PART I – POLICIES AND PROCEDURES

Institutional Review Board Policies and Procedures
Involving the Use of Human Subjects in Research

Abridged Version for Use by
MA in Counseling Students Only

A. Background and Responsibilities for Investigators

Central Michigan University 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 involved. The use of human subjects in research imposes both ethical and legal responsibilities upon the institution, the project director and those conducting 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 including: 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 Institutional Review Board (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 may also cause the University to lose federal funding, preventing individuals from applying for or receiving federal research funds, and preventing 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 Policies and Procedures Involving the Use of Human Subjects in Research” has institutional responsibility for use of human subjects in research, conducted by CMU faculty, staff, or students. 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 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 have his or her project approved whenever humans are used as subjects in research, even if the investigator does not consider the subjects to be “at risk.”
If at any time you don’t know what to do, think that your research might involve special circumstances, have questions about the policies or procedures, or need additional information, contact your monitor.

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 conducting of research involving human subjects. The investigator is responsible for the ethical treatment, and prevention or negligent of 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 titled *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.**
   a) Participation of human subjects must be voluntary, i.e., must occur as a result of free choice, without compulsion of 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.
   b) 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) A paramount responsibility of the investigator is to protect subjects from physical and mental discomfort, harm or danger. 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).
   b) 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.
   c) After the data is collected, the investigator should provide subjects with clarification of the nature of the study and remove misconceptions that may have risen.
   d) When 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.
   e) 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.**
   
a) Wherever possible, the research project should be designed with the intent that the knowledge gained will benefit the subjects and/or a larger community.

b) 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.**
   
a) 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 commitment made to subjects in a study.**
   
a) 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.

b) 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 has 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**

   Research is defined as 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 unless the work is done as a learning exercise for the student and will never be published or presented. Therefore, research leading to a thesis, dissertation and Capstone project requires prior approval by the IRB.

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 through publication or presentation in any medium must receive IRB approval prior to initiation whether it is conducted by faculty, students or staff. The types of review required depend upon the nature of the research involving the use of human subjects and are described below. In all cases, investigators must complete the application (see pp.45-47). The review procedure and length of time required for review varies for each category.

1. Research that Qualifies for Exemption from Board Review

   - All research involving human subjects which is exempt from Board review must maintain an adequate standard of informed consent and confidentiality of data. **Research meeting these criteria is only exempt from Board review. The investigator must still complete the entire application for Board review and submit it to the CED 670 monitor and the MA in Counseling Coordinator for review (see sample on page 91).**
Research activities in which the only involvement of human subjects will be in **one or more of the following activities are exempt** from Board review, **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.

a. When educational research (K-12) meets the following conditions, it is exempt from Board review and does not require parental consent. The investigator and/or the school system may, however, decide that parental consent should be obtained. Whenever possible, child **assent** should be obtained.

   (1) 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.

   (2) 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.

   (3) The study procedures do not represent a significant deviation in time or effort requirements from those educational practices existing at the study site.

   (4) The study procedures involve no increase in the level of risk or discomfort compared to normal, routine educational practices.

   (5) The study procedures do not involve sensitive topics (e.g., sex education).

   (6) Provisions are made to ensure the existence of a non-coercive environment for those students who choose not to participate.

   (7) The school or other institution grants written approval for the research to be conducted.

b. 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 “a” above. However, the presence of any one of the following conditions means that the research is **not exempt** from the review board.

   (1) Information obtained is recorded in such a manner that subjects can be identified, directly or through identifiers linked to the subjects. (Submit as requiring expedited review.)

   (2) 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. (Submit as requiring full board review.)

   (3) 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, of course, whether or not there is risk associated with a breach of confidentiality, should one occur. (Submit as requiring full board review.)

   (4) Research surveys and/or interviews involving children (subjects under 18 years of age) require an expedited or full board review.

c. Research involving the use of survey or interview procedures is exempt 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.
d. 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.

e. Research and demonstration projects which are conducted by or subject to approval or federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   (1) public benefit or service under those programs; or
   (2) procedures for obtaining benefits of services under those programs; or
   (3) possible changes in or alternatives to those programs or procedures; or
   (4) possible changes in methods or levels of payment for benefits or services under those programs

f. Taste and food quality evaluation and consumer acceptance studies:
   (1) if wholesome foods without additives normally contained in the food are consumed; or
   (2) 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 approval by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

2. Research that Qualifies for Expedited Board Review

   • Applications, which qualify for expedited review, are read by only two members of the board.
   • 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 Board 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.

   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 subjects’ 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. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required. Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.

   b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, nonpregnant adults who weight 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 2 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 2 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 collected either 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, electoretinography, 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 nonresearch 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 Board 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 research (such as research relating to illegal activity or sexual activity); or research involving children, pregnant women, prisoners, mentally incompetent people and other subject populations determined to be vulnerable, or research harmful to the subjects, automatically requires review by the full board. (See sample on page 125.)
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.

All other research involving the use of human subjects requires full review by the board unless it qualifies for exemption from full board review or expedited board review as described above.

E. Student Research

Student research follows the same guidelines as all other research. Instructors are responsible for screening individual research projects and making the initial determination as to whether the project requires IRB approval. If an instructor determines that a research project is assigned for the purpose of producing generalizable knowledge which may be presented or published, that it may involve risk to the subjects, or that it may be supported by grant funds, the student investigator must comply with the policies and procedures contained in this document. All CED 670 research must be approved prior to the student initiating the research.

Class assignments which are intended to provide research experience for the student and not generalizable results are not governed by the policies and procedures contained in this document. However, this does not relieve the student and instructor of the obligation for ethical use of human subjects. Consequently, the researcher should adhere to ethical standards and use informed consent and child assent procedures when appropriate. Although it is recommended that the instructor record all protocols used in the course work, no formal paperwork needs to be filed with the IRB.

F. Research Conducted Cooperatively with Another Institution

In the conducting 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. Joint or cooperative board review of such studies is allowed, and is intended to eliminate the duplication by each institution responsible for the same project.

Generally, in a cooperative research review agreement, one institution agrees to delegate the responsibility for initial and continuing review or review of a portion of the research activity to another board. In turn the other institution and board agree to assume responsibility for initial and continuing review in accordance with the agreement. The institution delegating the responsibility for review must understand that it is agreeing to abide by the reviewing board’s decisions. The delegating institution remains responsible for insureing the research conducted within its own institution is in full accordance with the determinations of the board at the institution providing the review.

The agreement for board review of cooperative research must be documented in writing with copies to be furnished to all parties to the agreement and the MA in Ed Director. Investigators should seek the counsel of the MA in Ed Director prior to engaging in cooperative research involving the use of human subjects.

G. Research Conducted in Foreign Countries

Research that is conducted in a foreign country should take into consideration the culture and local customs of the country when dealing with human subjects. In some cases, the usual board requirements may be utilized, while in others, the procedures to protect human subjects in that country may exceed the
policies and procedures set forth in this document. The disclosure of HIV positive serostatus may be more or less appropriate in different cultures or countries. It is best to discuss research projects conducted in foreign countries that involve the use of humans as subjects with your Capstone Project monitor during the planning phase of the project.

H. Institutional Review Board (IRB) Composition
The IRB is composed of the following 11 members nominated by the assistant vice president for research and approved by the Senate Executive Board: Three from the College of Arts and Sciences; one from the College of Business Administration; three from the College of Education, Health and Human Services; two at large from the university community; and one non-university member (who may not be part of the immediate family of a person who is affiliated with Central Michigan University); and one from the ORSP who will serve as executive secretary, voting. At least one member of the committee must have research interests in nonscientific areas. A quorum consists of six voting members of the committee.

Committee members will serve three year terms with one of the committee being replaced each year. The IRB chair may request that any committee member who misses three consecutive meetings be replaced.

I. IRB Committee Meeting Times
The committee will meet and select a chairperson during the week prior to the start of classes each fall semester. The IRB will normally meet on alternate Thursdays during the academic year. Summer meetings will be arranged as needed.

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

Instruction for Application for Review of
Research Involving the Use of Human Subjects

Important Notice: Students who collect data without written IRB approval are subject to the following sanctions:

1. Student will not be able to use the data collected. If the project has already been written, it will be rejected and
2. Student will have to request IRB approval to collect new data for the CED 670 project.

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. Descriptions of how to prepare an application, including sample exempt from full board, expedited review, and full board review applications, and the required forms are contained on the following pages.

A. Submission of Application Materials

Please submit completed application materials to your CED 670 monitor.

1. If the research qualifies for exemption from board review, submit one copy of the application packet to your CED 670 monitor. Within 5-6 weeks, you will receive one of the following decisions:
   • protocol approved as submitted; or
   • approval withheld pending submission of revisions and/or additional information; or
   • protocol requires either expedited or full board review.

2. If the research qualifies for expedited review, submit one copy of the application packet to your CED 670 monitor. Within 6-7 weeks, you will receive one of the following decisions:
   • protocol approved as submitted; or
   • approval withheld pending submission of revisions and/or additional information; or
   • protocol requires full board review.

3. If the research requires full board review, submit one copy of the application to your CED 670 monitor. Within 8-9 weeks, you will receive one of the following decisions:
   • protocol approved as submitted; or
   • approval withheld pending submission of revisions and/or additional information; or
   • protocol disapproved.

4. All notifications are in writing. Do not call or ask your monitor to call the Coordinator before the stated time period has been exceeded.
B. Application Instructions

The following instructions are provided as a guide to help investigators prepare a complete application. Direct all questions and requests for additional forms to your CED monitor. Please complete the Application Cover Sheet (see blank form on page 53 and samples on pages 93, 111 and 127), the Investigator’s Assurance Statement (see blank form on page 55 and samples on pages 94, 112 and 128), and the CED 670 IRB application (see blank form on page 57 and samples on pages 95, 113 and 129). The CED 670 IRB application will help you in developing your specific response to the various components of the IRB requirements.

♦ Include copies of consent forms, cover letters, questionnaires, interview questions, and letters of permission.

1. Application Cover Sheet
   - Complete only the top half of the page.
   - Be certain the project title is descriptive.
   - Give proposed project dates indicating when contact will be made with the subjects.
   - Ask your CED 670 monitor to select the appropriate category of review and to sign the cover sheet.

   Note: If your project is determined to fall in the “not required” category, this is the only form that must be submitted to the MA in Counseling Coordinator.

2. Investigator’s Assurance Statement
   - Attach the signed Investigator’s Assurance Statement; both the student and the faculty monitor must sign.

   - This application is required for all CED 670 projects which require IRB review and fall into the “Exempt from full board review”, “Expedited review”, or “Full board review” category. Please respond to each item on the application form. An incomplete application may delay approval of your IRB application. Your project proposal is not sent to campus, therefore, answers to all questions must be completed. A checklist is provided on page 1 of the application and includes all of the components of the IRB application packet.

C. Reporting Changes in a Research Protocol
   - Any change in a protocol that affects the human subjects must be approved by the board 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 to the CED 670 monitor who will forward it to the Cohort Coordinator for approval. If the protocol change requires changes in the consent forms, attach the new consent forms to the Request for Change in Protocol.

D. Submission of a Report of Injury
   - If a subject suffers an injury during research, the investigator must take immediate action to assist the subject and to notify the MA in Counseling Coordinator of the injury within 48 hours.

E. Reporting Non-Compliance with Board Policies and Procedures
   - Any incident of non-compliance with board policies and procedures should be reported immediately to the MA in Counseling Coordinator, (630) 553-7291 OR mlsdhjs@aol.com, 7798C Finnie Rd., Newark, IL 60541.
TIPS and FAQs

1. **Use of other CMU students as research subjects**
   CED 670 students may survey other CMU students provided that the permission of the instructor is obtained in advance. In the IRB application, the investigator should list the names of the instructors who have granted permission for survey distribution in their classes.

2. **Use of e-mail in distributing and collecting surveys**
   E-mail or a Web-based format may be used to distribute and collect surveys. Some Web-based surveys allow for anonymous return of surveys. If so, please state this in the IRB application materials and in the cover letter or informational section of the survey. Surveys sent by e-mail do not provide for anonymous return since the sender’s e-mail address and name often appear on the return e-mail. The investigator should note, in the survey cover letter or informational section, that while responses will not be anonymous, confidentiality will be maintained by, for example, deleting (blacking out, tearing off, etc.) the sender’s e-mail address and name from the printed response. In addition, subjects should be told how long the investigator intends to keep their response in the investigator’s e-mail system. In addition, these procedures should be noted in the “confidentiality” section of the application.

3. **Hospital IRBs**
   Students who have the opportunity to do research in schools or the healthcare field may be required to have their research projects approved through the institution’s own IRB committee. CMU does not require that students obtain approval from both CMU’s and the school district’s or hospital’s IRB committees. However, CMU must be notified in writing that the student has obtained permission to collect data from the school district or hospital IRB committee.
   
   In these cases, in order to receive IRB approval from CMU, students must submit:
   a. the CMU, IRB application cover sheet, marked “required,” and either “exempt,” “expedited,” or “full board,” and
   b. a copy of the IRB approval letter from the institution’s IRB committee.
   c. a statement concerning the age of potential research subjects.
   d. a copy of the survey or interview questions to be used in the research project.

   The standard CMU, IRB approval letter will be sent to the student.
   
   After the data has been collected, students must submit the CMU, End of Data Collection Report to their monitor.

   **Note:** Students should check with their or hospital IRB committee to determine if school or hospital IRB review is required. If the guidelines stated above are not consistent with the school or hospital's IRB procedures, please have your monitor call the MA in Counseling Coordinator.

4. **Secondary data**
   Secondary data encompasses many types of data, such as financial data, public records, and record reviews (student files, medical files, etc.). Previously administered surveys are also considered to be secondary data. If the data from the previously administered survey is not aggregate, a copy of the survey must be submitted and the research falls in the “exempt” category. If the data from the previously administered survey is aggregate, the research falls in the “not required” category.

   Projects involving record reviews may fall in the exempt or in the expedited category. Human subjects research regulations are based on the assumption that only persons authorized by the institution that made the records will be given access to those records. It is further assumed that anyone given access has been trained in the importance of maintaining the confidentiality of information, and he/she can be
trusted not to casually disclose confidential information. A records study is usually exempt as long the information is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to subjects, and consequently there is no possibility of an accidental breach of confidentiality (e.g., even if the researcher lost the data in the airport, there would be no way to link the information to individual persons). A key issue is not whether the researcher can see the names in the files, but whether the information is recorded for research purposes without identifiers or codes that link data to names.

An additional issue is whether using the records for research purposes might be viewed as an impermissible invasion of subject privacy. If the records were created for non-research purposes (such as medical treatment or diagnosis) and the subjects had high expectation that the records would be kept private, the study should be reviewed at the expedited level. If names or codes linked to names are recorded, the study is expedited.

5. **Telephone scripts**
   If a student is using a telephone survey, the opening statement by the researcher must disclose the same information as that found in a cover letter. Consent forms are not necessary when telephone surveys are used.

6. **Approval letters**
   Approvals to conduct surveys or interviews should be on company or institution letterhead. If the name of the person giving authorization is not clear, you may be required to supply the name. E-mail authorizations will not be accepted.

7. **Public Property**
   Remember that public property is just that; property belonging to the city or state. Surveys conducted in supermarket parking lots, in malls, or in front of a business location require letters of permission.

8. **Why is it important to state the number of subjects in my project?**
   This issue is of importance if the investigator is asking demographic questions, and also in projects where no demographic questions are used. If demographic questions are used, the investigator must first assess whether the subject population is so small that individual participants can be identified through responses to demographic questions? Second, are the demographic questions necessary and are responses to such questions important to the investigator’s hypothesis? For example, a project with 30 subjects and demographic questions which ask about ethnicity, gender, position, and years of employment at the company would probably allow for individual respondents to be identified. This problem can be addressed in a number of ways: 1) instructing subjects (in the cover letter) to return demographic questions separately from the survey instrument; 2) deleting the demographic questions; or, 3) reducing the number of demographic questions or broadening the ranges of response (for example, age or years of employment).

   If no demographic questions are used, the number of subjects may still be a factor contributing to potential risk. For instance, subjects need to be informed that they are only one of ten possible respondents. For example, a researcher wishes to assess the impact of a new supervisor. Questions on the survey ask participants to give their opinion of the new supervisor. No demographic questions are asked, but there are only ten potential subjects. In the cover letter, the investigator should point out to potential subjects that they are only one of ten possible respondents. This information would help the subject to make the decision on whether or not to participate. The investigator can help the decision-making process by explaining how confidentiality will be maintained and describing who will be given the results of the study.
9. **Why is it important to identify potential risk?**
The IRB committee is especially concerned with risk and whether or not risk is being adequately addressed in the IRB application. It is possible for a project to have some risk and to be approved if the risk is clearly identified, if subjects are informed of the risk, if the benefits outweigh the risk, and if the investigator has made provisions to minimize the risk. According to the Institutional Review Board, “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.” Risk can be more than a breach of confidentiality or the possibility of subject identification.

Additionally, risk may involve sociological issues, psychological issues, etc. The Institutional Review Board guidelines identify five major types of risk: physical, psychological, social, legal, and economic. Many proposals contain a mixture of risks.

10. **When do I use a cover letter and when do I use an informed consent form?**
A cover letter is used whenever the project involves a survey which can be returned anonymously by subjects. Anonymous return is achieved by using U.S. mail, interoffice mail, or a secured drop box. A consent form is used in the following types of projects:
   a. Personal interviews are conducted and questions are non-programmatic;
   b. Children are involved in the project (child assent and parental consent are also needed);
   c. Subjects are being observed and there is no expectation that their behavior is public;
   d. Subject population is so small that the investigator will know who is participating.

11. **What is the difference between programmatic questions and non-programmatic questions?**
Programmatic questions are factual in nature. The interview subject is being asked about things, not opinions. For example, “How many employees work here?” is programmatic in nature, while “Do you feel that staffing levels are adequate for your school?” is not. Non-programmatic questions ask the subject to express feelings, give an opinion, or make a judgment. Use of non-programmatic questions means that you are treating the interview subject as a human subject. Interviews with programmatic questions do not require the use of a consent form and such projects may fit into the “Not Required” category of IRB review. Interviews with non-programmatic questions require the use of informed consent forms and such projects go through “Expedited” or “Full board” review.

   *A tip:* When an investigator is interviewing subjects and questions concern a “thing” — a program, a project, an industry, etc. — interview questions can often be reworded to be programmatic in nature. If you are just looking for information, avoid questions which start “how do you feel about . . .”, or “what is your opinion on . . .”. For example, “What do you think the effect of this procedural change is on widget production?”, could be reworded as “What was widget production before the procedural change and after the procedural change?”

12. **What do I say in my cover letter or consent form if I am a supervisor?**
If you supervise any or all of your subjects, you must reduce the possibility of coercion. In the cover letter, you can add the following: “Although I supervise some (or all) of you, your decision to participate or not to participate in this project will not jeopardize your position in any way because I will have no way of knowing who participated and who did not participate.” In the consent form, you must acknowledge that you supervise the interviewee and assure the research subject that they may decide not to participate in the interview without repercussion and without putting their jobs in jeopardy.
13. **How do I address risk in my consent materials?**

If the project involves some potential risk to subjects such as recalling episodes of workplace violence, you can add the following to the cover letter or consent form: “Some of the questions included on this survey (or in this interview) may make you feel uncomfortable (Note: This is where you can specify the risk in more detail). Please answer only the questions you are comfortable in answering. If you experience any emotional distress because of this project, please call (555) 555-5555 which is a contact number for support services (specify the name of the service).” This information about risk should also be contained in the section on *Risks and Protection of Subjects* in the written portion of your IRB application.