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 Human Protections Manager for questions you may have regarding specific human participants research procedures.**

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 a completed "Proposal Abstract for Research Involving Human Subjects" form. Forms are submitted to the Research Foundation Office of Sponsored Programs, attn: Human Protections Manager in Bishop Hall Rm. 17. This form is available on the following website: http://www.rf.buffalostate.edu

WHO reviews it?
The College has named a Human Protections Officer 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.

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, sufficient time should be allowed for adequate review. The IRB meets monthly. If you are submitting a **grant proposal** for your project, you are required to submit the human participants protocol at the time of or prior to the grant submission**. A copy of the grant submission must also be included with your human participants protocol unless it is already on file in the Research Foundation Office of Sponsored Programs**.

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 Human Protections Manager is available in the Research Foundation Office of Sponsored Programs at, 878-6700, or gameg@rf.buffalostate.edu and can assist faculty, staff and students in submitting their protocols for review. You can also access information on our website.

II. APPROVAL AND REVIEW PROCEDURES

A. Planning a Research Project
Investigators conducting research involving human participants are advised to contact the Human Protections Manager as early as possible with any questions regarding their research. Problematic aspects of a project will be discussed and alternative procedures suggested. **(For additional guidance an "Investigator's Checklist" is available on-line and at the Research Foundation Office of Sponsored Programs).**

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 Human Protections 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
In response to the December 2000 Federal mandate on human participants protection training, we have adopted a **mandatory** initial and ongoing educational training program for ALL investigators and research personnel involved in human participants research. ALL faculty, students, and staff who conduct human participants research must complete the training course. The CITI course is accessible through the RF Website. http://www.miami.edu/citireg/
Students can complete this requirement by attending a workshop provided by the Research Foundation Office of Sponsored Programs staff.

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 three categories**, "Exempt Research," "Expedited Review" or**

"Full Board Review". Each researcher should make the initial determination regarding the appropriate category of review, although the IRB makes the final determination. The researcher can always request a higher level of review than that required.

1. Exempt Research

Certain types of research may be exempt from IRB review. Researchers seeking an exemption from review must complete the Research Foundation Office of Sponsored Programs form, "Proposal Abstract for Research Involving Human Subjects-Certification for Exemption," along with any appropriate documentation. The Human Protections Officer is responsible for designating the project as exempt. The research must be designated as exempt before it is begun. Examples include:

- Research conducted in established or commonly accepted educational settings such as on regular and special education instructional strategies or research on the effectiveness of or the comparison of instructional techniques.
- Research involving the use of educational tests, survey procedures, interview procedures, or interview procedures **UNLESS** the information is recorded in such a manner that human subjects can be identified; and disclosure could reasonably place the subject at risk because the information gathered concerns sensitive aspects of the subjects' behavior; or children are being interviewed or surveyed. **(For additional information see "Research Involving Minors" available at the website or in the Sponsored Programs Office)**
- Observation of public behavior where identifiers are not recorded by the project director and there is neither a risk of harm to the subject and the observation does not include sensitive aspects of the subjects' behavior **UNLESS** children are used in the study.
- Research involving the use of educational tests (cognitive, aptitude, achievement) with procedures that guarantee confidentiality during and after the research **UNLESS** the human subjects are elected or appointed officials or candidates for public office.
- Research involves the collection or study of existing data, documents or records, or pathological or diagnostic specimens, where publicly available, or the information is private but identifiers are not recorded by the project director.
- Research and demonstration projects designed to study, evaluate, or examine public benefit or service programs and procedures for obtaining benefits under these programs and/or possible changes or alternatives to these programs.
- Taste and food quality and evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if the food consumed contains a food ingredient at or below the level found to be safe, an agricultural, chemical or environmental contaminant at or below the level found to be safe by the FDA or approved by the FDA or the Food Safety Inspection Service.

2. Expedited Review

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
- Interviews and interactive surveys on non-sensitive topics
- Continuations and/or modification of proposals initially approved under the full review process, if they present no additional risks to participants

3. Full Board Review

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," Deception in Research," "Research Involving Minors" available at the website or the Research Foundation Office of Sponsored Programs)

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. Review Forms

The IRB has developed a unified Proposal Abstract for Research Involving Human Subjects that is used in submitting protocols in both expedited and full review categories. The investigator must sign the form; the signature of the faculty supervisor is required for all student research. A copy of the form can be obtained in the Research Foundation Office of Sponsored Programs, or on the website: www.rf.buffalostate.edu.

G. Additional Materials

The following items, where appropriate, must be included with the Human Participants Research Review Form:

- Copy of consent form(s)
- Copies of all questionnaires/surveys/interview questions
- School district/organizational permission to conduct the research
- Any recruitment fliers or announcements
- If you are applying for a grant, submit a copy of the grant application unless it is already on file in the Research Foundation Office of Sponsored Programs.

(For additional information see "Investigator's Checklist")

H. Continuations

For research involving no more than minimal risk, the approval period is generally one year. For research involving greater than minimal risk, the IRB will determine the appropriate approval period. The approval letter will indicate the approval period and the date for submitting a request for a continuation. It is the investigator's responsibility to request a continuation. **If project approval lapses, all research must stop immediately until approval has been obtained.**

I. 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. Explain the modification, and submit all supporting documents that have been modified; i.e., questionnaires, recruitment flyers, consents, etc.to the Research Foundation Office of Sponsored Programs.

J. 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 on campus unless otherwise exempt, 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.

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 "Consent Form Template" available at the website or the Research Foundation Office of Sponsored Programs)**

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.

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.. In most cases, 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 element 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

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. 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.

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 required educational training course provided by the Research Foundation Office of Sponsored Programs prior to conducting your research.
- 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. Adverse Events Reporting

Adverse events are defined as 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 any

unanticipated events, since it is the responsibility of the IRB to assess the risk/benefit ratio for participant safety.

C. Maintaining Records

Regulations require that all human participants' research records be retained for three years following the completion of the research. If possible, identifiers should be removed and separated from the data as soon as possible. To maintain the confidentiality promised to participants, data should be stored in a locked cabinet, or password protected on a computer.

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 age, race, gender, religion as 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,
- Identify the behavior expected and the context of the behavior during the intervention,
- How data resulting from this procedure will be obtained and recorded,
- Identify the anticipated and possible psychological, physiological, or social consequences of this procedure, paying particular attention to prevention of accidental harm or injury,
- Indicate 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. Taping (Audio/Video)

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

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

E. 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.

F. 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 at the Research Foundation Office of Sponsored Programs and the website. Written information is available on the following topics:

CITI Training
Collaborative Research
Consent Form Template
Deception in Research
Internet Research
Investigator's Checklist
Miscellaneous Categories of Research
Organizational Research
Research Involving Minors
Socially Sensitive Research

PLEASE CALL THE HUMAN PROTECTIONS MANAGER AT 878-6700 WITH ANY QUESTIONS