GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

Institutional Review Board

Stark State College

North Canton, Ohio

Dear Research Investigator:

Seeking approval to conduct your research investigations under the auspices of Stark State College gives the project viability and assures compliance with federal law for such activities. The primary purpose of the Institutional Review Board is to assure compliance with federal regulations which require specific research oversight functions to ensure that respect, protection from harm, and fairness are essential parts of the investigator's research protocol.

When people are involved as subjects in research or related activities conducted under the auspices of Stark State College, both the institution and the principal investigator incur responsibility for ensuring that the rights and welfare of participants are adequately protected. This responsibility extends to any mode of research development, instruction, training or related activity, including classroom and questionnaire studies, whether sponsored solely by the College or funded externally and conducted either on- or off-campus.

The Guidelines for the Conduct of Research Involving Human Subjects outlines definitions and processes, and should be reviewed in depth prior to submitting the research proposal. Please refer to the Appendix in the *Guidelines* for the forms to be submitted to the IRB. For further assistance in understanding the application process, please peruse the Sequence of Research Protocol Review located in the Appendix of the attached Guidelines.

Sincerely,

Peter Trumpower
Executive Director of Institutional Effectiveness

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Foreword

The publication of *Guidelines for the Conduct of Research Involving Human Subjects* serves two fundamental purposes:

1. To create an awareness and understanding among the Stark State College community of the policies and principles that underlie the regulations governing research with human subjects; and

2. To identify the salient issues to which one should be sensitive in designing or reviewing research proposals.

A number of federal laws and regulations explicitly address educational research and human research subjects protections. The substance of these protections is derived largely from *The Belmont Report*, which promulgates the ethical principles of autonomy, justice and beneficence to establish guidelines concerning informed consent, fair selection of subjects and risk/benefit considerations.

Applied to research, the principle of **autonomy** implies the need for informed consent, that is, the research subjects must be asked to consent to the research in which they participate. In order to meet the requirements of informed consent, the subject's consent must be knowing, voluntary and exercised by someone who possesses the capacity for making rational decisions. If the subject fails to meet these requirements, as is commonly the case with children, then the respect for the subject's autonomy is implemented by consent given by someone else whose role it is to protect the subject's welfare.

The principle of **justice** dictates that certain populations of subjects, especially those with a history of being discriminated against, should not bear an unfair burden of research risks and that they should receive a fair share of the benefits of research. Special classes of subjects to whom this principle may pertain include those who are physically or emotionally challenged, members of minority racial or cultural groups, prisoners, individuals who are economically disadvantaged and/or individuals of a particular gender.

The principle of **beneficence** requires that the outcome of an action have a salutary effect on those who are impacted by the action. Applied to research, because the outcome of the research activity is unknown (by definition), this principle takes the form of a judgment based on a risk/benefit analysis. The risk of harm to the subjects must be outweighed by the prospects of benefits to all who might gain from the application of acquired knowledge, including both the subjects themselves and others who benefit from the application of acquired knowledge in the future.

The three principles of autonomy, justice and beneficence are the ethical basis of the *Guidelines*. For a more in-depth discussion of these issues and others, you are invited to consult the National Institute of Health's *Protecting Human Research Subjects Guidebook.* This document is available in the Research & Planning Office.

GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

I. DEFINITION OF HUMAN SUBJECTS

When people are involved as subjects in research or related activities conducted under College auspices, both the institution and the principal investigator incur responsibility for ensuring that the rights and welfare of participants are adequately protected. This responsibility extends to any mode of research development and related activity, including classroom and questionnaire studies, whether sponsored solely by the College or funded externally, and conducted either on or off-campus. Federal law defines a **human subject** as 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.** Inherent in this definition is the concept of **minimal risk**.

'Research' means a systematic investigation. It includes the development of a project that will aid in answering a question, and involves testing and evaluation. Information gained from this project will contribute to generalizable knowledge. **'Intervention'** includes both physical procedures and manipulations of the subject or the subject's environment. **'Interaction'** includes any kind of communication or interpersonal contact between investigator and subject. **'Private information'** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). **'Private information'** must be individually identifiable (i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for

obtaining the information to constitute research involving human subjects. **'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.

II. SCOPE OF REVIEW

The scope of the Institutional Review Board (hereafter called the IRB or the Board) is broad. Generally, any College research that uses humans, human tissue, surveys of human subjects or human subjects' records requires IRB review, irrespective of its funding source. The IRB's charge extends to research in the social and behavioral sciences as well as research in the health and biological sciences. Specifically, IRB review and approval is required for any research involving human subjects that:

- is conducted by College faculty, staff or students;
- is performed on the premises of the College;
- is a course offered under the auspices of our College;
- is performed with or involves the use of facilities or equipment belonging to the College;
- involves College patients, students, staff or faculty;
- satisfies a requirement imposed by the College for a degree program or for completion of a course of study; or
- is certified by a dean or department head to satisfy an obligation of a faculty appointment at the College, including clinical or adjunct appointments.

IRB review is also required unless the researcher has a strict consulting relationship in which (1) the researcher is hired on his or her own time; (2) the researcher holds no rights in the work; and (3) neither the researcher nor the College retains any data. All three of these criteria must be met or the IRB will need to review the project.

The IRB *Guidelines* do ***not*** apply to the following:

- Field or clinical learning experiences which are under Stark State College direction and supervision (through contractual arrangements between the field agency and Stark State College) and which are limited to the implementation of customary and usual practices of the appropriate profession;

- Assignments for classes which require students to obtain (1) data through intervention or interaction with individuals, or (2) identifiable private information where access to such information is confined to class use only.

In these circumstances it is understood that the Stark State College supervisor or instructor is responsible for assuring ***confidentiality*** and ***informed consent*** when required for the student's experience.

III. ESTABLISHMENT OF THE IRB

In compliance with federal regulations, Stark State College has established an IRB, administered through the Institutional Research & Planning Office, to oversee its obligations with respect to human subjects. The IRB consists of one permanent member, the Director of Institutional Research and Planning, and at least five rotating representatives. There will be one rotating member from each academic division, with each member having appropriate expertise in his or her field of study. In addition, there is one member who is unaffiliated with the College and both genders are to be represented. A Chairperson will be selected by these representatives who will assign the reading of research proposals, prepare and maintain adequate documentation of IRB activities, call the Board together for Full Board decisions and communicate on behalf of the IRB with those who have presented proposals for IRB review. The jurisdiction of the institutional IRB includes all research and related activities covered under these *Guidelines*. **No research project involving human subjects may proceed without the explicit written approval of the Institutional Review Board.**

IV. PROCEDURE FOR REVIEW

Those individuals who conduct research involving human subjects must submit a research proposal to the Board. This includes faculty, staff, and students who are conducting research under the guidance and tutelage of a College advisor.

The principal investigator must submit one hard copy and one electronic copy of the research proposal which consists of three parts, to the Chair of the IRB. The three parts are: (1) Part 1: Application for Approval to Use Human Subjects in Research; (2) Part II: Research Protocol; and (3) Part III: Summary of Proposal. ***All research proposals must be submitted to and approved by the Institutional Review Board PRIOR to initiation of research.***

The IRB Chair will forward the application to the appropriate reviewer(s). Members with conflicts of interest may not participate in review. If the possibility of such conflict is unknown to the Chair, those who have such a conflict and have been asked by the Chair to participate are ethically bound to recuse themselves. The research proposal, consisting of Part I, Part II and Part III, is reviewed and returned to the Chair. In the case of a student researcher, the Chair will forward the status of the research proposal to the student's advisor or other appropriate individual. Normally, the review process will be completed within a three-week time frame. There are three types of Human Subjects Review Procedures, each to be discussed separately.

Investigators do not have the authority to determine whether research involving human subjects is exempt from a ***full*** IRB review. (A full IRB review would be when ***all*** of the Board members participate in the evaluation.) Hence, while research that involves only minimal risk to human subjects is sometimes exempt from ***full*** IRB review, this does not mean it is exempt from IRB review. At least one member of the Board will have to determine if there is no risk to human subjects. Researchers seeking review under these circumstances must file an application requesting that a project be classified as "exempt" from full review.

A. Research Activities Which May Be Exempted from Full Board Review

In general, the federal guidelines for research on human subjects allow a project to be exempt from ***full*** IRB review only if the research involves ***no risk to the subject***. It shall be the Chair of the Board who makes this determination. Criteria of exempt research include the following six categories:

1) The research is conducted in established or commonly accepted educational settings, involving normal education practices, such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

2) The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement) or observations of public behavior, ***except*** where any of the following conditions exist:
   a. Information obtained is recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
   b. Any disclosure of this information outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability or reputation; or
   c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior or use of alcohol.

3) The research involves the use of educational tests, survey or interview procedures, or observations of public behavior when the human subjects are elected or appointed public officials or candidates for public office.

4) The research involves the collection or study of existing (1) data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available, or (2) if the information is recorded by the investigator in such a manner that those subjects ***cannot*** be identified directly or through identifiers linked to the subjects.

5) Research and demonstration projects which are conducted by or are subject to the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine:
   a. public benefit or service programs;
   b. procedures for obtaining benefits or services under those programs;
   c. possible changes in or alternatives to those programs or procedures; or
   d. possible changes in methods or levels of payment for benefits or services under those programs.

6) Taste and food quality evaluation and consumer acceptance studies where:
   a. wholesome foods without additives are consumed, or
   b. a food is consumed that contains a food ingredient or an agricultural chemical or environmental contaminant at or below a level determined to be safe by the Food and Drug Administration (or approved by the Environmental Drug Administration, the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture).

B. Research Activities Which May Be Reviewed Through Expedited Review Procedures

Research activities involving ***no more than minimal risk*** and in which the only involvement of human subjects will be in one or more of the following 13 categories (carried out through standard methods) may be reviewed by the Chair and/or a designated voting member or group of voting members, rather than by the full IRB. When using this procedure, the IRB shall adopt a method for keeping all members advised of research proposals which have been approved under the procedure. Projects not covered by this list of 13 categories will require a Full Board review (all members must review the proposal). ***Informed consent is required in all cases.*** Confidentiality of identifiable information is required unless specific consent is received from the subject to disclose that information.

1) Research involving survey or interview procedures, except where ***any*** of the following conditions exist:
   a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects;
   b. The subject's responses, if they became known outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; or
   c. The research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

2) Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory or test development, where the investigator does not either manipulate the subjects' behavior and/or emotional state, or involve stress to subjects;

3) The study of existing data, documents, records, pathological specimens or diagnostic specimens. The consent of the subjects from whom the data, etc., were originally obtained is not needed if the data, etc., are publicly available. If the data, etc., are not publicly available, the custodian of the data, etc., may consent in place of the subjects only if the custodian is authorized to release the data, etc., for research. Otherwise, consent of the subjects must be obtained;

4) Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth and permanent teeth if patient care indicates a need for extraction;

5) Collection of excreta and external secretions, including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membranes prior to or during labor;

6) Recording of data from non-pregnant subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the

use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic ecography and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example x-rays, microwaves);

7) Collection of blood samples by venipuncture, in amounts not exceeding 50 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant;

8) Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;

9) Voice recordings made for research purposes such as investigations of speech defects;

10) Moderate exercise by healthy volunteers who are 18 years of age or older and are not pregnant. Moderate exercise is defined as less than 60% of age-adjusted maximums;

11) Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required;

12) Minor modifications or additions to existing approved studies; and

13) Continuing review of activities which the IRB determined in an earlier full review could have expedited, continuing review.

C. Full IRB Review Procedures

Research projects that do not meet the exempt or expedited review criteria ***require*** a full IRB review. For projects requiring full review by the IRB, the Chair will request six copies of Part I: Application for Approval to Use Human Subjects in Research; Part II: Research Protocol; and Part III: Summary of Proposal. Where a proposal for an external grant is involved, assessment will be made for the entire program proposed and will occur prior to or concurrent with the submission of the proposal. If a grant is **not** involved, the research proposal should reach the Chair at least 30 days in advance of the proposed implementation date for the research project.

Copies of the research proposal will be distributed to each IRB member for review seven days prior to the next convened meeting. The investigator may be asked to answer questions or meet with the IRB to clarify specific points regarding the involvement of human subjects in the proposed activity. Conversely, if specific questions are anticipated as a consequence of the proposal, the investigator may request a meeting with the IRB prior to the submission of the final draft. This meeting will not necessarily take the place of a regular review.

D. Possible Actions of IRB Review

After review by the IRB, one of the following four actions will be taken:

Action 1: Approve the research procedures;

Action 2: Approve the research procedures, subject to modifications;

Action 3: Disapprove the research procedures; or

Action 4: Defer action on the proposal pending receipt of additional information or further clarification of specific items as may be identified.

Additions or changes made after approval must be brought to the attention of the IRB Chair. The Chair will then direct the IRB to consider whether the original assessment should be modified in any way. If so, the IRB will treat the matter as a new case and no new procedures should be implemented until Board approval has been obtained.

At the time of approval, it will be determined which projects require review more often than annually or that require verification from sources other than the investigator that no material changes have occurred since IRB approval. Any project thus identified will be followed up on by the IRB chair or appropriate institutional official.

Each project not granted "exempt" status will be reviewed annually by the IRB to assure that investigators continue to follow approved procedures and practices regarding the use of human subjects. If subjects behave as if personal rights have been violated in any form, the investigator should inform the IRB Chair in writing.

V. Criteria for IRB Approval

In reviewing activities covered under these *Guidelines*, the IRB seeks to determine that all of the following requirements are satisfied:

1) Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk and, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2) Risks to subjects are reasonable in relation to any anticipated benefits to subjects, and in relationship to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.

4) Informed consent will be sought from each prospective subject or from the subject's legally authorized representative in accordance with, and to the extent required by, Section VII of these *Guidelines.*

5) Informed consent will be appropriately documented in accordance with, and to the extent required by, Section VII of these *Guidelines.*

6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

8) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as might be the case for children, prisoners, pregnant women, mentally disabled persons, and economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Once the IRB determines that all of the above points have been satisfied, approval may be given for the project to proceed, subject to further review or disapproval by other agencies. However, other agencies may **not** approve the project if it has been disapproved by the IRB.

The IRB may suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. Any suspension or termination shall include a statement of reasons for such action and shall be reported promptly to the investigator; appropriate College officials; and/or the funding agency, if applicable.

VI. APPEAL PROCEDURES

If a proposal or procedure receives final disapproval by the IRB and the principal investigator wishes a further hearing on the matter, an appeal may be made to the Board. In this case, an ad hoc appeals committee will be convened by the Chair of the IRB. The appeals committee will consist of three or more persons who have previously served on the IRB and the Provost, as well as any special consultants that may be required.

VII. INFORMED CONSENT OF RESEARCH SUBJECTS

A. Obtaining and Documenting Consent

Unless a waiver has been approved by the IRB, the investigator must obtain and document in writing the subject's informed consent. The key elements of **informed consent** are:

1) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which would be considered ground breaking;

2) A description of any reasonably foreseeable risks or discomforts to the subject;

3) A description of any benefits to the subject or to others which may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and how such identifiable information will be used now and in the future;

6) For research involving more than minimal risk, an explanation as to whether any compensation and/or medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained;

7) The name(s) of the person(s) to contact for answers to pertinent questions about the project and the subject's rights, and whom to contact in the event of a research-related injury. In the case of student research this should include the principal investigator(s) and research advisor;

8) A statement that participation is voluntary and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

For research involving minors, that is, individuals who have not attained the legal age of consent (18 years of age in Ohio), **a custodial parent or guardian must be given a pre-service briefing in written or oral form**, and a written consent form must be obtained from said custodial parent or guardian for each child. In the case of children over seven years of age, the child must also give assent. In research where the minor is old enough to give fully informed consent to non-sensitive, non-risky research procedures, researchers may request a waiver of parental consent. **Waiver of parental consent can only be granted by the IRB.**

Whatever forms are used as documentary evidence of informed consent, it is essential that all such evidence be preserved by the principal investigator for at least 36 months following termination of the project. If the investigator leaves campus before the 36 months have expired, copies of the appropriate documents must be filed in the Provost's Office. If the project was carried out at another institution, the files may be retained at that institution, but the IRB should be informed of their location. In any case, records are subject to audit by College as well as federal officials and must be retained for easy and quick access if requested. The investigator must specify to the IRB the procedures which will be used to preserve the confidentiality of these signed consent forms.

Some research may be so indirect, innocuous and innocent of imposition on the rights and welfare of human subjects as to make informed consent a moot requirement. Therefore, the IRB may choose to waive this requirement; however, such action must be based upon clearly defensible grounds, and the principal investigator must include these justifications in the proposal submitted to the IRB. This applies to waiver of parental consent for research with minors, as well.

VIII. GUIDELINES MODIFICATIONS

The Institutional Review Board shall have the discretionary power to address issues not presented herein. These *Guidelines* shall be amended or modified as any applicable laws are changed.

IX. REFERENCES

Code of Federal Regulations. The Common Rule: 38 CFR PART 16 "Protection of Human Subjects."
[Online] Available: http://www1.va.gov/oro/apps/compendium/Files/38CFR16.htm

The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Published April 18, 1979, as a report of the Office of Protection from Research Risks, the Department of Health, Education and Welfare.
[Online] Available: http://ohsr.od.nig.gov/guidelines/belmont.html

Ethical Principles in the Conduct of Research with Human Participants, by the American Psychological Association. Published in 1982 by the Committee for the Protection of Human Participants in Research.

Protecting Human Research Subjects: Institutional Review Board Guidebook. National Institutes of Health, Office for Protection from Research Risks, 1993.

(On file in the Research & Planning Office)

GUIDELINES FOR THE CONDUCT OF RESEARCH INVOLVING HUMAN SUBJECTS

APPENDIX

Please read the Guidelines (pages 1 through 14) carefully and submit pages A-2 through A-7 and all required forms and safeguards, including questionnaires, research instruments, letters of consent and approvals from authorized officials to the Institutional Review Board.

All forms are to be typed or word-processed.

SEQUENCE OF RESEARCH PROTOCOL REVIEW

Student-Directed Research

(Students work closely with your advisor)

1) Discuss project with advisor and receive approval to proceed.
2) Complete Institutional Review Board Application: Part I, Part II, Part III (Investigator must sign application)
3) Obtain advisor's signed approval and forward to:

Nicole R. Cleland, PhD., IRB Chair
Stark State College
6200 Frank Ave. NW E208I
North Canton, OH 44720-7299
ncleland@starkstate.edu

Peter Trumpower,
Executive Director of Institutional Effectiveness
Stark State College
6200 Frank Ave. NW S308D
North Canton, OH 44720-7299
ptrumpower@starkstate.edu

After Proposal is received by IRB Chair:

1) Chair sends the proposal to the appropriate reviewer(s).
2) Proposal is reviewed and returned to the Chair.
3) IRB Chair reviews, signs letter and forwards status of research proposal to the student's advisor.

Faculty Research

1) Complete Institutional Review Board Application (Part I, Part II, Part III)
2) Forward proposal to Grant Development Office *if external funds are to be sought:*

After Proposal is received by Grant Development Office:

1) Director of Strategic Grant Development sends the proposal to the Chair of the IRB who assigns the proposal to the appropriate reviewer(s).
2) IRB or review members review proposal and return proposal to Grant Development Office.
3) IRB Chair reviews, signs letter and forwards status of research proposal to faculty member, with copy to Director.

EXAMPLE OF TYPICAL CONSENT FORM
(Parental Consent)
"Title of Research Study"

Dear _____:

The Department of _____ at Stark State College supports the practice of informed consent and protection for human subjects participating in research. The following information is provided for you to decide whether you will allow _____ to participate in the present study. You are free to withdraw _____ at any time.

Your child will be asked to play a game with another child with a disability in a room that has toys and books, and your child's behavior will be observed. One session will last approximately 25 minutes. We are interested in studying the interaction between children in order to develop methods for increasing the effectiveness of efforts to integrate children with disabilities into the regular education classroom.

Your child's participation is solicited but is strictly voluntary. We assure you that your child's name will not in any way be associated with the research findings. The information will be identified only through a code number.

If you would like additional information concerning this study before or after it is completed, or have any issues or concerns, please contact one of us by phone or mail. Thank you very much for your time. We appreciate your interest and cooperation.

Sincerely,

Name of investigator
Graduate Student
Phone No. (____)_____
Address _____
City, State, Zip _____

Name of Faculty Member
Professor
Phone No. (____)_____
Address _____
City, State, Zip_____

****

I have read and understand the information about "Title of Research Study." I give consent for my child to participate in this study. I understand that this consent is voluntary and can be withdrawn without penalty at any time.

_____
Signature of parent or legal guardian

_____
Date

EXAMPLE OF TYPICAL CONSENT FORM
(Participant Consent)

"Gender Differences in Communication Strategies of
Pleasant and Unpleasant Feelings"

A. PURPOSE AND BACKGROUND

Messrs. Smith and Jones in Stark State College's Psychology Department are conducting a research study to help understand how men and women communicate pleasant and unpleasant feelings. You are being asked to participate in this study because…

B. PROCEDURES

If you agree to be in the study, the following will occur:

1. You will view two 15-minute videotapes; one will be of pleasant and the other of unpleasant content.

2. After viewing both videotapes, you will be asked to take part in a focus group discussion led by Smith and Jones. Everyone in this focus group will have viewed the tapes. During the focus group, you and other group members will be asked to discuss reactions to scenes in both tapes. An audiotape will be made of this discussion. This discussion is expected to last about thirty minutes.

3. You will respond to a questionnaire about your reaction to the videotapes. It should take approximately fifteen minutes to complete the questionnaire.

4. You will answer questions on a standard paper and pencil personality test. It should take about an hour to complete this test.

These procedures will be done…and will take a total time of about two and one-half hours.

C. RISKS/DISCOMFORTS

1. Some of the videotapes are likely to produce unpleasant feelings, but you will be able to stop watching at any time if you feel too uncomfortable.

2. Some of the focus group discussion questions may make you uncomfortable or upset but you are free to decline to answer any questions you do not wish to answer or to leave the group at any time.

3. Confidentiality: Participation in research will involve a loss of privacy; however, your records will be handled as confidentially as possible. The researchers will ask you and the other people in the focus group to use only first names during the group session. They will also ask group members not to tell anyone outside the group what any particular person said in the group. However, the researchers cannot guarantee that everyone will keep the discussion private. Only Smith and

Jones and their assistant will have access to your study records and audiotapes. After the group discussion has been transcribed from the tapes, the tapes will be destroyed. No individual identities will be used in any reports or publications that may result from this study.

D. BENEFITS

There will be no direct benefit to you from participating in this study. However, the information that you provide may help health professionals better understand differences in how males and females communicate pleasant and unpleasant feelings.

E. COSTS

There will be no costs to you as a result of taking part in this study.

F. PAYMENT

You will be paid $20 for your participation in this study. If you decide to withdraw prior to study completion, you will receive $10. You will be paid in cash immediately after you complete your participation in the study.

G. QUESTIONS

You have talked to Messrs. Smith and Jones, or the person who signed below, about this study and have had your questions answered. If you have further questions, you may call him/her at….

If you have any comments or concerns about participation in this study, you should first talk with the researchers. If for some reason you do not wish to do this, you may contact the Institutional Review Board, which is concerned with the protection of volunteers in research projects. You may reach the Board office between 8:00 and 5:00, Monday through Friday, by calling or writing…..

H. CONSENT

You will be given a copy of this consent form to keep.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You are free to decline to be in this study or to withdraw from it at any point. Your decision as to whether or not to participate in this study will have no influence on your present or future status as a [patient, student or employee].

If you agree to participate, sign below where indicated.

_____ _____

Date Signature of Study Participant

_____ _____

Date Signature of Person Obtaining Consent

Notes to Researcher:

1. **Research involving sensitive aspects of the subject's own behavior:** The Procedures section should discuss in detail the kinds of sensitive questions that will be asked during interviews, in questionnaires, or in focus groups (i.e., you should specify that questions

about sexual activity, drug or alcohol use, domestic violence or child abuse, or other illegal activities will be asked).

In studies in which you think it is likely that subjects will reveal actions that you are legally or morally obligated to report to authorities (e.g., when child, spousal, or elderly abuse is suspected), a statement should be added to the consent form's discussion of confidentiality, briefly saying that such circumstances may arise.

When questions about drug use or other illegal activities are involved, research subjects are placed at risk since research discussions and records do not enjoy the same legal privilege as medical records. In order to protect your subjects better, you may wish to obtain a Federal Certificate of Confidentiality through your funding agency. This Certificate prevents courts from compelling researchers to reveal information about their subjects. Whether or not you obtain a Certificate, subjects should be warned in the consent form about the risk of loss of confidentiality. Wording like the following is recommended:

> Participation in research will cause a loss of privacy. In this study you will be asked about drug use and other possibly illegal activities. The researchers will keep information about you as confidential as possible, but complete confidentiality cannot be guaranteed. On rare occasions, a court has subpoenaed research records.

If you obtain a Certificate of Confidentiality for the study, the end of the statement can be revised as follows:

> ….On rare occasions, research records have been subpoenaed by a court, but the National Institute on Drug Abuse [or other issuing agency] has given the researchers a Federal Certificate of confidentiality which says courts cannot force the researchers to reveal information about your participation in the study.

2. **Collecting long-term tracking information:** If relatives, neighbors, co-workers, employers, or government agencies will be contacted during the study to provide information on subjects' whereabouts, you should explain so in Procedures. Subjects should be reminded that they could ask to have these tracking procedures stopped at any time.

RESEARCH PROPOSAL SUBMISSION CHECKLIST

The *Guidelines for the Conduct of Research Involving Human Subjects* outlines definitions and processes and should be reviewed in depth **prior** to submitting the research proposal. The Appendix in the Guidelines contains the forms to be submitted to the Institutional Review Board.

All proposals will be screened using the following checklist. Incomplete proposals will be returned to the principal investigator, and the proposal will not be examined further. **Please examine the proposal carefully before submitting two copies of the proposal.**

- ❑ Complete information/signatures on page A-2

- ❑ Complete information on page A-3 including:

  - ❖ Type of review
  - ❖ Category(ies)
  - ❖ Explanation

- ❑ Written authorization attached (indicated by "yes" on item K on page A-4)

- ❑ Questionnaire(s) attached (indicated by "yes" on item L on page A-4)

- ❑ Project description included (item 1 on page A-5)

- ❑ Explanation of how subjects will be informed attached (see 4A. on page A-6)

- ❑ Written consent form or justification attached (see 4B. on page A-6)