



CMU

CENTRAL MICHIGAN
UNIVERSITY

Human Subjects in Research:

Institutional Review Board

Policies and Procedures

Central Michigan University

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IRB policies and procedures are continually reviewed and updated. Please check <http://www.orsp.cmich.edu> for the latest version of this document.

**INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES
INVOLVING THE USE OF HUMAN SUBJECTS IN RESEARCH**

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SECTION I

INSTITUTIONAL REVIEW BOARD POLICIES AND PROCEDURES INVOLVING THE USE OF HUMAN SUBJECTS IN RESEARCH

Central Michigan University (CMU) has provided a formal guarantee (Multiple Project Assurance M-1317) to the Department of Health and Human Services (DHHS) that it will follow mandated procedures to assure the protection of all human subjects involved in research projects. This guarantee applies to all research conducted at this institution or under the direction of any employee or agent of this institution, whether funded or not, and regardless of the source of funding.

In order to comply with the DHHS and the Federal Drug Administration (FDA) regulations for the Protection of Human Subjects, CMU has established an Institutional Review Board (IRB) to review all research involving the use of human subjects and to implement institutional policy regarding such research. The primary function of the IRB is to assist researchers in the protection of the rights and welfare of human subjects. The IRB, composed of faculty and staff from a variety of disciplines plus community members, is directly responsible to the Vice Provost for Research.

All research (see page 7 for a definition of the term "research" as it is used in this document) involving the use of human subjects conducted by CMU faculty, staff, or students or sponsored in part or in whole by CMU must be reviewed and approved prior to the start of the project and then conducted in full compliance with IRB policies and procedures. This includes research conducted in conjunction with classroom assignments as well as a student's dissertation, thesis, or Plan B paper. It also includes all interviews, questionnaires, surveys, observations, educational tests, and secondary analyses of data and incorporates all forms of methodology contained within.

This set of guidelines is intended to provide a resource for the preparation and submission of research applications for IRB review. Section I includes information on the ethical and legal responsibilities of investigators during the conduct of research involving the use of human subjects. The categories for review are also described in this section. Section II includes instructions on how to submit an application online through the required online submission system (IRBNet). Section III includes federal regulations that apply to special groups and informed consent. Informed consent guidelines and information regarding the consent and assent forms contained within the online submission system are provided in Section IV. Section V contains the guidelines which will guide the IRB review process.

A. Background and Responsibilities for Investigators

Central Michigan University (CMU) recognizes and affirms the need for academic freedom in the conduct of research, and the value of well-designed, responsible activities which involve

human subjects. At the same time, the University recognizes and accepts its responsibility to ensure the protection of any human subject so involved. The use of human subjects in research imposes both ethical and legal responsibilities upon the institution, the principal and co-investigators and all those involved in the conduct of the research, for ensuring that the rights and welfare of those subjects are adequately protected.

These University policies and procedures have been prepared to help investigators meet individual and institutional obligations with respect to human subjects. They have been developed in accord with federal requirements (DHHS Regulations Title 45 CFR Part 46 and FDA Regulations Title 21 CFR Parts 50 and 56) and the ethical principles embodied in respect for the rights and well being of persons who may be subjects of research. These basic ethical principles include: respect for persons (acknowledging autonomy and protecting those with diminished autonomy), beneficence (doing no harm and maximizing possible benefits while minimizing possible harms), and justice (sharing equitably the burdens and benefits of the research study).

Current law places the burden of liability for negligence and harm directly on the *investigator* and the institution. The IRB policies and procedures are formulated to protect the University, the investigator, and in the case of students, the faculty advisor, from liability through imposition of minimum standards for research, and procedures for careful review of projects. Failure to follow these policies and procedures may cause individuals to incur personal liability for negligence and harm. Failure to follow these policies and procedures also may cause the University to lose federal funding, prevent individuals from applying for or receiving federal research funds, and prevent the University from engaging in research. In addition, failure to follow these policies and procedures will be viewed by Central Michigan University as a violation of university policies and procedures and will result in appropriate administrative action.

The Central Michigan University Institutional Review Board (CMU-IRB) has institutional responsibility for use of human subjects in research under the auspices of, or utilizing the students, personnel, or facilities of Central Michigan University. All projects must be accomplished in accord with this policy, and all projects covered by this policy can be undertaken only after appropriate approval and may be continued only in accordance with the terms of that approval, only so long as that approval remains in effect. Changes in a project, or continuation of the project following adverse or untoward occurrences during the project, are also subject to review and approval.

It is the responsibility of the investigator to refer his or her project to the IRB whenever humans are used as subjects in research, even if the investigator does not consider the subjects to be "at risk." The determination of the classification of the study, and the resultant appropriate review and approval, rests with the Institutional Review Board and not the researcher or Principal Investigator.

B. Ethical Principles for the Use of Human Subjects in Research

It is the responsibility of the individual investigator to ensure that appropriate ethical principles are adhered to in the conduct of research involving human subjects. The investigator is responsible for the ethical treatment, and prevention of negligent treatment, of research subjects by collaborators, assistants, students, or employees who are assisting in the research of the investigator, as well as his or her own behavior.

The University is guided by the ethical principles regarding all research involving human subjects as set forth in the report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," The Nuremberg Code, and the World Medical Association Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects. The primary ethical principles which must be considered in all research involving human subjects include:

1. Maintaining subject autonomy.

Participation of human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion or obligation, based upon disclosure of relevant information in a clear, concise, and understandable way. It is the responsibility of the investigator to ensure that subjects understand the principles described and language used in the explanation of the research project. The investigator must also take care to avoid coercing individuals to participate in the study or to remain in the study.

Adequate standards for informed consent must always be satisfied. The principle of informed consent is derived from the legal and ethical obligation of the investigator to ensure that prospective subjects have sufficient understanding of the benefits and risks of their participation in the study to make an informed decision concerning participation.

2. Maintaining the safety of the subject.

A paramount responsibility of the investigator is to protect subjects from risk. Risk can include physical or mental discomfort, harm, or danger, social embarrassment, economic burden, or legal jeopardy. The potential for benefit to others does not justify placing the subjects of the study at risk. A research procedure may not be used if it is likely to cause serious and lasting harm to subjects (e.g., health problems).

If an investigation utilizes deception, the investigator is required to later explain to the subjects the reasons for this action and to restore the quality of the relationship with the investigator.

After the data are collected the investigator should provide subjects with clarification of the nature of the study and remove misconceptions that may have arisen.

Where research procedures result in undesirable consequences for subjects, the investigator has the responsibility to detect and remove or correct these consequences, including, where relevant, long-term after-effects.

Where scientific or humane values justify delaying or withholding information, the investigator has a special responsibility to ensure that there are no damaging consequences to subjects.

3. *Promoting benefit to the subjects and larger community.*

Wherever possible, the research project should be designed with the intent that the knowledge gained will benefit the subjects and/or a larger community.

The benefits of the research should be made available to all subjects in the study regardless of their role in the research project. For example, positive outcomes found for any treatment group must be made available to all subjects at the completion of the study.

4. *Conducting research in a fair and equitable manner.*

The research should be designed to treat all individuals fairly. The selection of subjects must be based upon fair procedures and not overburden, over-utilize, or unfairly favor or discriminate against any subject pool.

5. *Honoring commitments made to subjects in a study.*

The investigator must honor all commitments made to subjects, contributors, or collaborators in a research project. Changes which are made in design must be clearly presented to all individuals involved in the study. It is the responsibility of the investigator to ensure that all parties clearly understand the commitments included in the agreement to participate in or support the study.

Standards of confidentiality must be respected, particularly in research where this is guaranteed to subjects. If there is a possibility that others may obtain access to any information about subjects which have been gathered during the investigation, ethical research practice requires that this possibility, together with the plans for protecting confidentiality, be explained to subjects as part of the procedure for obtaining informed consent.

C. Definition of Research

HHS regulations define *research* at 45 CFR 46.102(d) as follows: *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Research encompasses work which is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the subject involvement even if this work is preliminary to a more extensive study. This definition includes any systematic

collection of data from human subjects which occurs in conjunction with all research including classroom projects, theses, dissertations, and Plan B papers.

D. Categories of Research Involving the Use of Human Subjects

All research involving human subjects which is designed, in whole or in part, to develop or contribute to generalizable knowledge must receive IRB approval *prior to initiation* whether it is conducted by faculty, students, or staff. The type of review required depends upon the nature of the research, the subjects, and the risk imposed on the subjects, and the decision as to the type of review rests with the Director of the Institutional Review Board and/or the Vice Provost for Research. The three categories of research involving the use of human subjects are described below. In all cases investigators must complete the online application (see page 24). The review procedure and length of time required for review varies for each category.

1. Research that qualifies for exemption from ongoing IRB review

An adequate standard of informed consent and confidentiality must be maintained for all research involving human subjects, even that which is exempt from federal regulations. The code of federal regulations – [Title 45 CFR Part 46](#) – identifies several different categories of minimal risk research as being exempt from Federal Policy for the Protection of Human Research Subjects. The following are the "Exempt" Research Categories:

- Educational strategies, curricula, or classroom management methods
- Tests, surveys, interviews, or observations of public behavior
- Existing data, documents, or records
- Secondary data analyses

General characteristics of all exempt research include the following:

- With very few exceptions, private identifiable information cannot be recorded by the investigator or members of the research team.
- Research participants are typically given a consent form that does not require a signature

The review process differs as well. Investigators who argue that their research would qualify for the exempt category must submit a completed application to the IRB. This is reviewed by the IRB, who determines whether it meets the federal criteria for an exemption. Applications that do not qualify will be recommended for either an expedited review, if they meet those specific requirements, or will be recommended for full review at one of the convened IRB committee meetings.

Educational Strategies, Curricula or Classroom Management Methods - Basic Exempt Criteria {§46.101b(1)}

Research takes place in established or commonly accepted educational setting

Involves study of normal educational practices (e.g., regular and special education

instructional strategies; studies effectiveness or comparison among instructional techniques, curricula, or classroom management methods)

Subjects (or their parents, if subjects are minors) should be provided with overview of project that contains basic elements of informed consent, but no formal written consent is obtained.

If tests, surveys or interviews are ALSO included in this study...{46.101(b)2}

If subjects are children, only educational tests and/or passive observation of behavior is permitted; investigators cannot interact with subjects

If subjects are adults, tests, surveys, interviews or behavioral observations can be included

For subjects of any age, identifiers can be recorded only if no sensitive information is collected as part of the test, survey or interview.

Copies of all measures must be attached for IRB review

Additional General Requirements or Considerations

When children are studied in school or other institutional settings, approval from relevant school official (including the school system IRB or research review committee, if available) must be attached to this application at the time it is submitted to the IRB

Tests, Surveys, Interviews, Observations - Basic Exempt Criteria {§46.101b(2)}

Research includes evaluation of individuals using educational or cognitive tests, surveys, questionnaires, structured or open-ended interviews, or systematic observations of public behavior.

NOTE: Studies cannot be exempt if the participant's name (or other identifiers like birth date and initials, social security number, phone number, etc.) is linked to "private" or "sensitive" information.

If subjects are children, this exemption category cannot be used. **In other words, surveys or interviews with children do not qualify as exempt.**

If subjects are adults, tests, surveys, interviews or behavioral observations can be included

Data should ordinarily be recorded without identifiers

If **appropriately justified**, identifiers may be recorded, but only if no sensitive information is collected

Subjects (or their parents, if subjects are minors) should be provided with overview of project that contains basic elements of informed consent, but no formal written consent is obtained.

Additional Requirements or Considerations

If subjects are followed over time and assessed repeatedly, written informed consent should be obtained (and the study submitted for expedited review)

Focus groups can be considered to be open-ended interviews, and may be approved for adults, provided the basic exempt criteria are met

Copies of all measures must be attached for IRB review.

When studies are conducted in foreign countries, written authorization to conduct the research at that location must be attached to this application. If identifiers are collected as part of that research activity, the investigator has the responsibility to ensure that responses to questionnaires or interviews about political, economic, cultural, or religious topic will not affect the participant's reputation, employability, or financial standing. This may require additional documentation from someone with first-hand familiarity with the country's laws and mores.

Existing Data, Documents, or Records - Basic Exempt Criteria §46.101b(4)

Research is most commonly conducted on data derived from patients' medical records or school records, but other research or clinical records may also be accessed under this exemption. Although investigators can review those records (if they have a legitimate right to access those records), they cannot record any private identifiable information from these records (see HIPAA "Safe Harbor" De-Identification of Medical Record Information guidelines). An [Honest Broker](#) can be used, however.

All data are currently in existence

All information is publically available, OR

All information is recorded anonymously, OR

If the data are from health-care records, they must be recorded in such a way that researchers cannot identify subjects. Two acceptable strategies for this de-identification exist:

Identifiable data are de-identified by an appropriate software program OR

The de-identification of data is carried out by a person who is independent of the research (i.e., an independent "[honest broker](#) ") and who has been identified by name in the protocol, and has completed the "honest broker" certification form. Information linking the assigned code numbers to the subjects' identity (if applicable) is maintained solely by the independent "honest broker"

Additional Requirements or Considerations

A copy of the data extraction form or a list of variables to-be-studied must be submitted with the IRB application

Investigator's right to access records (including medical records) must be documented in protocol, including permission letters if applicable.

HIPAA Guidelines for De-Identification of Medical Record Information HIPAA "Safe Harbor" De-Identification of Medical Record Information requires that each of the following identifiers of the individual or of relatives, employers, or household members of the individual must be removed from medical record information in order for the records to be considered de-identified:

1. Names
2. All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial 3 digits of a zip code if, according to the currently publicly available data from the Bureau of Census: a. The geographic unit formed by combining all zip codes with the same 3 initial digits contains more than 20,000 people; and b. The initial 3 digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.
4. Telephone numbers
5. FAX numbers
6. Electronic mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers; license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) address numbers
16. Biometric identifiers
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except a code to permit re-identification of the de-identified data by the Honest Broker.

Secondary Data Analyses - Basic Exempt Criteria §46.101b(4)

Data analysis is considered to be a research activity and for that reason, it necessarily requires IRB oversight. From an IRB perspective, there are several different strategies for handling changes in the data analytic plan

If the original IRB protocol has been closed, and the original investigators now wish to re-analyze or otherwise examine data from that protocol - i.e., conduct a 'secondary analysis' of their own data, they should submit a new protocol to the IRB describing the analysis plan. If the analysis includes data that remain identifiable, and if the IRB protocol was originally reviewed and approved either by an expedited or full board review, this new protocol should be submitted for an expedited review. Please follow the instructions in the IRB Manual for an expedited review submission. Because expedited reviews necessarily require a consent form, please attach a copy of the original IRB-approved consent forms.

If the original IRB protocol has been closed, and the original investigators now wish to share their data with a student or colleague, the data must be de-identified before it can be shared. Exceptions to that requirement occur when the data (a) are publicly available or (b) were recorded originally without identifiers or (c) were archived by the original investigators without identifiers. Secondary data analyses that fall into this category can be reviewed by the IRB as exempt, and the basic exempt criteria, with appropriate forms, are provided below.

All data are currently in existence and previously approved by an IRB.

All information is publicly available, OR

All information was recorded without identifiers, OR

If data are health-care records, they should be recorded in such a way that researches cannot identify subjects. Two acceptable strategies for this de-identification exist:

Identifiable data are de-identified by an appropriate software program OR

The de-identification of data is carried out by a person who is independent of the research (i.e., an independent "honest broker") and who has been identified by name in the protocol, and has completed the "honest broker" certification form. Information linking the assigned code numbers to the subjects' identity (if applicable) is maintained solely by the independent "honest broker"

2. Research that qualifies for expedited IRB review

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 categories** (carried out through

standard methods) may be reviewed by the IRB through the expedited review process. The activities listed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when specific circumstances of the proposed research involve no more than minimal risk to subjects. In addition, previously approved (within one year or less) research with only minor changes qualifies for expedited review.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no more than minimal.

Applicants are reminded that the requirements for informed consent apply regardless of the type of review--expedited or full board.

a. Clinical studies of drugs and medical devices **only when** condition (1) or (2) is met.

1. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increase the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

2. Research on medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts must not exceed 550 ml in an 8-week period and collection may not occur more frequently than two times per week; or from other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than two times per week.

c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include hair and nail clippings in a non-disfiguring manner; deciduous teeth at the time of exfoliation or if routine patient care indicates a need for extraction, permanent teeth if patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva either collected in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; placenta removed

at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; supra- and sub-gingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; sputum collected after saline mist nebulization.

d. Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples include physical sensors that are applied either to the surface of the body or at a distance and do not involve the input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy; weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis) although some research in this category may be exempt.

f. Collection of data from voice, video, digital, or image recording made for research purposes.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt).

3. Research requiring full IRB review

All research involving the **deception** of subjects (the researcher deceives the subject with regard to the purpose of the research and/or the results of the subject's actions in the study); **sensitive behavioral or biomedical research** (such as research relating to illegal activity or sexual activity); research involving **vulnerable groups** (e.g., pregnant women, prisoners, people with decisional impairments); or research **involving risk** to the subjects automatically requires review by the full IRB. Additionally, if a proposal is submitted as an expedited proposal but does not receive approval at the expedited level, it will be reviewed at the full IRB level. This may occur if information is omitted or procedures are unclear. In such cases, expedited

reviewers are unable to evaluate risks to subjects, and must request a full board review. Such action often delays onset of the project.

E. Student Research

Student research follows the same guidelines as all other research. IRB approval must be received **prior** to the student initiating the research.

F. Classroom Research (as part of a course)

To provide guidance to faculty members, the IRB has developed the following criteria to determine if classroom assignments require IRB approval. Formal approval by the IRB may not generally be required if **ALL** of the following are true:

- The project is a class requirement and the requirement is stated on the class syllabus.
- The project involves only members of the class (i.e., only enrolled students and the instructor(s) of the course), such that data are collected only from and by such members.
- The data are collected within the confines of the classroom or laboratory assigned to that course, or data are conducted as part of small group settings consisting only of members of the class, as defined above.
- The project carries no risk, as determined by the IRB (see risk categories below).

If research is conducted outside the confines of any classroom or laboratory, or is intended to be presented outside of the classroom, it must be approved by the IRB in all cases. Faculty and students may contact the IRB Chair and Members to discuss the assignment and obtain assistance in determining if review is needed.

1. If the faculty member believes that the assigned classroom research does not require formal IRB approval, he/she should complete an application for “**Classroom Research Not Requiring IRB Review**” for the course being taught, including the course syllabus as an attachment and submit to the IRB office for approval.

2. If the faculty member believes that classroom research does require IRB approval (based on the above criteria), he/she should complete an “**IRB-Classroom Research**” application for the course being taught, including classroom research assignment forms for each student. Each student in the course must complete the “classroom assignment form” and submit to the faculty instructor with all pertinent information necessary to determine if the project needs formal IRB review and/or approval. For these activities,

PLEASE NOTE: If any of the following criteria are met, the project would not qualify for review through the Classroom Research Review process. Rather, these projects must be reviewed by the IRB through the regular IRB review process. This list is not all inclusive and

the IRB withholds the right to request that any classroom research project be reviewed through the regular IRB review process.

- Participants are from a special population such as minors (under 18 years old), prisoners, patients, physically or mentally challenged individuals, or pregnant women.
- The assignment requires using a setting such as prisons, nursing homes, hospitals, or schools.
- The assignment focuses on sensitive topics such as alcohol/drugs, depression/suicide, learning disabilities, abortion/AIDS/HIV/Sex, sexually transmitted diseases, eating disorders, or other sensitive psychological inventories.
- The assignment involves potential risk (physical, psychological, emotional, social, or economic).
- The assignment includes audio taping or videotaping.
- Participants can be directly identified through the assignment.
- The project will be formally presented to an audience outside of the class (including SRCEE or other on-campus forums).

Applications for classroom research can be found on pages (49-53). It is the responsibility of the instructor to ensure that all documents are completed for all members of the course.

G. Research Conducted Cooperatively with another Institution

In the conduct of research involving more than one institution, **each** institution is responsible for safeguarding the rights and welfare of human subjects and for complying with federal regulations. Institutions may enter into a joint review of another qualified IRB, or make similar arrangements for avoiding duplication of effort. The agreement for IRB review of cooperative research must be documented in writing with copies to be furnished to all parties to the agreement, and those responsible for ensuring compliance with the regulations and the IRB's determinations. Such agreements must be noted on CMU's Federal Wide Assurance documents and filed with the OHRP. Investigators should seek IRB counsel prior to engaging in cooperative research involving the use of human subjects.

H. Institutional Review Board (IRB) Composition

Each IRB Committee is composed of a minimum of 5 voting members nominated by the Vice Provost for Research. : 3(or more) members of the university faculty and/or staff, at least one non-university member (who may not be part of the immediate family of a person who is affiliated with Central Michigan University), and at least one person from the ORSP who will serve as executive secretary. At least one member of the committee must have research interests in scientific areas and at least one member of the committee must have research interests in nonscientific areas. A quorum consists of at least half of the voting members of the

committee, and must include the non-scientist representative. In the event that applications involve the review of special populations, additional members may be required in order to review the application. For example, all projects involving prisoners as human subjects require that a prisoner advocate be present at the full board meeting in which the protocol is reviewed. Committee members will serve three year terms with 1/3 of the committee being replaced each year. The IRB chairperson may request that any committee member who misses three consecutive meetings be replaced.

I. IRB Committee Meeting Times

Each committee will select a chairperson at the first full-board meeting of the academic year. Both IRB Committees will normally meet on one Friday per month during the academic year. When deemed necessary, the full board committee may hold additional meetings during the month. Summer meetings will be arranged as needed.

J. IRB Deadlines

Applications for review by the full IRB must be submitted through the online submission system (IRBNet) by 5:00 p.m. EST, two weeks prior to the scheduled meeting date to be considered at that meeting. Late applications will be carried over to the next scheduled meeting. Applications applying for exempt status or for expedited review may be submitted through the online system at any time.

K. Noncompliance Policy

Human subjects research that deviates from the policies, procedures, stipulations, decisions, state, or federal law is noncompliant and subject to further inquiry by the IRB and Office of Research and Sponsored Programs (ORSP). Federal Mandate 45 CFR Part 46.113 states that

An IRB shall have 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 subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

All reports and complaints of non-compliance should be directed to the IRB or ORSP (via email, phone, mail, or in person). The IRB or ORSP will immediately investigate all allegations of non-compliance. If necessary, the IRB or ORSP will send the investigator/s in question a notice requesting the immediate suspension of all specified research activities while the issue of non-compliance is reviewed. This initial notice will also include a statement detailing the rationale for the IRB's action. There are three categories of non-compliance: general, serious, and continuing.

1. **Non-compliance:** Any deviation from CMU's IRB policies and procedures, federal regulations, or state law is "non-compliance." Failure to follow requirements and determinations of the IRB is also considered "non-compliance."

2. Serious Non-compliance: All Non-compliance substantially affecting participants' rights and/or welfare, or impacting upon the risks or benefits is serious non-compliance.

3. Continuing Non-Compliance: Is a pattern of non-compliance that indicates an inability or unwillingness to comply with the regulations or the requirements of the IRB.

Non-compliance can include, but is not limited to:

- Failure to obtain IRB approval for research involving human subjects;
- Failure to follow study protocol;
- Inadequate procedures for informed consent;
- Inadequate supervision of research involving experimental drugs, devices or procedures;
- Failure to follow requirements made by the IRB to ensure the safety of subjects;
- Failure to report adverse events;
- Failure to act on, or report to the IRB, information from the sponsor which affects subject safety;
- Failure to report proposed protocol or consent form changes to the IRB;
- Failure to solicit IRB approval for proposed recruitment methods and materials prior to use;
- Failure to provide timely continuing review of on-going studies;
- General non-compliance with IRB policies or research regulations.

The IRB may also review allegations of conflict of interest, financial mismanagement, etc.

The IRB requests that individuals observing investigator non-compliance report to the IRB within 72 hours (or as soon as reasonably possible), any (i) unanticipated problems involving risks to subjects or others; (ii) any serious or continuing noncompliance with Federal Regulations or the requirements or determinations of the IRB; and (iii) any suspension or termination of sponsor approval.

In response to an allegation of non-compliance, the IRB will investigate the allegation. Documentation of the event will be recorded in a report generated by the IRB. The documentation will be kept in the IRB office and provided to all required parties.

If necessary, the IRB will conduct an on-site audit during the investigation. Alternatively, the IRB may audit the investigator at a predetermined future date in order to ensure that the investigator has made efforts to initiate the recommended compliance requests.

Possible IRB actions may include, but are not limited to:

- Dismissal of the complaint as unjustified;
- Require education of Principal Investigator (or other investigator or study personnel);
- Impose specific monitoring of compliance with applicable rules;

- Require increased reporting by the Principal Investigator of his/her human subjects research activities;
- Suspend approval for one or more of the Principal Investigator's studies;
- Terminate approval for one or more of the Principal Investigator's studies;

The IRB will send a copy of its final decision to the Principal Investigator. If the allegation involves activities occurring at a non-CMU facility or institution, the IRB will share the information with that site, as appropriate.

Suspension or Termination 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 subjects.

Suspension or termination of approval includes written documentation of the reasons for the IRB's action that is promptly reported to:

The principal investigator and any other investigators;
 The Vice Provost for Research;
 The appropriate institutional officials;
 The Food and Drug Administration, if the study is a drug or device study (per regulations set forth at 21 CFR 56.108(b)(3));
 The Office for Human Research Protection (OHRP) (per regulations set forth at 45 CFR 46.103(B)(5)(ii));
 The Study Sponsor.

Study Suspension. A study may be temporarily suspended to further enrollment if the IRB finds additional information is needed to ensure the ongoing safety of participants or while awaiting a response from the investigator regarding an initial allegation. Once the investigator has satisfactorily provided the IRB with sufficient information/corrected actions, the IRB may once again allow the study to be open to accrual.

Temporary suspensions to enrollment which are not due to investigator non-compliance (i.e. possible increased risk to subjects, needing investigation and/or clarification) are only reported to the investigator and, if relevant, the appropriate institutional officials.

Reasons for suspension may include:

- Discovery of increased risk to study participants.
- New findings that impact enrolled subjects.
- Failure to report unanticipated problems to the IRB.
- Failure to obtain legally effective informed consent.
- Failure to document informed consent.
- Deficient informed consent documents in general.

- Enrollment procedures that did not minimize the possibility of coercion or undue influence.
- Failure to seek continuing review in a timely manner.
- Other evidence of non-compliance

Study Termination. A study may be terminated if the issues surrounding the suspension of a study cannot be satisfactorily addressed and resolved. Serious issues of investigator non-compliance may lead to the termination of all of an investigator's active studies. Sufficient and substantive evidence is required to justify the termination of all of an investigator's studies.

L. Appeal Process

If the application is disapproved, the investigator has the right of appeal to the IRB. When necessary, the IRB will seek consultation from nationally recognized experts in the field, other IRBs, and the Federal Office of Protection from Research Risks. Every attempt will be made to resolve the identified problem(s). The IRB, however, retains final authority over whether or not an application can be approved.

M. Continuing Review and Submission of the Annual Update

Expedited and full board applications are approved for a **maximum** period of one year (exempt proposals do not require continuing review and annual updates); however, the IRB reserves the right to monitor projects throughout the approval period. In the event that the IRB determines that the project poses risk or is noncompliant with regulations, the IRB may suspend or revoke the approval. If the IRB determines that a project requires review more often than annually, the investigator will be notified. For projects which continue beyond one year, it is the responsibility of the investigator to submit to the IRB (Foust 251) a request for an annual update. The first update is due 60 days prior to the date of expiration (10 months following the date the application was approved). To simplify this process, a Request for Annual Update form has been provided on page 38. Projects can be updated annually for a maximum of 5 years. Continuation of projects beyond 5 years requires resubmission.

N. End-of-Project Report, Storage and Disposal of IRB Records

For expedited or full board projects, researchers are required to submit an end-of-project report at the conclusion of the project (this is not required for exempt proposals). An end-of-project report form is provided on page 45. Students who conduct human subjects research in fulfillment of a graduate degree requirement must file an end-of-project report to be eligible for graduation. If the project is not complete within 12 months following project approval, it is the responsibility of the researcher to submit to the IRB an annual update form (see D above, also page 45).

IRB files pertaining to approved applications are maintained for a period of three years beyond the End of Project Report and then destroyed. Files regarding denied applications are kept for a

period of three years following the date of application and then destroyed. The IRB will maintain a list of approved and unapproved projects (i.e., the name of the principal researcher and the title of the study) for a period of ten years following the application date.

O. Reporting Changes in a Research Protocol

Any change in a protocol must be approved by the IRB prior to implementation except where an immediate change is necessary to eliminate a hazard to the subjects. Investigators should submit a Request for Change in Protocol (page 41) to the IRB (Foust 251). If the protocol change requires changes in the consent forms, attach the new consent forms to the Request for Change in Protocol. Minor changes will be reviewed by an expedited review procedure. More substantial changes will need to be reviewed by the full board committee.

P. Submission of a Report of Injury

If a subject suffers an injury or experiences an adverse event as a result of or during the research, the investigator must take immediate action to assist the subject and notify the IRB of the injury within 48 hours. Examples of adverse or reportable events include any situation in which participants must withdraw from the study because of the effects of the study conditions, become ill, or are injured during the course of the time of participation. It is ultimately the decision of the IRB to determine the actions necessary when an adverse or reportable event occurs. For this reason, the researcher is required to complete an Adverse Event/Reportable Event Form (see page 43) and submit it to the IRB (Foust 251).

SECTION II

INSTRUCTIONS FOR APPLICATION FOR REVIEW OF RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

Prior to submitting an application, you are encouraged to read and understand the preceding information on the Institutional Review Board Policies and Procedures Involving the Use of Human Subjects in Research. A description of how to prepare an application and the required forms are contained on the following pages. **PLEASE NOTE: PAPER SUBMISSIONS WILL NO LONGER BE ACCEPTED AFTER JANUARY 1, 2009. AFTER THAT DATE, ALL SUBMISSIONS MUST BE MADE THROUGH IRBNET (THE ONLINE APPLICATION SYSTEM).**

It is essential that you provide adequate time for your proposal to be reviewed. The time frames listed below are for initial responses from the IRB. This does not assure approval within that time frame. **IN ORDER TO ASSURE ADEQUATE TIME FOR POTENTIAL REVISIONS, RESEARCHERS ARE ENCOURAGED TO SUBMIT THEIR PROPOSALS AT LEAST FOUR (4) WEEKS PRIOR TO THE ANTICIPATED DATE FOR RESEARCH TO BEGIN.**

1. **EXEMPT PROPOSALS:** If you believe your project is eligible for exempt status, submit 1 copy of the application to your Department Chairperson for review. The Department Chairperson may appoint a departmental member to review applications. Once you have received approval from the departmental representative, the application should be submitted to the IRB. **PLEASE NOTE: The IRB is the final determination of whether a project qualifies as exempt. Do not begin the project until the IRB has granted this exemption.** Applications for exempt status may be submitted at any time to the IRB (Foust 251). Typically, within **one to two weeks** you will receive one of the following decisions:

- a. protocol approved as submitted,
- b. approval withheld pending submission of revisions and/or additional information, or
- c. protocol requires either expedited or full IRB review.

2. **EXPEDITED PROPOSALS:** If the research qualifies for expedited review, submit three copies of the application to the IRB (Foust 251), with the signature from the departmental chair or designee. Applications for expedited review may be submitted at any time to the IRB (Foust 251). Typically, in approximately **two-four weeks**, you will receive one of the following decisions:

- a. protocol approved as submitted,
- b. approval withheld pending submission of revisions and/or additional information, or
- c. protocol requires full IRB review.

3. **FULL BOARD PROPOSALS:** If the research requires full IRB review, submit 8 copies of the application to the IRB (Foust 251), with the signature from the departmental chair or

designee. **Applications for review by the full IRB must be submitted to the IRB (Foust 251) by 5:00 p.m. EST, two weeks prior to the scheduled meeting date to be considered at that meeting. Late applications will be carried over to the next scheduled meeting.** Within **one-two weeks after the committee meeting**, you will receive one of the following decisions:

- a. protocol approved as submitted,
- b. approval withheld pending submission of revisions and/or additional information, or
- c. protocol disapproved.

4. **SUBMITTING REQUESTED REVISIONS:** If the decision was (b) Approval withheld pending submission of revisions and/or additional information, the investigator must submit one copy of the revisions to the IRB before final approval can be granted. Revisions will be evaluated as soon as they are received by the IRB office, and the investigator will be notified once the project is approved. Please note: formal approval from the full board committee is required for all expedited and full board proposals. Therefore, once revisions have been satisfactorily completed, approval will be contingent upon the convened full board vote.

All notifications will be communicated either by email or by letter, if appropriate email addresses are not provided.

APPLICATION INSTRUCTIONS

Beginning January 1, 2009, all applications to the IRB (with the exception of “classroom research”) must be submitted through the online IRBNet system. During the Fall Semester of 2008, researchers are encouraged to begin using the IRBNet system, as applications processed through the system will allow researchers to track the status of their proposals. If the researcher chooses to apply to the IRB during the Fall Semester 2008 using a paper application, the following application is required to be submitted for review. Direct all questions to the IRB (Foust 251, ext. 6401). Please complete all of the following information. The application should include required information but not information which is irrelevant for IRB review (for example, do not submit full copies of thesis or dissertation proposals). Copies of consent forms, questionnaires, or other instruments must be included. Page numbering will facilitate review.

APPLICATION FOR REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

This application form will only be accepted through the end of 2008. As of January 1, 2009 all applications must be submitted to the IRB through the online IRBNet system.

Federal regulations and Central Michigan University's (CMU) Institutional Review Board (IRB) policy require that all research involving humans as subjects be reviewed and approved by the University's IRB prior to the commencement of the research (including recruitment and data collection). Any person (CMU faculty member, student, staff member, or other person) wanting to engage in human subject research must receive written approval from the IRB before conducting the research. This approval by the IRB only signifies that the procedures adequately protect the rights and welfare of the subjects.

1. Title of Project:

2. Principal Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Has PI completed human-subjects training?

Note: All student investigators must have a faculty co-investigator.

3. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Has co-PI completed human-subjects training?

4. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Has co-PI completed human-subjects training?

Please attach additional pages as needed for multiple co-investigators.

5. Will there be any non-investigators working on the project (e.g., research assistants, data analysts, etc.)? If yes, then each individual must complete the “confidentiality agreement found below.

6. Level of review sought:

- a. Exempt (submit Exempt Category Form – see page 36)
- b. Expedited
- c. Full Board

7. Is the research funded? (please attach a copy of the funded proposal)

- a. Internally
 - i. Program _____
- b. Externally
 - ii. Funding Source _____
- iii. Grant/Contract Number _____
- c. No funding source _____

8. Is this research being conducted for:

- a. Thesis (Submit evidence of committee approval. Do not submit the thesis proposal.)
- b. Dissertation (Submit evidence of committee approval. Do not submit the dissertation proposal.)
- c. Class project
- d. Independent study/Honor’s Thesis
- e. Faculty Research
- f. Other

9. Special Populations: Indicate the categories of subjects to be included in this study. Check ALL that apply.

- a. Decisionally impaired
- b. Decisionally impaired and institutionalized
- c. Minors (under age 18 – give age ranges)
- d. Patients
- e. Prisoners
- f. Pregnant Women
- g. Students
- h. Existing/Secondary Data
- i. Normal volunteers
- j. Other (specify

10. Types of Consent Forms and Assent Forms required: Check ALL that apply.

- a. Normal volunteers (ages 18 and above)
 - Anonymously returned survey – submit consent form for anonymous survey
 - Telephone/informal interview – submit consent form for interview
 - Other – submit standard adult consent form

b. adults with decisional impairment submit adult assent form for impaired AND guardian consent form

c. Minors

i. Under age 7—submit child assent form for children under age 7 AND parental consent

ii. Ages 7-12 – submit child assent form for children ages 7-12 AND parental consent form

iii. Ages 13-17 – submit child assent form for children ages 13-17 AND parental consent form

11. Number of subjects to be: Recruited _____ Enrolled _____

12. Risk Level: Indicate which of the categories listed below accurately describes this protocol:

a. Not greater than minimal risk

b. Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects

c. Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalized knowledge about the topic

d. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and welfare of subjects

13. Will this research be conducted elsewhere (other than CMU, such as at an agency, school, or place of employment)? - attach permission letters from all agencies, schools, etc. granting you permission to conduct the study at their location.

14. Will you use flyers or advertisements to recruit participants? - attach flyers, ads, emails, etc used for recruiting

15. Does this research involve past, present, or future physical or mental health or condition of subjects; provision of health care to subjects, or the past, present, or future payment for the provision of health care to subjects?

a. Yes: see HIPAA website: <http://www.hhs.gov/ocr/hipaa/guidelines/research.pdf>

b. No

16. Does this research involve identifiable information from students' educational records?

a. Yes: see FERPA website: http://www.ed.gov/policy/gen/guid/fpco/ferpa/library/nashville_tn2004.html

b. No

17. Does this research involve minor students in which any of the following information will be ascertained: political affiliations or beliefs of the student or student's parent; mental and psychological problems of the student or the student's family; sex behavior or attitudes; illegal, anti-social, self-incriminating, or demeaning behavior; critical appraisal of others with whom respondents have close family relationships; legally recognized privileges or analogous relationships (e.g., lawyer, physician, minister); religious practices, affiliations, or beliefs of the student or student's parent, or income?

a. Yes: see PRA website: <http://www.ed.gov/policy/gen/guid/fpco/ppra/index.html>

b. No

18. Are you collecting data at your place of employment or internship?

a. Yes – what is your role in relation to the potential subjects?

b. No.

19. Is this a web-based survey?

a. Yes – what is the URL and password (if applicable)?

b. No.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the protocol and/or consent/assent form(s) and will not implement the changes until I receive IRB approval for these changes. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB via phone or email immediately, and then in writing within 5 days of the occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

Principal Investigator's Signature

Date

Faculty Assurance (required when PI is a student)

I certify that I have reviewed this proposal and discussed it with the PI.

Faculty Advisor's Signature

Date

Administrator (e.g., department chair, dean, or supervisor) Assurance

This is to certify that I have reviewed this proposal.

Administrator's Signature

Date

ATTACH THE COMPLETED FORMS FROM ABOVE WITH RESPONSES TO THE FOLLOWING QUESTIONS AND SUBMIT THE COMPLETE APPLICATION TO THE IRB.

Abstract: Provide a brief overview of the project, describing the purpose, objectives, design and site of the research in straightforward non-technical language.

It is important for the review of your study that you respond to all questions. The review time will be extended if reviewers must request this information at a later time.

Protocol

- Where will the research be conducted?

- Who will conduct the research and how many investigators will be involved?
- Describe the training procedure for the researcher and/or persons assisting in the research. This should include information which demonstrates the researcher's ability to carry out the responsibilities in the project (such as clinical training and/or certification, course work, etc.).
- Describe the data gathering instruments that will be used. Attach copies of all questionnaires, interview schedules, or other data collection instruments. All measures should be submitted in Word or as .jpg files. If your measures are copy written materials that cannot be uploaded, you may submit them separately to the IRB office
 - Describe any apparatus that will be used for data collection.
 - Will videotape or audiotape be used to collect data?
 - Please describe the procedures that will be used to maintain confidentiality during taping.
 - Please describe how tapes will be stored and disposed of.
 - Who will have access to the tapes and who will make the transcriptions?
 - Describe the procedure that will be used during transcription to remove identifying information.

Describe any plans to use the taped information for purposes other than this research.

- State the amount of time required of a subject to participate in your study. This should include the number and length of times of participation (e.g., two sessions lasting 30 minutes each).

Characteristics of Subjects

- How many subjects do you estimate will participate in your study?
- Describe the expected ages, gender, ethnic backgrounds and health status of subjects.
- If any of the subjects will be children, cognitively impaired, prisoners, pregnant women and/or fetuses, or from other vulnerable groups, please provide a rationale for their participation.
- Will data collection be done in a classroom setting?
- Explain what students who do not participate in the research will be doing.

- What is the source of the subject pool (e.g., all teachers at a school, department subject pool, community members, etc.)? If the list of potential subjects is publicly available, please indicate so.
- How will participants be selected or recruited?
- Will selection be accomplished on the basis of document review?
 - Explain how document review will take place and provide assurance that the researcher will not have access to private or confidential files.
- Will selection of participants be accomplished on the basis of primary data collection (e.g., a screening measure)?
 - The screening process must be made clear to the subjects during the initial consent process. Include appropriate debriefing information for individuals removed from the research and an additional consent form for those remaining as subjects in the research project.
- Attach any advertisements, flyers, cover letters, or scripts to be used in recruiting subjects.
- Is participation voluntary?
- Explain how the researcher will minimize any possibility of perceived coercion to participate.
- Is the researcher a teacher and/or supervisor of potential subjects?
 - Coercion should be specifically addressed both here and in the consent form. For example, in the consent form, you might write something like “Although I am your teacher, I will not know who participated in this project and your relationship with me and your performance in this class will not be affected by participation or non-participation.”
- Attach a letter giving approval from any agencies or schools that will be involved with the data collection.
- Will there be any unauthorized access to private or confidential information in the securing of the pool of potential subjects?
- Document that you have the right to access the information (include letter from agency or school if appropriate).
- Will any of the data be taken from archives that are subject to HIPAA regulations?
- Assure that none of your data files will contain any of the 18 identifiers listed by HIPAA (click here for list of identifiers).

Benefits

- What are the benefits of participation to the subjects or larger community?
- State clearly the importance of expected knowledge to be gained from this research project.

Risks and Protection of Subjects

- Does the proposed study pose a physical risk to participants?
- Describe how you will attempt to protect the participant from this risk.
- Does the proposed study pose a psychological risk to participants?
- Describe how you will attempt to protect the participant from this risk.
- Does the proposed study pose a social risk to participants?
- Describe how you will attempt to protect the participant from this risk.
- Does the proposed study pose a legal risk to participants?
- Describe how you will attempt to protect the participant from this risk.
- Does the proposed study pose an economic risk to participants?
- Describe how you will attempt to protect the participant from this risk.
- Is there a possibility of any potential reactive effects of the instrumentation as well as the treatment that have not been addressed in the above risk questions?
- Describe how you will attempt to protect the participant from this risk.
- Describe how confidentiality will be maintained. Have the risks of a breach of confidentiality been considered? What precautions have been taken to minimize these risks?
- Describe the final disposition of materials used to gather data (e.g., questionnaires, inventories, tapes, etc.) if necessary.
- Address issues of privacy and potential coercion for research involving vulnerable subjects.

Confidentiality

- Describe the precautions that will be taken to ensure the privacy of subjects and

confidentiality of information by answering the following questions. Be explicit if the data are sensitive.

- How and where will information be kept that could identify subjects?
- Who has access to information which could identify subjects?
- How long will information be kept that could identify subjects?
- What is the plan for disposition of information that could identify subjects, if appropriate?
- Will coding be used to replace names in your data?
- Describe the coding procedure, ensuring that no individual identifiers will be used and that codes could not be used to link a participant with his/her responses or data.
- Will data be collected by observation of behavior without explicit agreement of the subjects?
- Specify that the subjects have no reasonable expectation that their behavior is private.
- State that the data will have no individual codes or coding will be unrelated to the individual under observation.

Consent and Assent Forms

- Will any subjects be under age 7?
- If so, submit child assent form for this age group and a parental consent form.
- Will any subjects be between ages 8-13?
- If so, submit child assent form for this age group and a parental consent form.
- Will any subjects be between ages 14-17?
- If so, submit child assent form for this age group and a parental consent form.
- Will any subjects be of adult age (18+), but unable to provide consent to participate?

(This may include cognitively impaired adults or those deemed unable to provide consent).

- If so, submit assent form for adults unable to provide consent and a guardian consent form (modify parental consent form for this purpose).
- Will any subjects be adults (age 18+) that are able to provide consent?
- Will any of the adult participants be provided with a survey that will be returned anonymously?
- If so, submit consent form for anonymous surveys.
- Will any of the adult participants be asked to complete a survey “on the street” or on the phone?
- If so, submit consent form for telephone or informal surveys.
- Will any of the adult participants be interviewed in person?
- If so, submit adult consent form.
- Will any of the adult participants be asked to complete surveys, questionnaires, or other instruments and measures not included in the above questions?
- If so, submit adult consent form
- Describe the process for obtaining consent and/or assent. Remember that the form used (above) is simply to document that consent and/or assent was obtained. The objective of informed consent is to provide a person with enough information to be able to make an informed decision, without coercion, to participate or not participate in your study.

SUBMIT RESPONSES TO THE ABOVE QUESTIONS AND APPLICATION COVER PAGES TO THE IRB COORDINATOR, OFFICE OF RESEARCH AND SPONSORED PROGRAMS, FOUST HALL 251. INCLUDE COPIES OF ALL CONSENT/ASSENT FORMS, DATA COLLECTION MATERIALS, AND ANY FORMS BELOW THAT APPLY TO YOUR STUDY. APPLICATIONS WILL NOT BE REVIEWED UNTIL ALL RELEVANT MATERIALS HAVE BEEN SUBMITTED TO THE IRB.

This form is for individuals who conduct specific research tasks such as: transcribing, interpreting, translating, collecting, entering data, and shredding data. Please submit one copy for each individual.

Central Michigan University Institutional Review Board

Research Assistance Confidentiality Agreement

Project Title:

I, (Name) _____, a
Research Assistant agree to:

1. Keep all the research information shared with me confidential by not discussing or sharing the research information in any form or format (e.g., including but not limited to disks, tapes, transcripts) with anyone other than the Researcher(s).
2. Return all research information in any form or format (e.g., including but not limited to disks, Tapes, transcripts) to the Researcher(s) when I have completed the research tasks.
3. After consulting with the Researcher(s), erase or destroy all research information in any form or format regarding this research project that is not returnable to the Researcher(s) (e.g., including but not limited to information stored on computer hard drive).
4. Other (specify, or N/A):

(Print Name)
Research Assistant

(Signature)

(Date)

(Print Name)
Researcher

(Signature)

(Date)

This study has been reviewed and approved by the CMU IRB. For questions regarding participant rights and ethical conduct of research, contact the Director of the IRB.

Research Assistance Confidentiality Agreement

Non-Human Research Determination Form

Complete this form if you believe that your project either does not involve human subjects or that it does not qualify as "research."

1. Date of Report:

2. Title of Project:

3. Principal Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Note: All student investigators must have a faculty co-investigator.

4. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

5. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

6. Project Begin Date: Project End Date:

Provide responses to the following items and submit your responses along with this form. Each response should be numbered or labeled to correspond to the following items.

7. Determination of "Human Subjects:"

a. Does the activity involve the interaction or intervention with living individuals?

b. Does the project only involve data/samples from living individuals?

c. If applicable, what kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires, etc.) will be involved in your project?

i. Indicate the number of participants' data/samples you are planning to use.

ii. Will you be collecting or receiving samples or data?

Do the samples or data already exist or are they being collected for the express purpose of this study?

iv. Please check any that apply:

1. _____ Samples and/or data will be anonymous and cannot be linked to individual subjects by you or your collaborators.

2. _____ Samples and/or data will be coded; however that code cannot be used to identify specific individuals.

3. _____ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the researcher will not be able to do so.

8. What role will you have in this project?

a. _____ Analyze samples/data only.

b. _____ Consultant/advisor to collaborator(s) listed above.

c. _____ Author of the protocol that is being implemented.

d. _____ Co-author on publications pertaining to this research.

9. Has the activity that **you are proposing in this form** been approved by an IRB elsewhere?

a. _____ No IRB review of the activity has taken.

b. _____ Yes, the activity has been reviewed by the following IRB(s). (Please provide the following information for each IRB):

i. Name of institution that provided the review.

ii. Address of reviewing institution.

iii. Name of PI for the IRB approved protocol.

iv. Title of IRB approved protocol and protocol number.

10. Will you send results back to the provider(s)?

a. _____ No, I will not send results back to the provider(s).

b. _____ Yes, I will send aggregate results to the provider(s).

c. _____ Yes, I will send results to the provider(s) that are linked to identifiable individuals.

Signatures. All of the individuals listed below must sign your application prior to submission of this report. By so doing, each attests to the statement following that respective person's role.

Investigator Date

I certify that the information provided for this project is correct.

Faculty Advisor (required when PI is a student) Date

I certify that I have reviewed this report and discussed it with the PI.

Administrator (e.g., department chair, dean, or supervisor) Date

I certify that I have reviewed this report.

Exempt Categories Form

All requesting exempt status for their proposed research must specify under which category they are seeking approval for exempt status. The exempt categories are listed below. It is important to remember that the IRB is responsible and the final authority for determining whether a project qualifies as exempt. This form must be submitted with the Application for Review of Research Involving Human Subjects.

Principal Investigator's Name: Co- Investigator's Names:

Date of Request: Title of Project:

Research activities in which the **only** involvement of human subjects will be in one or more of the following activities are exempt from federal regulations provided that the information taken from or about these subjects is recorded in such a manner that subjects cannot be identified either directly or through identifiers linked to the subjects.

Please check the exempt category under which you are applying.

_____ 1. When educational research meets **ALL** of the following conditions, it is exempt from federal regulations and does not require parental consent, although parental notification is appropriate. The investigator and/or the school system may, however, decide that parental consent should be obtained. Whenever possible, child **assent** should be obtained.

- a. All of the research is conducted in established or commonly accepted educational settings, 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.
- b. If the research involves educational tests (cognitive, diagnostic, aptitude, achievement), this information must be recorded in such a manner that subjects cannot be identified, directly or indirectly or through identifiers linked to the subjects.
- c. The study procedures do not represent a significant deviation in time or effort requirements from those educational practices already existing at the study site.
- d. The study procedures involve no increase in the level of risk or discomfort compared to normal, routine educational practices.
- e. The study procedures do not involve sensitive topics (e.g., sex education).
- f. Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.
- g. The school or other institution grants written approval for the research to be conducted.

_____ 2. The research involves the use of surveys, interview procedures, or observation of public behavior and is not part of educational research conducted in an established or commonly accepted educational setting described in paragraph "1" above. **However, the**

presence of any one of the following conditions means that the research is NOT exempt from federal regulations and requires an expedited or full board review.

- a. Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects.
- b. Any disclosure of subject responses outside the research setting which could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.
- c. Survey research dealing with sensitive or highly personal aspects of the subject's behavior, life experiences, or attitudes (e.g., chemical substance use and abuse, sexual activity or attitudes, sexual abuse, criminal behavior, sensitive demographic data, and detailed health history). The principle determinant of sensitivity is whether or not the survey research presents a potential risk to the subject in terms of possible precipitation of a negative emotional reaction. An additional consideration is whether or not there is risk associated with a breach of confidentiality should one occur.
- d. Research surveys and/or interviews involving children (subjects under 18 years of age) require an expedited or full board review.

_____ 3. Research involving the use of survey or interview procedure is exempt from federal regulations without exception when the respondents are elected or appointed public officials or candidates for public office and the interview or survey concerns the responsibilities of the office.

_____ 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

_____ 5. Research and demonstration projects which are conducted by or subject to approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

- a. public benefit or service programs; or
- b. procedures for obtaining benefits or services under those programs; or
- 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:

- a. if wholesome foods without additives normally contained in the food are consumed, or
- b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or an 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.

Request for Annual Update Form

Federal regulations and Central Michigan University's Institutional Review Board (IRB) policy require that the IRB conducts a continuing review of research at intervals appropriate to the degree of risk, but not less than once per year. To conduct this review, the IRB will review, at a minimum, a protocol summary, informed consent/assent form(s), and a status report on the progress of the research.

1. Date of Request:

2. Title of Project:

3. Principal Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Note: All student investigators must have a faculty co-investigator.

4. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

5. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Provide responses to the following items and submit your responses along with this form. Each response should be numbered or labeled to correspond to the following items.

6. Is the research funded?
- a. Internally
 - i. Program _____
 - b. Externally
 - i. Funding Source _____
 - ii. Grant/Contract Number _____
 - iii. No funding source

7. Approximate total number of NEW subjects to be enrolled:
- a. Number of subjects enrolled as of this date:
 - b. Number of subjects who have dropped out:
 - c. Number of subjects who have formally withdrawn:

If subjects have dropped out or withdrawn, please summarize reason(s) for withdrawal.

8. Since the last IRB review, have any injuries or adverse events occurred?
- a. Yes – Summarize injuries or events
 - b. No

9. Since the last IRB review, have any unanticipated problems involving risks to subjects or others occurred?
- a. Yes – summarize problems
 - b. No

10. Since the last IRB review, have any complaints about the research been received?
- a. Yes – summarize complaints
 - b. No

11. Are there any changes to the protocol requested?
- a. Yes – describe proposed changes to the protocol and attach a protocol summary include amendments or modifications to the research since the last review.
 - b. No—attach a protocol summary. Include any amendments or modifications that were approved through the protocol change procedure.

12. Are there any changes to the informed consent/assent procedure?
- a. Yes—describe change(s) and attach new consent/assent form(s) with changes highlighted.
 - b. No—attach consent/assent form(s)

13. Are there any additions or changes in sites where data are being collected?
- a. Yes – list additional sites or changes and attach approval letters
 - b. No

14. Are there changes in key personnel assisting in the research project?
- a. Yes—list changes (i.e., who is being added, who has left project). Include for new personnel, name, rank/degree, affiliation, and responsibility in project.
 - b. No

15. Summarize any relevant interim findings.

16. Summarize any other relevant information, especially risks association with the research, not requested above.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the protocol, other than those described above. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB via phone or email immediately, and then in writing within 5 days of the occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

Principal Investigator's Signature Date

Faculty Assurance (required when PI is a student)

I certify that I have reviewed this request and discussed it with the PI.

Faculty Advisor's Signature Date

Administrator (e.g., department chair, dean, or supervisor) Assurance

This is to certify that I have reviewed this request.

Administrator's Signature Date

SUBMIT MATERIALS TO THE IRB COORDINATOR, OFFICE OF RESEARCH AND SPONSORED PROGRAMS, FOST HALL 251.

Request for Protocol Change Form

The Request for Protocol Change form may be used to report the following events to the IRB for protocols that have already been approved:

- Protocol Change – any change to the procedure of the study
- Changes to the Informed Consent/Assent Form(s)
- Change of location of data collection
- Change of key personnel, including investigators

1. Date of Request:

2. Title of Project:

3. Principal Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Note: All student investigators must have a faculty co-investigator.

4. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

5. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Provide responses to the following items and submit your responses along with this form. Each response should be numbered or labeled to correspond to the following items.

6. Are there any proposed changes to the protocol requested?

a. Yes—describe proposed changes to the protocol, including rationale for the change (attach additional sheet if necessary)

- b. No.
7. Are there any proposed changes to the informed consent/assent form(s)?
- Yes—describe changes, including rationale and attach the revised form(s) with changes highlighted.
 - No.
8. Are there any additions or changes in sites where data are collected?
- Yes—identify specific sites or agencies to be used or changed. Attach permission letters from the sites or agencies authorizing data collection to be conducted at the site(s)
 - No.
9. Are there changes in key personnel assisting in the research project?
- Yes—list changes (i.e., who is being added, who has left project). For new personnel, include name, rank/degree, affiliation and responsibility in project.
 - No.
10. If there are changes in key personnel, is the research being conducted for:
- Thesis (Submit evidence of committee approval. Do not submit the thesis proposal.)
 - Dissertation (Submit evidence of committee approval. Do not submit the dissertation proposal.)
 - Class project
 - Independent study/Honor's Thesis
 - Faculty Research
 - Other
11. Describe any proposed changes not listed above.

Investigator Assurance

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the protocol, other than those described above. I will comply with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB via phone or email immediately, and then in writing within 5 days of the occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB, the Continuation Request or Completion of Research Activities Forms.

Principal Investigator's Signature Date

Faculty Assurance (required when PI is a student)

I certify that I have reviewed this request and discussed it with the PI.

Faculty Advisor's Signature Date

Administrator (e.g., department chair, dean, or supervisor) Assurance

This is to certify that I have reviewed this request.

Administrator's Signature Date

SUBMIT MATERIALS TO THE IRB COORDINATOR, OFFICE OF RESEARCH AND SPONSORED PROGRAMS, FOUST HALL 251.

Adverse Event/ Reportable Event Form

The Adverse Event/Reportable Event form must be used to report the following events to the IRB:

Adverse Events—any experience that has taken place during the course of a research project, which **potentially may** have cause harm to a subject participating in the research, increased the risk of harm in the research, or had an unfavorable impact on the risk/benefit ratio..

- Deviations in the study that may impact subject safety, condition, or status, pose a risk of harm and thereby change the risk/benefit ratio and/or affect a subject’s willingness to participate in the study.

1. Date of Report:

2. Title of Project:

3. Principal Investigator’s Name:

Phone Number: CMU Email:

4. Co- Investigator’s Names:

Phone Number: CMU Email:

Provide additional requested detail in response to the following items and submit your responses along with this form. Each response should be numbered or labeled to correspond to the following items.

5. Description of problem involving risk to subjects or others, or adverse effects:

a. Date of event.

b. The problem, adverse event, or risk was: ___Mild ___Moderate ___Severe ___Fatal

c. Was the event related to the research procedure? ___Yes ___No ___Maybe ___Unknown

d. Provide a brief description of the problem, adverse event, or risk on a separate sheet.

6. Was treatment provided to the subject or other?

a. Yes _____

i. Date of treatment

ii. Description of Treatment

b. No – Explain why treatment was not provided

Changes necessitated by adverse event:

7. Change in protocol—in your judgment, is a change in your protocol necessary to reduce or eliminate risk?

a. Yes—Submit a Request for Protocol Change form explaining the changes and how they will prevent future adverse events. Note that data should not be collected until the revised protocol is approved by the IRB.

b. No – Provide a brief rationale.

8.Changes in Informed Consent/Assent Document(s): Are any changes required in the informed consent /assent document(s) to better inform and protect the rights and welfare of the subjects?

- a. Yes—Attach the revised consent/assent forms(s) with changes highlighted. Note: no new subjects may be enrolled in the study until the revised consent/assent form(s) is approved by the IRB.
- b. No – Provide a brief rationale.

9. Additional comments:

Electronic Signatures. All of the individuals listed below must electronically sign your application on IRBNet prior to submission of this report. By so doing, each attests to the statement following that respective person’s role.

Investigator

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree that I will not implement the proposed changes and will discontinue work on this project until I receive IRB notification.

Faculty Advisor (required when PI is a student)

I certify that I have reviewed this report and discussed it with the PI.

Administrator (e.g., department chair, dean, or supervisor)

I certify that I have reviewed this report.

End of Project Report Form

This form should be submitted when the project has been completed. Once this form has been submitted, the following should not occur: data collection, analyses, manuscript publication and/or presentation. If you wish to continue the project by conducting any of these activities, please submit a Request for Annual Update form prior to the expiration date for approval of the project.

1. Date of Report:

2. Title of Project:

3. Principal Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

Note: All student investigators must have a faculty co-investigator.

4. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

5. Co- Investigator's Name:

Department:

College:

Status: ___ Faculty ___ Student ___ Staff ___ Other (specify)

Campus or Mailing Address

Phone Number: CMU Email:

6. Project Begin Date: Project End Date:

Provide responses to the following items and submit your responses along with this form. Each response should be numbered or labeled to correspond to the following items.

7. Subject Recruitment:
a. Total number of subjects enrolled in study:
b. Number of subjects who voluntarily withdrew from study at their own request:

8. Please identify any problems that participants may have encountered during the research study. If any, describe how the problems were handled.

9. Provide a summary of the completed research (an abstract is sufficient).

Investigator Assurance

I certify that the information provided for this project is correct.

Principal Investigator's Signature Date

Faculty Assurance (required when PI is a student)

I certify that I have reviewed this end of project report.

Faculty Advisor's Signature Date

Administrator (e.g., department chair, dean, or supervisor) Assurance

I certify that I have reviewed this end of project report.

Administrator's Signature Date

SUBMIT MATERIALS TO THE IRB COORDINATOR, OFFICE OF RESEARCH AND SPONSORED PROGRAMS, FOUST HALL 251.

TYPE OF WAIVER REQUESTED FORM

_____ Waiver of All Elements of Consent

_____ Waiver of Some Elements of Consent

Specify Elements to be waived:

Please describe with details specific to your research how your study satisfies ALL four of the following conditions. If you are requesting a waiver of some of the elements, be sure to explain how waiving each of the specified elements meets the following conditions in your study.

1. All of the research plans present no more than minimal risk to participants.

Justification:

2. Not obtaining consent from participants or not including all elements of consent will not adversely affect the rights and welfare of the subjects.

Justification:

3. The research could not be practicably carried out without this waiver.

Justification:

4. Subjects will be provided with additional pertinent information after participation (e.g., a debriefing). If this is not appropriate or necessary, please explain why.

Justification:

All of the individuals listed below must electronically sign your application on IRBNet prior to submission. By so doing, each attests to the statement following that respective person's role.

Investigator Assurance

I certify that the information provided for this project is correct.

Principal Investigator's Signature

Date

I certify that the information provided for this project is correct and that no other procedures will be used in this protocol. I agree to conduct this research as described in the attached supporting documents. I will request approval from the IRB for changes to the protocol and/or consent/assent form(s) and will not implement the changes until I receive IRB approval for these changes. I will comply

with the IRB policy for the conduct of ethical research. I will promptly report significant or adverse effects to the IRB via phone or email immediately, and then in writing within 5 days of the occurrence. I will be responsible for ensuring that the work of others involved with this project complies with this protocol. I will complete, on request by the IRB or annually, the "Request for Annual Continuation of Project" or "End of Project" forms. I have read and understood the Intellectual Property Rights policy and am aware of its implications for my research.

Faculty Assurance (required when PI is a student)

I certify that I have reviewed this end of project report.

Faculty Advisor's Signature Date

Administrator (e.g., department chair, dean, or supervisor) Assurance

I certify that I have reviewed this end of project report.

Administrator's Signature Date

SUBMIT MATERIALS TO THE IRB COORDINATOR, OFFICE OF RESEARCH AND SPONSORED PROGRAMS, FOUST HALL 251.

**Application for
Classroom Research Not Requiring IRB Review**

Name of Course:

Name of Instructor:

Semester/Term of Course:

The above named instructor is seeking approval for the conduct of research within the classroom and assures that all of the following criteria are met:

- The project is a class requirement and the requirement is stated on the class syllabus.
- The project involves only members of the class (i.e., only enrolled students and the instructor(s) of the course), such that data are collected only from and by such members.
- The data are collected within the confines of the classroom or laboratory assigned to that course, or data are conducted as part of small group settings consisting only of members of the class, as defined above.
- The project carries no risk, as determined by the IRB (see risk categories below).

Please attach a syllabus for the course, highlighting the description of the research project.

**Application for
IRB-Classroom Research Requiring IRB Review**

Name of Course:

Name of Instructor:

Semester/Term of Course:

The above named instructor is seeking approval for the conduct of classroom research which **does not meet** all of the following criteria:

1. The project is a class requirement and the requirement is stated on the class syllabus.
2. The project involves only members of the class (i.e., only enrolled students and the instructor(s) of the course), such that data are collected only from and by such members.
3. The data are collected within the confines of the classroom or laboratory assigned to that course, or data are conducted as part of small group settings consisting only of members of the class, as defined above.
4. The project carries no risk, as determined by the IRB (see risk categories below).

Please provide a brief description of the research project for the class (you may include a copy of the syllabus, with the project highlighted).

Please provide a "classroom assignment form" for each student (or student group) in the course.

**CLASSROOM ASSIGNMENT FORM
FOR REVIEW OF STUDIES INVOLVING
THE USE OF HUMAN SUBJECTS
CENTRAL MICHIGAN UNIVERSITY**

Name of Investigator _____ Department: _____

Mailing Address: _____ Phone: _____

Email: _____

Name of Class: _____ Name of Instructor _____

Project Title: _____

Proposed project dates: from / / to / / _____

Protocol:

1. Where will the research be conducted?
2. Who will conduct the research and how many investigators will be involved?
3. Describe the data gathering instruments that will be used. Attach copies of all questionnaires, interview schedules, or other data collection instruments.
4. Describe any apparatus that will be used for data collection.
5. State the amount of time required of a subject to participate in your study. This should include the number and length of times of participation (e.g., two sessions lasting 30 minutes each).

Characteristics of Subjects:

1. How many subjects do you estimate will participate in your study?
2. Describe the expected ages, gender, ethnic backgrounds and health status of subjects.
3. Will data collection be done in a classroom setting? If this answer is "Yes", explain what students who do not participate in the research will be doing.
4. What is the source of the subject pool (e.g., all teachers at a school, department subject pool, community members, etc.)? If the list of potential subjects is publicly available, please indicate so.
5. How will participants be selected or recruited?
 - a. Will selection be accomplished on the basis of document review? If this answer is "Yes", explain how document review will take place and provide assurance that the researcher will not have access to private or confidential files.
 - b. Will selection of participants be accomplished on the basis of a screening measure? If this answer is "Yes", the screening process must be made clear to

the subjects during the initial consent process. Include appropriate debriefing information for individuals removed from the research and an additional consent form for those remaining as subjects in the research project.

6. Attach any advertisements, flyers, cover letters, or scripts to be used in recruiting subjects.
7. Is participation voluntary?
8. Explain how the researcher will minimize any possibility of perceived coercion to participate.
9. Attach a letter giving approval from any agencies or schools that will be involved with the data collection.
10. Will there be any unauthorized access to private or confidential information in the securing of the pool of potential subjects? If this answer is "Yes", document that you have the right to access the information. (Include letter from agency or school if appropriate).
11. Will any of the data be taken from archives that are subject to HIPAA regulations? If yes, assure that none of your data files will contain any of the 18 identifiers listed by HIPAA (click here for list of identifiers).

Benefits

1. What are the benefits of participation to the subjects or larger community?
2. State clearly the importance of expected knowledge to be gained from this research project.

Confidentiality

1. Describe the precautions that will be taken to ensure the privacy of subjects and confidentiality of information by answering the following questions. Be explicit if the data are sensitive
 - a. How and where will information be kept that could identify subjects?
 - b. Who has access to information which could identify subjects?
 - c. How long will information be kept that could identify subjects?
 - d. What is the plan for disposition of information that could identify subjects, if appropriate?
2. Will coding be used to replace names in your data?
 - a. Describe the coding procedure, ensuring that no individual identifiers will be used and that codes could not be used to link a participant with his/her responses or data.
3. Will data be collected by observation of behavior without explicit agreement of the subjects?
 - a. Specify that the subjects have no reasonable expectation that their behavior is private.
 - b. State that the data will have no individual codes or coding will be unrelated to the individual under observation.

Consent and Assent Forms

1. Will any of the adult participants be provided with a survey that will be returned anonymously? If yes, submit a **Consent Form for Anonymous Surveys**
2. Will any of the adult participants be asked to complete a survey "on the street" or on the phone? If yes, submit a **Consent Form for Phone or Informal Surveys**
3. Will any of the adult participants be interviewed in person, be asked to complete surveys, questionnaires, or other instruments and measures not included in the above questions? If yes, submit an **Adult Consent Form**
4. Describe the process for obtaining consent and/or assent. Remember that the form used (above) is simply to document that consent and/or assent was obtained. The objective of informed consent is to

provide a person with enough information to be able to make an informed decision, without coercion, to participate or not participate in your study.

**Investigator’s Assurance Statement for Research Involving the Use of Human Subjects:
Central Michigan University**

“I understand Central Michigan University’s policy concerning research involving human subjects and agree:

1. to accept responsibility for the ethical conduct of this research study (including appropriate procedures to ensure informed consent);
2. to obtain approval from the University’s IRB prior to instituting any change in the research project;
3. to report to the University’s IRB any serious adverse reactions or unexpected effects on subjects, and;
4. to submit to the IRB an End of Project Report at the completion of the project.”

Student Signature(s) (ALL investigators on **this** project must sign below)

_____	Date_____
_____	Date_____
_____	Date_____
_____	Date_____

Instructor Signature_____

SECTION III

RESEARCH INVOLVING THE USE OF SPECIAL GROUPS

The federal government has identified several *special populations* which are considered to be *vulnerable*. These populations include: children, fetuses, pregnant women, human *in vitro* fertilizations, and prisoners. Because of their special classification, research involving any of these populations must follow all requirements listed in this section **in addition** to the policies and procedures contained in Section I of this document.

The information provided below is a summary of federal regulations. A copy of the federal regulations governing research involving any of these special groups may be obtained from the Office of Research and Sponsored Programs, Foust 251, and Department offices. The investigator is responsible for following **all** of the applicable guidelines contained in 45 CFR 46.

A. Research Involving Prisoners as Subjects

Due to their incarceration, prisoners may be under constraints which could affect their ability to make a truly voluntary and uncoerced decision whether to participate as subjects in research. Therefore, special safeguards are provided for their protection.

1. A majority of the IRB should not have any involvement with the prison or facility from which the subjects will be selected. In addition, at least one member of the IRB must be a prisoner or a prisoner representative with appropriate experience and background.
2. When designing research involving prisoners, the researcher should take care to insure that:
 - a. Any possible advantages accruing to the prisoners are not of such magnitude that their ability to weigh the risks of the research is impaired.
 - b. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or other prisoners.
 - c. Unless waived in writing by the IRB, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the research project.
 - d. Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research project in making decisions regarding parole, and each prisoner is clearly informed of this in advance.

- e. Where follow-up procedures are required as a part of the research project, adequate provision must be made taking into account the varying lengths of individual prisoner's sentences.
3. Prisoners may be used in research conducted for the following purposes **only**: research studying the possible causes, effects, and processes of incarceration, criminal behavior, prisoners as incarcerated persons, and prisons as institutional structures provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
4. Prisoners may be used as subjects in the following types of studies **only after approval by the Secretary of DHHS**: research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults); research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the prisoner; and studies which require the assignment of prisoners to control groups which may not benefit from the research.

B. Research Involving Fetuses, Pregnant Women, and Human *in vitro* Fertilization

Special care is taken to protect this group of subjects in research. Absolutely no research involving human *in vitro* fertilization may be undertaken until the application has been approved by the Ethical Advisory Board of the DHHS.

1. The following general limitations apply to all research projects involving fetuses and pregnant women.
 - a. No research may take place unless appropriate studies on animals and nonpregnant women have been completed except where the purpose of the activity is to meet the health needs of the mother or the particular fetus, the risk to the fetus is minimal and, in all cases, is the least possible risk for achieving the objectives of the activity.
 - b. Individuals engaged in the activity will have no part in any decisions as to the timing, method, and procedures used to terminate the pregnancy and in determining the viability of the fetus at the termination of the pregnancy.
 - c. No procedural changes which may cause greater than minimal risk to the fetus or the pregnant woman will be introduced into the procedure for terminating the pregnancy solely in the interest of the activity.
 - d. No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity.

- e. Consent must be obtained from the mother and father unless the purpose of the activity is to meet the health needs of the mother only in which case the father's consent is not needed or if the father's identity or whereabouts cannot be ascertained, he is not reasonably available, or the pregnancy resulted from rape.
2. Pregnant women may be involved as research subjects only when the risk to the fetus is minimal or when the health needs of the mother and the fetus will be placed at risk only to the minimum extent necessary to meet such needs.
3. No fetus *in utero* may be involved as a subject in research unless the purpose of the research is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or the risk to the fetus imposed by the research is minimal and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
4. Until it has been ascertained whether a fetus *ex utero* is viable, it may not be used as a subject in research unless there will be no added risk to the fetus and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means, or the purpose of the activity is to enhance the possibility of survival of the particular fetus to the point of viability.
5. No nonviable fetus may be involved as a subject unless vital functions will not be artificially maintained, experimental activities which would terminate the heartbeat or respiration of the fetus will not be employed, or the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.
6. Activities involving a dead fetus, macerated fetal material, or cells, tissues, or organs excised from a dead fetus shall be conducted only in accordance with State or local laws.

C. Research Involving Children

Children are considered to be a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and, therefore, considerations are required by the federal regulations for research involving children except that which is conducted in an educational setting as described on page 9 of this document.

Note that, whenever feasible, appropriate studies should be conducted on animals, adults, and older children before young children are involved as research subjects.

The IRB is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children, as well as the permission of parents or legal guardians. The IRB's policy with respect to obtaining consent from the parents or legal guardians and assent from minors is specified below:

1. In most cases, parental consent must be obtained if the research involves minor persons (under the age of 18). A written consent form must be used to document informed consent. Parents must sign the consent form unless this requirement is waived by the IRB. (The requirement for parental consent may be inappropriate in some cases, such as research on child abuse.)
2. Unless the requirement is waived by the IRB, documentation of assent is also required for all children. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. The form should include a simplified version of the elements of informed consent which were described in the general instructions. Note that the child should be given an explanation, at a level appropriate to the child's age, maturity, and condition of the procedures to be used, their meaning to the child in terms of discomfort, risk, and inconvenience, and the general purpose of the research. (See the Models of Child Assent forms for various age groups on pages 71-75) If the child's developmental ability precludes obtaining written assent, documented oral assent is sufficient.

D. Research Involving Mentally Incompetent Subjects

A mentally incompetent prospective subject is a person who has either been adjudicated to lack the capacity to give informed consent or is judged by the investigator to lack that capacity. A prospective subject who lacks the capacity to give informed consent cannot participate as a subject in research unless proxy consent is obtained by the subject's legally authorized representative. Whenever possible, subject assent must also be obtained. Information in greater detail and assistance developing forms for consent, assent, and durable power of attorney may be requested from the IRB (Foust 251).

E. Research Involving Previously Collected Health-Related Data

The new HIPAA guidelines require that research involving the use of health-related data must follow certain guidelines in addition to those required by the IRB. Although HIPAA recognizes that health-related information may never be made truly anonymous, the risk of re-identification of an individual is greatly decreased by removing certain elements from research data. Data lacking these elements is said to be de-identified and is excluded from the rules governing use of

F. HIV/AIDS Studies

Because of the special sensitivity of HIV/AIDS research, researchers must exercise meticulous care in ensuring accurate and complete informed consent procedures. In addition, all aspects of confidentiality must be considered including how to respond to requests by third parties who have authorizations for disclosure of information. Procedures must be in place which afford full opportunity for potential subjects to make informed decisions and for the protection of the

rights, welfare, and dignity of those who agree to assist in obtaining important knowledge that will benefit society.

Subjects participating in research projects which determine HIV serostatus must be informed of their own test results and provided with the opportunity to receive appropriate counseling. Individuals may not be given the option "not to know" the results, either at the time of consenting to be tested or thereafter. This policy does not apply to testing situations in which subjects consent to be tested but specimen results cannot be linked to individual subjects by anyone other than the subjects themselves.

DHHS policies in this area are very explicit and continue to be updated. Researchers are encouraged to read the complete federal guidelines pertaining to research on AIDS and HIV testing. These guidelines may be obtained from ORSP (Foust 251).

SECTION IV

INFORMED CONSENT GUIDELINES AND MODEL FORMS FOR RESEARCH INVOLVING THE USE OF HUMAN SUBJECTS

A. Informed Consent Guidelines

The investigator has a legal and an ethical obligation to ensure that the prospective subject sufficiently comprehends the elements of the informed consent materials and is able to make an enlightened decision to participate in the research project. Informed consent should be obtained by utilizing a simple but complete consent form written at the appropriate educational level. The consent form, however, does not by itself constitute informed consent. Rather, the informed consent form should serve as a guide by which the investigator carefully, patiently, and simply explains the elements of consent to the prospective subject. The investigator should periodically assess the prospective subject's comprehension by asking appropriate questions. After the investigator has determined that the prospective subject has sufficient knowledge and comprehension of each element of consent, the subject should voluntarily sign and date the consent form in the presence of the investigator. A witness and a short form written consent are required if the elements of informed consent must be presented orally to subjects rather than in writing. Consent for treatment is not the same as consent to participate in research. A subject may desire treatment without desiring to participate in a research study. The guidelines in this document deal with consent to participate as a research subject only.

The legal obligation to secure informed consent is founded on the principles outlined in DHHS Regulations 45 CFR 46.116, 117; Principle I of the Nuremberg Code, and Principles 9, 10, 11 of the Declaration of Helsinki. Subjects must be informed of all features of the research that may influence their decision to participate. If the research creates any risks of physical or mental discomfort, harm, or danger, the investigator is required to inform the subject of that fact and

to secure consent before proceeding. If the subject is to be videotaped, photographed, or audiotaped, this information must be provided, along with a description of where tapes will be stored and when they will be destroyed. In addition, if the tapes will be used for purposes other than the research project in which the subject is enrolled, the subject must provide permission for the other use(s). An explanation of who will maintain custody of the data, who will have access to them, and how they will be used must be provided. All aspects of the research about which the subjects inquire must be explained to their satisfaction. The subject must be given a copy of the informed consent document and must be provided adequate opportunity to read it before signing. If the elements of informed consent will be presented to the subject orally, there must be a witness to this presentation who signs a summary statement of both the research project and the material presented to the subject orally.

The following elements should be included in any informed consent decision:

1. Materials must be written in language that the subject can understand, including simple or lay explanations for apparatus and procedures to be employed. Ordinary language should replace technical terms (e.g., upper extremities should be referred to as arms, hematoma as a bruise, venipuncture as taking blood from the arm with a needle, the amount of blood to be withdrawn should be described in terms of teaspoons rather than milliliters).
2. Describe the nature and purpose of the research. If applicable, students should state that the research is being conducted in fulfillment of degree requirements at Central Michigan University.
3. Estimate the duration of the subjects' participation.
4. Describe the procedures to be followed, including how any audio or visual recordings will be used. Identify any procedures which are experimental.
5. For research involving more than minimal risk, provide an explanation as to whether any compensations or medical treatments are available if injury occurs, and, if so, what they consist of, where they may be obtained, and where additional information may be obtained.
6. Discuss any foreseeable discomforts or risks which may be expected from the research.
7. Discuss any foreseeable benefits to the subject or others which reasonably may be anticipated.
8. Describe the extent to which confidentiality of records identifying the subject will be maintained. If there is a possibility that others may obtain access to any information about the subject gathered during the research, this must be made known to subjects along with the plans for protecting confidentiality.

9. Include a statement that participation is voluntary and the subject is free to withdraw at any time without risk of penalty or loss of benefits to which the subject is otherwise entitled.
10. Include an offer to answer any questions about the procedures. Provide the name and phone number(s) of the investigator(s) (or in the case of student investigators, the faculty advisor) who may be contacted for further information. Provide contact information for the Institutional Review Board (IRB) for questions about the subject's rights as a research participant.
11. In no case may the person's consent be based on an agreement, written or oral, through which the subject is made to waive, or appear to waive, any legal rights, or to release the University, its agents, or the investigator, from liability for negligence. (Question for us: we do have researchers who state that medical care, if needed, will not be provided at a cost to CMU, but rather that the participant is required to pay for such care. Can we allow this??)
12. If subjects are minors (under 18 years of age) a parent or guardian must sign the Informed Consent Form.

Model consent forms for adults are found on pages 62-70. The forms differ depending on the type of project conducted. The standard adult consent form will be used for most projects. Special consent forms are included for parental consent for a minor to participate in research, projects in which anonymously returned surveys are conducted or when phone or informal interviews are conducted. In the event that an adult subject is determined unable to provide legal consent, an assent form is used. The assent form should be provided to the participant and the participant's legal guardian should provide consent similar to that of the parental consent form.

B. Assent Procedures for Research Subjects Who are Children

Legally, children (those under the age of 18) cannot give consent on their own behalf. The consent of their parent(s) or a legal guardian is, therefore, required before they can participate in research projects as a subject. In addition to obtaining parental/legal guardian consent, the investigator must also solicit assent of children who participate in the research as subjects. Assent forms for children must contain simple language written at the appropriate educational level of the youngest prospective subject. In most circumstances, a child's deliberate objection should be regarded as a veto to involvement in the research. However, parents or guardians may, with IRB approval, override a minor's objections to interventions that hold the prospect of direct benefit to the child.

Model child assent forms are presented on pages 71-75. Assent forms are included for three different age groups: younger than age 7, between ages 7-12, and between ages 12-17. Care should be taken that the language used in the assent forms reflects both the reading ability and language comprehension ability of the targeted age groups.

C. Preparing Consent/Assent Forms

A prospective subject's ability to understand the elements of informed consent is a function of intelligence, education, maturity, and language skills. It is, therefore, necessary to adapt the language level of the consent form to fit the subject's capabilities. The informed consent form must be written in simple enough language so that it is readily understood by the least educated, least sophisticated of the subjects to be utilized. The informed consent form should be lengthy enough to explain consent factors adequately, but not so lengthy or detailed as to lose the attention of the subject or to cause confusion.

The informed consent form should be printed on CMU letterhead stationery. It should be written in the second person (e.g., you are invited to participate) until the paragraph preceding the subject signature line.

If the consent form is longer than one page, a blank for the subject to initial should be placed at the bottom of all pages except the page containing the subject's signature. The signature of a witness is required for all research studies involving more than minimal risk. The witness should be someone who is not involved in the study.

Then, sign and date the consent form in the presence of the subject and the witness (if required).

If the consent form will be used for parents or other legally authorized representatives consenting on behalf of a minor or other legally incompetent subject, the consent form should be written in a style that reflects the fact that it is the minor or other subject who is the participant and the consentor is agreeing to allow said subject to participate in the study. The informed consent form must not contain any language through which the subject or the subject's representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the research investigator, the sponsor, the institution or its agents from liability for negligence.

Signed copies of informed consent and child assent forms must be maintained by the principal investigator and be stored in a secure manner. The usual retention period is three years beyond the termination of the study. If the investigator resigns from the University before the end of the designated period, the informed consent forms must be maintained by the department of record.



Adult Consent Form

[The following format for the body of the informed consent form is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the document must include all of the elements identified in this model consent form. Remember that your audience may not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.]

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

Introductory Statement

Provide a brief introduction to the study, inviting the subject’s participation and explaining that details of the study are provided in the consent document. At this point, you can explain that you are available to answer any questions the subject may have about the project.

What is the purpose of this study? State that the study involves research; explain in non-technical language the purpose of the research.

What will I do in this study? Describe the procedures to be followed and their purpose; and identify any procedures that are experimental.

How long will it take me to do this? Describe the expected duration of the subject’s participation.

Are there any risks of participating in the study? Describe any risks and/or discomforts to the subject that can reasonably be expected as a result of participating in this study.

What are the benefits of participating in the study? Describe any benefits to the subject, society, or both that can reasonably be expected from the research

Will anyone know what I do or say in this study (Confidentiality)? Identify the persons or agencies to whom confidential information will be disclosed, including the sponsor and state the nature of the information to be disclosed and the purpose of disclosure. State that in all other instances, any data under the investigator's control will, if disclosed, be presented in a manner that does not reveal the subject's identity, except as may be required by law. If the study involves videotaping or audio taping, explain what will happen to the tapes after the study is completed or if a subject withdraws before completion. Note where the tapes will be stored to ensure confidentiality of the data.

Will I receive any compensation for participation? Describe the amount and nature of any compensation or fee to be paid to the subject for participating in the study.

Is there a different way for me to receive this compensation or the benefits of this study? Disclose appropriate alternative procedures, if any, that might be available to the subject.

Who can I contact for information about this study? Provide the name and telephone number of a specific office or person to contact for answers to questions about the research, research subjects' rights, or in case of a research-related injury to the subject.

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect your relationship with the institution(s) involved in this research project.

If you are not satisfied with the manner in which this study is being conducted, you may report (anonymously if you so choose) any complaints to the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

My signature below indicates that all my questions have been answered. I agree to participate in the project as described above.

Signature of Subject Date Signed

A copy of this form has been given to me. _____ Subject's Initials

For the Research Investigator—I have discussed with this subject the procedure(s) described above and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

Signature of Responsible Investigator Date Signed



Parent/Guardian Consent Form

ALL GREEN SECTIONS ARE FOR THE RESEARCHER ONLY AND SHOULD NOT APPEAR IN THE ACTUAL FORM

The following format for the body of the informed consent form is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the document must include all of the elements identified in this model consent form. Remember that your audience may not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

Introductory Statement

Provide a brief introduction to the study, inviting the parent/guardian’s child/ward to participate and explain that details of the study are provided in the consent document. At this point, you can explain that you are available to answer any questions the subject may have about the project.

What is the purpose of this study? State that the study involves research; explain in non-technical language the purpose of the research.

What will my child/ward do in this study? Describe the procedures to be followed and their purpose; and identify any procedures that are experimental.

How long will it take my child/ward to do this? Describe the expected duration of the child’s participation.

Are there any risks of participating in the study? Describe any risks and/or discomforts to the child’s that can reasonably be expected as a result of participating in this study.

What are the benefits of participating in the study? Describe any benefits to the subject, society, or both that can reasonably be expected from the research

Will anyone know what my child/ward does or says in this study (Confidentiality)? Identify the persons or agencies to whom confidential information will be disclosed, including the sponsor and

state the nature of the information to be disclosed and the purpose of disclosure. State that in all other instances, any data under the investigator's control will, if disclosed, be presented in a manner that does not reveal the subject's identity, except as may be required by law. If the study involves videotaping or audio taping, explain what will happen to the tapes after the study is completed or if a subject withdraws before completion. Note where the tapes will be stored to ensure confidentiality of the data.

Will my child/ward receive any compensation for participation? Describe the amount and nature of any compensation or fee to be paid to the subject for participating in the study.

Is there a different way for my child/ward to receive this compensation or the benefits of this study? Disclose appropriate alternative procedures, if any, that might be available to the subject.

Who can I contact for information about this study? Provide the name and telephone number of a specific office or person to contact for answers to questions about the research, research subjects' rights, or in case of a research-related injury to the subject.

You are free to refuse to allow your child/ward to participate in this research project or to withdraw your consent and discontinue your child/ward's participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect your child/ward's or your relationship with the institution(s) involved in this research project.

If you are not satisfied with the manner in which this study is being conducted, you may report (anonymously if you so choose) any complaints to the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

My signature below indicates that all my questions have been answered. I agree to allow my child participate in the project as described above.

Signature of Parent/Guardian Date Signed

Name of Child/Ward

A copy of this form has been given to me. _____ Parent/Guardian Initials

For the Research Investigator—I have discussed with this subject the procedure(s) described above and the risks involved; I believe he/she understands the contents of the consent document and is competent to give legally effective and informed consent.

Signature of Responsible Investigator Date Signed



Consent Form for Anonymous Surveys

[The following format for the body of the informed consent form is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the document must include all of the elements identified in this model consent form. Remember that your audience may not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.]

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

Introductory Statement

Provide a brief introduction to the study, inviting the subject’s participation and explaining that details of the study are provided in the consent document. At this point, you can explain that you are available to answer any questions the subject may have about the project.

What is the purpose of this study? State that the study involves research; explain in non-technical language the purpose of the research.

What will I do in this study? Describe the procedures to be followed and their purpose; and identify any procedures that are experimental.

How long will it take me to do this? Describe the expected duration of the subject’s participation.

Are there any risks of participating in the study? Describe any risks and/or discomforts to the subject that can reasonably be expected as a result of participating in this study.

What are the benefits of participating in the study? Describe any benefits to the subject, society, or both that can reasonably be expected from the research.

Will anyone know what I do or say in this study (Confidentiality)? Identify the persons or agencies to whom confidential information will be disclosed, including the sponsor and state the nature of the information to be disclosed and the purpose of disclosure. State that in all other instances, any

data under the investigator's control will, if disclosed, be presented in a manner that does not reveal the subject's identity, except as may be required by law.

Will I receive any compensation for participation? Describe the amount and nature of any compensation or fee to be paid to the subject for participating in the study.

Is there a different way for me to receive this compensation or the benefits of this study? Disclose appropriate alternative procedures, if any, that might be available to the subject.

Who can I contact for information about this study? Provide the name and telephone number of a specific office or person to contact for answers to questions about the research, research subjects' rights, or in case of a research-related injury to the subject.

You are free to refuse to participate in this research project or to withdraw your consent and discontinue participation in the project at any time without penalty or loss of benefits to which you are otherwise entitled. Your participation will not affect your relationship with the institution(s) involved in this research project.

My return of this survey implies my consent to participate in this research and I have been given a second copy of this form to keep for my records..

If you are not satisfied with the manner in which this study is being conducted, you may report (anonymously if you so choose) any complaints to the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.



Consent Form for Phone or Informal “on-the-street” Interviews

The purpose of this research study is to [explain purpose briefly]. For that reason, we will be surveying [state who you are asking]. If you are willing to participate, our questionnaire will ask about [state what you will ask about]. [State how long the questions will take]. There are no foreseeable risks associated with this project, nor are there any direct benefits to you. [State whether there will be any compensation for participating]. This is an entirely anonymous questionnaire, and so your responses will not be identifiable in any way. All responses are confidential, and results will be kept under lock and key. Your participation is voluntary, and you may choose to stop at any time if you want. This study is being conducted by [State your name and department], who can be reached at [provide your phone number], if you have any questions.



Assent Form for Adults Unable to Provide Legal Consent

The following format for the body of the informed assent document is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved and the reading ability of your study population, but the assent document must include all of the elements identified in this model assent document. Remember that your audience may not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

What is this research about?

We would like you to join in a research study about [Provide a brief introduction to the study.] You can ask a question at any time and you can say no anytime you want to. You may talk to your guardian about this before deciding whether or not to participate. Your guardian said that it is OK for you to be in this study, but we want to let you choose if you want to do this.

What will happen to me in this research? - Explain the reason for the research and what the subject will be expected to do as part of the study, describing those parts of the research where the subject will be expected to do or provide something. Describe which part of the study is experimental. Describe all procedures using simple terms and explaining any medical terms.

How long will it take me to be in your research? Describe how long – in minutes/hours and also if more than one session, how many different times.

Can anything bad happen to me? Explain any possible risks to the subject, using simple terms. If something might be painful, state this in the assent. Explain that the subject should inform his/her parents if they are sick or in pain as a result of being in the study.

Can anything good happen to me? Only describe known benefits to the subject. You may include any possible future benefits to others.

Do I have other choices? Describe any alternative procedures that might be available to the subject other than this study. If this section doesn't apply, do not write "there are no other choices". Instead write "you may choose not to do this."

Will anyone know I am in the research? Your name and the fact that you are in this study will be kept secret from those people not involved in the study.

Will I be paid? Describe any payment to the subject for participating in the study, including the amount and how it will be paid or say no.

Who can I talk to about the research? List those individuals the subject can contact if he/she has any questions or has any problems related to the study.

What if I do not want to do this? You do not have to be in this research study. You can say no at any time. No one will be upset with you if you stop.

SIGNATURE CLAUSE

If you have any problems with this study, you may contact the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

Do you want to be in the study?

Yes, I want to be in the study No, I do not want to be in the study

Name of Participant (Print)

Signature of Participant Date

Signature of Person Explaining Assent Date

A copy of this form has been given to me _____ Participant's Initials



Child Assent Form for Minors Aged Under Age 7
(To be read to the child)

The following format for the body of the informed assent document is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the assent document must include all of the elements identified in this model assent document. Remember that your audience is young and will not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.

Title of Project: Factors Involved in Playing with Children

Name of Investigator: Jane Doe, PhD **Phone:** 774-XXXX

Invitation to Participate:

You and your mom/dad have been asked to help us learn about **describe as simply as possible what you are studying**. If you decide to do this, you will **describe as simply as possible what the child will do**. Your parents said that this is okay for you to do. Do you want to do this?



Child Assent Form for Minors Aged 7–12

The following format for the body of the informed assent document is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the assent document must include all of the elements identified in this model assent document. Remember that your audience is young and will not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc. .

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

What is this research about?

We would like you to join in a research study about [Provide a brief introduction to the study.] You can ask a question at any time and you can say no anytime you want to. Your parents or legal guardian said that it is OK for you to be in this study, but we want to let you choose if you want to do this.

What will happen to me in this research? - Explain the reason for the research and what the subject will be expected to do as part of the study, describing those parts of the research where the subject will be expected to do or provide something. Describe which part of the study is experimental. Describe all procedures using simple terms and explaining any medical terms.

How long will it take me to be in your research? Describe how long – in minutes/hours and also if more than one session, how many different times.

Can anything bad happen to me? Explain any possible risks to the subject, using simple terms. If something might be painful, state this in the assent. Explain that the subject should inform his/her parents if they are sick or in pain as a result of being in the study.

Can anything good happen to me? Only describe known benefits to the subject. You may include any possible future benefits to others.

Do I have other choices? Describe any alternative procedures that might be available to the subject other than this study. If this section doesn't apply, do not write "there are no other choices". Instead write "you may choose not to do this."

Will anyone know I am in the research? Your name and the fact that you are in this study will be kept secret from those people not involved in the study.

Will I be paid? Describe any payment to the subject for participating in the study, including the amount and how it will be paid or say no.

Who can I talk to about the research? List those individuals the subject can contact if he/she has any questions or has any problems related to the study.

What if I do not want to do this? You do not have to be in this research study. You can say no at any time. No one will be upset with you if you stop.

SIGNATURE CLAUSE

If you have any problems with this study, you may contact the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

Do you want to be in the study?

Yes, I want to be in the study No, I do not want to be in the study

Name of Child (Print)

Signature of Child Date

Signature of Person Explaining Assent Date

A copy of this form has been given to me _____ Subject's Initials



*Child Assent Form for
Minors Aged 13-17*

ALL GREEN SECTIONS ARE FOR THE RESEARCHER ONLY AND SHOULD NOT APPEAR IN THE ACTUAL FORM. The following format for the body of the informed assent document is flexible to cover the majority of research studies and is designed to comply with the minimum requirements of DHHS and FDA regulations. The format may be modified or expanded, depending on the nature of the particular study involved, but the assent document must include all of the elements identified in this model assent document. Remember that your audience is young and will not understand complex language, including legal or medical terminology, so use simple language. Avoid using the terms “You understand,” “You agree,” etc.

Study Title:

Research Investigators’ Names and Departments (include Advisor, if researcher is a student):

Contact information for researcher (and Advisor, if researcher is a student):

What is this research about?

We would like you to join in a research study about [Provide a brief introduction to the study.] You can ask a question at any time and you can say no anytime you want to. You may talk to your parents about this before deciding whether or not to participate. Your parents or legal guardian said that it is OK for you to be in this study, but we want to let you choose if you want to do this.

What will happen to me in this research? - Explain the reason for the research and what the subject will be expected to do as part of the study, describing those parts of the research where the subject will be expected to do or provide something. Describe which part of the study is experimental. Describe all procedures using simple terms and explaining any medical terms.

How long will it take me to be in your research? Describe how long – in minutes/hours and also if more than one session, how many different times.

Can anything bad happen to me? Explain any possible risks to the subject, using simple terms. If something might be painful, state this in the assent. Explain that the subject should inform his/her parents if they are sick or in pain as a result of being in the study.

Can anything good happen to me? Only describe known benefits to the subject. You may include any possible future benefits to others.

Do I have other choices? Describe any alternative procedures that might be available to the subject other than this study. If this section doesn't apply, do not write "there are no other choices". Instead write "you may choose not to do this."

Will anyone know I am in the research? Your name and the fact that you are in this study will be kept secret from those people not involved in the study.

Will I be paid? Describe any payment to the subject for participating in the study, including the amount and how it will be paid or say no.

Who can I talk to about the research? List those individuals the subject can contact if he/she has any questions or has any problems related to the study.

What if I do not want to do this? You do not have to be in this research study. You can say no at any time. No one will be upset with you if you stop.

SIGNATURE CLAUSE

If you have any problems with this study, you may contact the Institutional Review Board by calling 989-774-6777, or addressing a letter to the Institutional Review Board, 251 Foust Hall Central Michigan University, Mt. Pleasant, MI 48859.

Do you want to be in the study?

Yes, I want to be in the study No, I do not want to be in the study

Name of Child (Print)

Signature of Child Date

Signature of Person Explaining Assent Date

A copy of this form has been given to me _____ Subject's Initials

SECTION V

GUIDELINES FOR IRB REVIEW

The following information is provided to assist the IRB in its review process. It is included here as it may be helpful to investigators in preparing application materials for review.

In order to approve a research project involving human subjects, the IRB must assure itself of the following:

- 1) the prospective subject population is appropriate in terms of characteristics and number,
- 2) the recruitment of subjects is free of coercion,
- 3) the experimental design of the study is sound,
- 4) any risks associated with the research project are minimized to the greatest extent possible,
- 5) the potential benefits are maximized to the greatest extent possible,
- 6) the risks to the subject are outweighed or balanced by the potential benefits,
- 7) the level of subject compensation (if any) is fair and non-coercive,
- 8) the degree to which confidentiality is maintained is acceptable,
- 9) the method used to obtain informed consent is ethically and legally acceptable, and
- 10) the investigator has the appropriate qualifications, experience and facilities to conduct the research.

The IRB review process is not particularly concerned with the nature of a research topic, (Question for us: do we want to keep the prior phrase in the manual? See paragraph 1 in #3 below) as long as the rights and welfare of the subjects are adequately protected and the protocol will be conducted in full compliance with DHHS regulations.

1. Review of the Prospective Subject Population

The prospective subject population must be appropriate with respect to the nature and goals of the research. In addition, the investigator should be guided by the principles which lead to an equitable selection of subjects with regard to the potential risks and benefits of the research. The IRB, therefore, will examine carefully the characteristics of the subject population. Factors such as the required number of subjects, age range, sex, ethnic background, and health status will be considered. The utilization of any vulnerable classes of subjects such as pregnant women, fetuses, prisoners, children, and mentally incompetent persons must be clearly justified. Although the use of vulnerable persons as subjects is not prohibited by any regulations or ethical codes, justification for involving vulnerable persons in research generally becomes more difficult as the degree of risk and vulnerability increases.

Naturally, there are exceptions to the principle of "equitable selection of subjects. For instance, research involving the social consequences of a disease to which only one ethnic or racial group is susceptible would not require the application of this principle.

2. Review of Method(s) of Subject Recruitment

The IRB will review the method of prospective subject identification and recruitment in order to be assured it is ethically and legally acceptable. Advertisements used to recruit subjects are considered an extension of the recruitment and informed consent processes, and therefore, must be reviewed by the IRB.

3. Review of Experimental Design

The IRB will review the experimental design in order to be assured that the potential risks to the subjects are minimized and the potential benefits to the subjects are maximized by using procedures consistent with sound research design.

The IRB accepts the need for certain types of behavioral and social science studies to employ strategies that include either deception and/or the withholding of information. Employment of such strategies must, however, be fully justified. In general, deception is not acceptable if in the judgment of the IRB the subject would have declined to participate had they been informed of the true purpose of the research. Studies which use deception and/or the withholding of information as part of their experimental design must include a post-study debriefing unless a waiver is granted by the IRB.

4. Review of the Potential Risks

A risk is a potential harm (injury) associated with the research that a reasonable person, in what the investigator knows or should know to be the subject's position, would be likely to consider significant in deciding whether or not to participate in the research. The concept of risk includes discomfort, burden, or inconvenience a subject may experience as a result of the research procedures. Underlying the consideration of risk is the implicit moral guideline that all investigators have a duty not to harm their subjects and must minimize potential risk to the greatest extent possible.

The five major types of risks are: a) physical risk (e.g., pain, bruising and infection associated with venipuncture, muscle soreness and pain as a consequence of exercise testing, heart attack induced by maximal exercise test); b) psychological risk (e.g., stress associated with psychological testing, feelings of guilt or discomfort precipitated by a sensitive survey); c) social risk (e.g., invasion of privacy, embarrassment, loss of community standing); d) legal risk (e.g., criminal prosecution or revocation of parole); and e) economic risk (e.g., loss of employment, loss of potential monetary gain).

Both immediate and latent (delayed) risks of any procedure involving human subjects will be reviewed by the IRB. In addition, the estimated probability, severity, average duration, and reversibility of any potential harm will be considered according to available empirical data. Furthermore, since certain populations of vulnerable subjects may be at greater risk than others, the IRB will take into consideration the potential risk characterization of the subject. Victims of child abuse or assault, for example, may be at increased risk in sociological or psychological studies. Children, the elderly, prisoners, the mentally incompetent, and various ethnic groups may incur an increased level of risk in certain kinds of research projects.

Risk can also be classified as less than minimal, minimal, and greater than minimal. Federal regulations (45 CFR 46.102g) define minimal risk as "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." The term "minimal risk" is used as a base or standard by which the risk associated with research is judged.

Examples of "less than minimal risk" procedures include collection of urine, collection of sweat, weighing, pulse measurement, blood pressure measurement, voice recordings, skin fold body composition measurements, and any standard psychological testing with no stress. In actuality, most less than minimal risk procedures are interventions that usually (but not always) have no known associated risk but which are not considered exempt from federal regulations under 45 CFR 46.101b and, therefore, must be reviewed by the IRB using the expedited or full board method. For example, if an investigator were to take one blood pressure measurement using a sphygmomanometer, this would clearly be a "no known risk" procedure. If, however, the investigator's protocol requires monitoring of the subject's blood pressure every thirty minutes during a five hour written exam given for Board certification, the associated risk would be at least "less than minimal" as opposed to "no known risk. This is because of the inconvenience and discomfort associated with the multiple interventions. Since risk is such a relative concept, the IRB classification system does not distinguish between "no known risk" and "less than minimal risk" research except for the purpose of risk disclosure on the consent form.

5. Review of Potential Benefits

A benefit is a valued or desired outcome. Benefits associated with participation in research can be classified generally as those that accrue to the subject directly (e.g., acquisition by the subject of knowledge considered of value) and those that accrue to society (e.g., additions to the knowledge base). The IRB will review the anticipated benefits to both the subject and to others. In addition, the IRB will consider whether the benefits are maximized to the greatest extent possible through proper protocol design. Therefore, an underlying moral notion of "beneficence" should guide the investigator.

Financial or other forms of compensation are not considered a benefit to be derived from research participation. Although the subject may consider financial compensation a desirable outcome, this fact will not be used in the risk/benefit analysis.

6. Risk/Benefit Analysis

Once the potential risks and benefits are identified, an ethical review of research requires an examination of the relationship of the risks to the benefits. Risks and benefits cannot be considered parallel constructs and, therefore, no formula is applicable. The various ethical codes and regulations, however, require a favorable balance between harm and benefit. To assist the investigator and the IRB in assessing the risk/benefit relationship the following principles are provided.

- a. In non-therapeutic research the potential risk to the subject must be outweighed, or balanced, by the potential benefit to the subject and/or by the potential benefit to society.
- b. In research where a standard therapy not part of the research protocol is employed solely for the benefit of the subject along with additional procedures performed solely for research purposes, the anticipated benefits of the therapy must not be used to justify exposing subjects to the risks associated with the research procedures. Such risks can only be justified in light of the potential benefits of the research procedures. Conversely, only the risks associated with the research procedures should be used in determining the risk/benefit ratio.

7. Review of Subject Compensation

The IRB will review the amount of compensation (monetary as well as other forms) in order to be assured that it is not coercive and is equitable in distribution.

8. Review of Confidentiality

The IRB will review the methods to be used to preserve confidentiality. If research data with subject identifiers will be made available to persons other than the listed investigators, the IRB will review the justification for sharing these data and determine acceptability. In addition, participants should be notified, in the consent form, who will receive copies of the data prior to their decision to participate.

9. Review of Informed Consent

Although there are federal regulations requiring the subject or the subject's legally authorized representative to give consent prior to the subject's participation in an experiment, the principal reason for informing subjects about an experiment is that they have a moral right to know what is to be done to them and what risk this entails before they

give their consent. Human beings are considered autonomous and the requirement of informed consent is designed to uphold the ethical principle of "respect for persons". The use of human subjects is a privilege granted to the researcher or experimenter, rather than a right. An experiment is something that is done to the subject either primarily or solely for the purpose of advancing knowledge. Indeed, in non-therapeutic research, the subject seldom receives any benefit.

In order for consent to be ethically and legally valid it must meet the requirements stated in Principle 1 of the Nuremberg Code and the informed consent section of the Federal Regulations (45 CFR 46:116) which is based, in part, upon the Nuremberg Code. Principle 1 of the Nuremberg Code states, "The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

The legal documentation of informed consent is the consent form signed by both the subject and the investigator. The ethical and, indeed, legal validity of consent is, however, dependent upon the process of informed consent which requires the investigator to engage in dialogue or negotiation with the prospective subject. The consent form, therefore, should be used by the investigator as an instrument to guide the negotiations with the prospective subject. The informed consent form must embody the elements of informed consent contained in the DHHS regulations as reflected in the IRB Guidelines. The IRB will review both the consent form and the process of informed consent to ensure its acceptability.

10. Review of Investigator Qualifications

The IRB will review investigator qualifications and must be assured that (a) the investigator has the appropriate qualifications and licensure to carry out the procedures involving human subjects, and (b) that the investigator has adequate facilities and equipment to conduct the research.

11. Review of Monitoring Requirements

The IRB will determine whether or not a research project requires review more often than annually and will establish an appropriate monitoring procedure which may include observation of the consent process, observation of on-going research, and review of research records.

GLOSSARY

ASSENT: A minor's (or person with decisional impairment's) explicit affirmative agreement, oral or written, to participate in research. Failure to object cannot be construed as assent.

CONFIDENTIALITY: Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure without permission.

DEBRIEFING: Giving subjects previously undisclosed information about the research project following completion of their participation in research.

DEAD FETUS: An *ex utero* fetus which exhibits neither heartbeat, spontaneous movement of voluntary muscles, nor pulsation of the umbilical cord if still attached.

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

ETHICAL CODES AND STATEMENTS OF ETHICAL PRINCIPLES: There are three major ethical codes that provide general ethical guidelines for the responsible conduct of research in the United States and which provide the basis for the federal regulations (and hence, CMU's regulations) on the protection of research involving the use of human subjects. They are the Belmont Report, the Nuremberg Code, and the Declaration of Helsinki, all of which are available in the ORSP.

FETUS: The product of conception until the pregnancy is terminated.

GUARDIAN: See Legally Authorized Representative.

HUMAN SUBJECT: 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.

INFORMED CONSENT: A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic therapeutic or preventative procedure.

INTERACTION: Includes communication or interpersonal contact between investigator and subject.

INTERVENTION: Includes both physical procedures by which data are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

IN VITRO FERTILIZATION: Any fertilization of human ova which occurs outside the body of a female.

LEGALLY AUTHORIZED REPRESENTATIVE: An individual or judicial or other body who is authorized under applicable state or local law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved.

MINIMAL RISK: 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.

MINOR: Any person under the age of 18 years.

NONVIABLE FETUS: An *ex utero* fetus which is not viable (see Viable).

PARENT: A child's biological or adoptive parent.

PREGNANCY: The period of time from confirmation of implantation, through any of the presumptive signs of pregnancy, such as missed menses or by a medically acceptable pregnancy test, until expulsion or extraction of the fetus.

PRINCIPAL INVESTIGATOR: The scientist or scholar with primary responsibility for the design and conduct of a research project.

PRISONER: Any individual involuntarily confined or detained in a penal institution or an alternative facility including those detained pending arraignment, trial, or sentencing.

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 (e.g., a medical record).

RESEARCH: Any systematic investigation designed to develop or contribute to generalizable knowledge. Research encompasses work which is conducted on or off campus and includes questionnaires, interviews, tests, observations, surveys, and other experiments, regardless of the content or routine nature of the subject involvement even if this work is preliminary to a more extensive study. This definition includes any systematic collection of data from human subjects which occurs in conjunction with classroom projects.

RESEARCH PROTOCOL: The procedures and rules for dealing with the subject and the records derived from the subject.

VIABLE FETUS: A fetus which is able to survive given the benefit of available medical therapy to the point of independently maintaining heart beat and respiration.

VOLUNTARY: A subject's decision to participate in research made free of coercion, duress, or undue inducement.

Addendum: This document is based upon the following federal guidelines.

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects in Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, U.S. Department of Health, Education, and Welfare.

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

In addition, the following institutions graciously shared their guidelines, procedures, and application materials for use as we developed our own. Language is taken in whole or in part from some of them to fit the situation at Central Michigan University. We want to thank each institution listed below for their cooperation.

Amended Policies and Procedures Pertaining to Research Involving the Use of Human Subjects, Northern Illinois University, Institutional Review Board.

Application for Review and Approval of Activity Involving Human Subjects, Southwest Missouri State University, Human Subjects Protection Review Committee.

Ethical Principles for the Conduct of Research with Human Participants, Institutional Review Board, St. Cloud State University.

Guidelines for Research Involving Human Subjects, Miami University Committee on the Use of Human Subjects in Research.

Guidelines for Submitting Protocols to the Institutional Review Board, Ball State University Institutional Review Board.

Human Subjects Institutional Review Board, Informational Notes and Procedures Manual, Western Michigan University.

Human Subjects Institutional Review Board Packet for Investigators, San Jose State University.

IRB Guidelines for the Protection of Human Subjects in Research Studies, University of Nebraska, Institutional Review Board for the Protection of Human Research Subjects.

Protecting Human Subjects, The University of Toledo Policy for Protection of Human Subjects in Research and Investigational Activities.

Research Submissions Involving Human Subjects, Indiana University/Purdue University at Indianapolis.

Texas Woman's University Application to Human Subjects Review Committee, Human Subjects Review Committee, Texas Women's University.

UNLV Review Requirements and Procedures for Faculty and Student Research Involving Human Subjects, University of Nevada-Las Vegas.

click here for Section III