advice on this question. **Final authority for making this determination rests with the IRB or its designee.** In general, research that involves data

gathered solely for internal, on-campus use would not need to be reviewed (e.g., course evaluation or institutional research).

C. Education Requirement

All faculty members conducting human subjects research or supervising student research need to complete ethics training, as specified by the federal regulations. All students conducting human subjects research also need to complete this training. Although researchers may complete other federally-approved training programs to satisfy this requirement, we encourage researchers to complete the CITI program, for which the College has a site license. To access this training, visit the CITI website.

D. Project Review Categories

Once it has been determined that an activity is to be considered human participants research, it will be handled under one of four categories**, "Department Review," "Exempt Research," "Expedited Review" or "Full Board Review."** All human participants research protocols, excluding Department Review, must be submitted via the SUNY RF PACS IRB system. The Research Compliance Manager will determine the level at which the protocol will be reviewed.

1. Department Review (Level 1) – Department Level Review Checklist

Certain student research projects do not have to be submitted for Institutional Review Board approval but should be reviewed at the department level. Projects that may be reviewed at the Department Level include laboratory projects, educational exercises and class projects, and action research within a classroom with performance or grades as the sole outcome measure. Each department is to designate one representative to the IRB to serve as the reviewer for Department Level protocols.

In order to qualify for Department Level Review, the research must be disseminated only within the BSC campus. For example, research presented at the Student Research and Creativity Celebration or theses bound and filed in the library may be reviewed departmentally, but any research that will be presented at regional or national conferences or published in journals should be reviewed at the Exempt, Expedited, or Full Board levels.

All faculty research, all research that may be risky or on a sensitive topic, or that includes children, except as noted for action research, must be reviewed at the Exempt, Expedited, or Full Board levels.

2. Exempt Review (Level 2)

Certain types of research may be exempt from IRB review. Examples include:

(1) Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(3)(i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a

prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

(4) Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*

(5) Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and

demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

(ii) [Reserved]

(6) Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

(7) Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

(8) Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with §46.116(a)(1) through (4), (a)(6), and (d);

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §46.117;

(iii) An IRB conducts a limited IRB review and makes the determination required by §46.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

When appropriate, the limited review procedure is carried out by the IRB chair or one or more experienced reviewers designated by the IRB.

3. Expedited Review (Level 3)

The authorized designee or the IRB carries out the review. The designee may approve the project, request additional information, or submit the proposal to the IRB for Full Board Review

and approval. The IRB may require a Full Board Review to reconsider any protocol approved under the expedited review process. The investigator is notified if a Full Board Review is required. If the investigator questions any determination made under the expedited review, he/she has the option of requesting full review by the IRB, which will make the final determination. Some examples include:

- Educational research involving no interaction with students; e.g., observation of intact classes without modifying or disrupting regular classroom activity.
- Research involving the use of educational records if information taken from these sources is provided to the researcher in such a manner that participants cannot be identified.
- Research on individual or group behavior of normal adults where there is no psychological intervention, physiological intervention or deception, or interviews and interactive surveys on non-sensitive topics, assuming the research is not exempt.
- Continuations and/or modification of proposals initially approved under the full review process if they present no additional risks to participants.

4. Full-Board Review (Level 4)

The review is conducted at the next convened meeting of the IRB. You will be advised in writing of the IRB's decision. Notification will indicate if your protocol has been given final approval, if additional information/clarification is required, or if there are any changes to be made in order to receive final approval. On rare occasions, if the protocol has been disapproved, the investigator will be requested to attend an IRB meeting to discuss the study. Some examples include:

- Research which might put participants at risk, such as research on domestic violence or illegal drug use
- Research involving psychological or physiological intervention
- Non-curricular, interactive research in schools
- Research involving deception
- Interviews or surveys on sensitive topics
- Research on special populations (e.g., minors, prisoners, and the mentally incompetent)
- Research conducted outside the United States, regardless of the procedures involved

(For additional information see "Socially Sensitive Research" and "Policy for Research Involving Minors" available on the Sponsored Programs website (sponsoredprograms.buffalostate.edu).)

E. Review Criteria

No evaluation is made of the scientific merit of the project, unless participants are found to be "at risk," at which time the risk/benefit ratio of the project will be evaluated. Review of protocols focuses on issues such as risks to participants, informed consent, voluntary participation, equitable selection of participants, and maintaining confidentiality. Issues include:

- **Risk/Benefit:** Risks to participants are minimized by using sound research design procedures. Risks to participants are reasonable in relation to anticipated benefits to participants, and/or the importance of the knowledge that may be expected to result from the research.

- **Equitable Selection of Participants and Recruitment:** Selection criteria should consider all populations that might potentially benefit from the research. The recruitment of participants is equitable and free of coercion.
- **Informed Consent Process:** Informed consent will be sought from each prospective participant or the participant's legally authorized representative and will be appropriately documented, in accordance with Federal regulations.
- **Privacy and Confidentiality:** Adequate provisions have been taken to protect the privacy of participants and for ensuring the confidentiality of an individual's participation and confidentiality of study data, as appropriate.
- **Special Populations:** When some or all of the participants are likely to be vulnerable to coercion or undue influence (such as children, prisoners, pregnant women, handicapped or mentally disabled persons, or economically or educationally disadvantaged persons), additional safeguards must be included in the study to protect the rights and welfare of these participants.

F. Additional Materials

The following items, where appropriate, must be uploaded with your request for review:

- Consent / Assent form(s)
- Recruitment materials
- Copies of all questionnaires/surveys/interview questions
- Site agreement form(s)
- If you are applying for a grant, submit a copy of the grant application unless it is already on file in the Sponsored Programs Office.

(For additional information see "Investigator's Checklist for Human Participants Compliance" on the Sponsored Programs website (sponsoredprograms.buffalostate.edu).

G. Continuations

The revised federal regulations no longer require continuing review for Exempt and some Expedited review studies. The revised federal regulations also no longer require continuing review for full-board studies for which data collection is complete and the only research activities are data analysis and write up. If this change applies to your study, there will simply be no ending date listed on your letter of approval. However, we would appreciate it if you would close your study in the online SUNY Pre-Award and Compliance System (SUNY PACS) IRB when it is completed so that we can know what research is ongoing on our campus.

H. Modifications

No changes to an approved protocol can be implemented until the changes have been approved. This includes subject recruitment methods, consent form changes, survey changes, etc. Submit a modification in SUNY RF PACS with all supporting documents, e.g., questionnaires, recruitment flyers, consents, etc. (Create and Submit a Modification / Continuing Review)

I. Suspension or Termination of IRB Approval of Research

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with

unexpected serious harm to participants. Investigators will be given the opportunity to respond to the IRB and will be invited to an IRB meeting.

Research Conducted Without IRB Approval
ALL research using human participants on campus must be approved prior to conducting the research. For research conducted without approval, the IRB has the authority to decide if the researcher:

- Can use the data already collected
- Must provide proof of consent, re-consent participants, or retroactively consent
- Can continue the research and which, if any, modifications need to be made

A letter from the Chair of the IRB will be sent to the investigator, indicating the Board's review, what actions the IRB is requiring, and an opportunity to respond to the IRB.

Program evaluations do not fall under the IRB's purview; however, if an investigator decides to publish data they collected from the program evaluation, they must submit an IRB protocol in Pre-Award and Compliance System (PACS) stating they are conducting a research study with existing data.

III. RECRUITMENT AND OBTAINING INFORMED CONSENT

A. Recruitment of Participants
Investigators are to submit a description of the recruitment process and copies of materials to be used. Recruitment should be free of coercion or undue force and provide enough information for the potential participant to make an informed decision whether or not to participate. Once a potential participant has indicated his/her interest in the study, the process of consent can begin. Recruitment cannot begin until the project has received final approval.

B. Informed Consent
Informed consent is one of the primary ethical principles governing human participants research. It assures that prospective human participants will understand the nature of the research and can knowledgeably and voluntarily decide whether or not to participate. "Informed Consent" means the knowledgeable consent of an individual, or his/her legally authorized representative, who is able to exercise free power of choice without undue inducement or any form of force, fraud, deceit, duress or other form of constraint or coercion. To be informed, prospective participants must fully understand the risks involved, any benefit to the individual or society, exactly what will be expected of them during their participation, and their rights as a participant. **(For guidance see Informed Consent template available on Sponsored Programs website.)**

C. The Consent Process
Informed consent is not a single event, nor is it merely a form to be signed; rather, it is an educational process that takes place between the investigator and the prospective participant. The basic elements of the consent process include full disclosure of the nature of the research and the participant's participation, adequate comprehension on the part of the potential

participants, and the participant's voluntary choice to participate. In the case of student research, the sponsoring faculty member must retain the consent forms.

D. Comprehension

Factors such as age, education level, cognitive ability, and language fluency directly affect subject comprehension of information. Informed consent is not valid unless the consenter understands the information that has been provided. Although no one can guarantee that another person has understood the information, it is the responsibility of the investigator to enhance each prospective participant's comprehension of the information. The investigator should be aware that even if a consent procedure has been approved, it is his/her responsibility to ensure that each potential subject understands the information and to take whatever steps are necessary to facilitate that comprehension. Individuals may not be used as research participants unless they understand the information that has been provided.

E. Voluntary Consent

Consent is a legal concept and only legally competent adults can give consent. Minors cannot give consent – only parents or legal guardians can give consent for minors to participate in research. Incompetent adults cannot give consent – this may include the developmentally disabled, the cognitively impaired elderly, or unconscious or inebriated individuals. Even though children and incompetent adults cannot give consent to participate in research, their **"assent"** or agreement to participate should be obtained whenever possible. In addition, the "deliberate objection" of a subject should be construed as a veto of the consent of a parent or guardian, whether that objection is verbal or non-verbal.

In order to be valid, consent must be freely given. This means that it is **free from all forms of coercion**. In addition, the investigator needs to be sensitive to more subtle forms of coercion, such as social pressure, requests from authority figures, and incentives for participation.

F. Consent in No More Than Minimal Risk Studies

In projects where participants are determined to be at not more than minimal risk:

- Provisions may be made, with the approval, for oral or written presentation and consent. The participant is informed of those basic elements of consent which are applicable to low risk procedures. No signed document is necessary on the part of the participant.
- A sample copy of the presentation must be submitted and approved. A major exception to this policy occurs when research involves minors as participants, in which case written parental consent is usually required.

G. Consent in Greater than Minimal Risk Studies

In projects where participants are determined to be at greater than minimal risk:

- The actual procedure utilized in obtaining "legally effective informed consent" must be fully documented. This is accomplished by using a written consent form embodying all of the elements of information required for the project.
- The consent form must be reviewed and approved by the IRB.

- The consent form must be read by or to the subject or his/her legally authorized representative and signed by the person giving consent.
- A copy of the consent form should be given to the person signing the form, and the signed form must be maintained in the investigator's files.

H. Waiving/Modifying Consent Requirements

In rare cases, where consent procedures will surely invalidate important objectives of the project, IRB approval of modified procedures may be sought. An IRB may approve a consent procedure that does not include, or which alters, some or all of the elements of informed consent set forth in this section or waive the requirement to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the Participants; and
3. The research could not practicably be carried out without the waiver or alteration.

I. Consent Forms

Informed consent is a process of understanding between the investigator and participant that is documented by a signed consent form. Consent forms must include any information that might reasonably affect a participant's willingness to participate. Documentation of "legally effective informed consent" usually involves the use of a written consent form containing all of the information to be disclosed and signed by the participant or the participant's legal representative. It should be emphasized that the consent form is merely the documentation of informed consent and does not, in and of itself, constitute informed consent. The fact that a participant signed a consent form does not mean that he/she understood what was being agreed to or truly gave their voluntary consent. Federal regulations also require that researchers indicate whether or not participant data will be used in future, secondary research. If the researcher anticipates that identifiable data will be used in the future, the researcher may wish to include a statement of broad consent.

J. Script for face-to-face discussions with the potential participants

Face-to-face discussions between researcher and potential subject are the most important part of the process of informed consent. If the verbal explanation is almost identical to the written consent form, each will reinforce the other and potential inconsistencies will be avoided. One benefit of this approach is that the form/script prompts the researcher to use simple language for the verbal explanation. Another benefit is that the same form/script can be used for potential participants who have difficulty reading or a low level of literacy or who need a translation, which also should enhance consistency of explanation among all participants.

IV. INVESTIGATOR'S RESPONSIBILITIES

A. It is the responsibility of all researchers to comply with the following:

- Approval is obtained **prior** to initiating any human participants research.

- You acknowledge and accept your responsibility to protect the rights and welfare of human research participants and for complying with all applicable regulations.
- You must complete the CITI Online Ethics Training prior to conducting your research study.
- You must provide a copy of the approved informed consent document to each participant at the time of consent, unless this requirement has been waived.
- You must promptly report proposed changes/modifications to approved studies.
- You must immediately report to the Board any problems (injuries, unanticipated problems, continuous anticipated problems, subject complaints, etc.) involving risks to participants that arise in connection with your use of human participants.
- You must not continue research after expiration of approval as it is a violation of federal regulations. If approval has expired, research activities must stop and no new participants may be enrolled in the study until the research is re-approved.

B. Reportable New Information

Reportable New Information is defined as adverse events, i.e., events that are unfavorable, harmful, or detrimental to the welfare of participants. These events are either unanticipated or anticipated but are occurring at a higher level or greater frequency than expected. Investigators are responsible for prompt reporting of any unanticipated events, since it is the responsibility of the IRB to assess the risk/benefit ratio for participant safety. **These events must be reported in SUNY RF PACS IRB.**

C. Maintaining Records

Regulations require that all human participants' research records be retained for three years following the completion of the research. To maintain the confidentiality promised to participants, data should be stored in a locked cabinet or on a password-protected computer.

The IRB mandates that the faculty advisor is responsible for storing the signed informed consent documents, as opposed to students retaining the documents, to maintain security and confidentiality.

V. ADDITIONAL GUIDANCE

A. Confidentiality vs. Anonymity

Confidentiality and anonymity are NOT the same. Anonymity means that NO ONE, not even the investigator, can identify an individual subject or their data. Simply eliminating names and other obvious identifiers does not guarantee anonymity; demographics can sometimes identify participants as well. Any information or pattern of information that can uniquely identify an individual eliminates anonymity. Confidentiality means that a subject's identity is known, but will be protected by the investigator.

When considering whether data is identifiable, you must consider more than just the participant's name and social security number. Demographics, such as age, race, gender, and religion, can also be identifying. The fewer participants used, the more identifying the information may be.

B. Intervention (Non-medical/psychological)

If participants of the proposed research will be exposed to any psychological intervention such as contrived social situations, manipulation of the participant's attitudes, opinions or self-esteem, psychotherapeutic procedures, or other psychological influences, an investigator must provide the following information, in detail:

- Description of the intervention, including the means used to administer the intervention,
- Identification of the behavior expected and the context of the behavior during the intervention,
- How data resulting from this procedure will be obtained and recorded,
- Identification of the anticipated and possible psychological, physiological, or social consequences of this procedure, paying particular attention to prevention of accidental harm or injury,
- Indication of the investigator's competence and qualifications, by training and experience, to conduct the intervention, and a
- Description of how the participants are debriefed after the intervention (if applicable.)

C. Paying Human Participants

Payment to research participants may be made as an incentive for participation in research projects or to compensate participants for their time expenditure. However, the payment must never be so large that a potential participant feels coerced. Payment to participants should not be considered the "benefit" of the study, but rather a "reimbursement" for volunteering their time. All participants must be provided equal payment and/or equal opportunity for rewards. Fliers or advertisements for participation in research may mention, but not emphasize, the payment. The consent form must include clear descriptions of the remuneration and the method of payment and/or pro-rating of payment for certain portions of research participation. If over $600 per calendar year is possible, include the following statement: "By accepting payment(s) for participating in this research, certain identifying information about you may be made available to professional auditors to satisfy federal and state reporting requirements, but confidentiality will be preserved. Please note that if you earn over $600 per calendar year as a research subject, these earnings will be reported to the Internal Revenue Service."

D. Recording (Audio/Video)

If a research project includes either audio recording or video recording, the researcher must provide the following information on their protocol form:

- Procedures for recording
- How will records be stored and disposed of (to maintain confidentiality)?
- A separate signature line for permission to record should be used if the participant can agree to participate in the study without being recorded. (If a researcher does not want to include anyone who does not wish to be recorded, then a single signature line is sufficient.)
- Procedures for those who wish not to be recorded (e.g., in a classroom setting).

E. Security for Digital Multimedia Files Policy

All persons conducting research with human participants are required to protect the confidentiality of those participants. Because digital images, whether still photos or video, are

inherently unable to be deidentified, researchers must take additional steps to secure the data. Therefore, digital image files are to be encrypted using software supported by the college, such as TrueCrypt. Such protection is necessary for image files stored on CD, DVD, flash drive, computer hard drives, or the college server or any other method of data storage. This is to be a minimum level of security. Should an investigator conduct highly sensitive research, additional protection, such as pathway encryption, may be required. In that instance, the investigator will be instructed to work with the Sponsored Programs Office and Information Technology Services to determine the best course of action.

F. Minimal Risk Definition

According to the federal regulations, 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.

Risks in social and behavioral type research may not involve the physical risks, but may include psychological, social, economic and legal risks. Risks involved may include the following: embarrassment, loss of self-confidence, lower self-esteem, shame or guilt, financial loss, loss of employment, social stigmatization, invasion of privacy or prosecution and civil or criminal liability. These risks may affect not only the participant, but others, such as family members, social groups, or ethnic populations.

G. Vulnerable Populations

Vulnerable populations are persons who may be incapable of protecting their own interests. This population includes children, prisoners, fetuses and pregnant women, terminally ill, students/employees, and individuals with questionable capacity to consent, such as persons with psychiatric illness, neurological conditions, substance use and various metabolic disorders. The Code of Federal Regulations 45 CFR 46, Subparts B, C, and D provide additional protections for these populations. In the instance where capacity to consent is questionable, consent by a legally authorized representative may need to be obtained. When submitting a research protocol that includes the participation of this population, you must provide the following information:

1. Who will be assessing the participants' capacity to consent, and their qualifications to assess?
2. How will consent and/or assent be obtained?

Researchers must also be careful not to "overprotect" vulnerable populations so that they are excluded in research in which they wish to participate.

Additional information is available on Sponsored Programs website.

Please email the Research Compliance Manager at gameg@buffalostate.edu with any questions.