

**BRIEF GUIDELINES  
FOR HUMAN SUBJECTS RESEARCH**

Andrews  University

A Guide to Developing an  
Application for Approval of Research Involving Human Subjects

**ANDREWS UNIVERSITY**

Institutional Review Board

February 2005

# BRIEF GUIDELINES FOR HUMAN SUBJECTS RESEARCH

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## INTRODUCTION

The expansion of knowledge through research is a primary goal within the traditions and mission of a university. Andrews University strongly supports that mission and seeks to create a climate and policies and procedures designed both to stimulate research and to safeguard research subjects and the general community. The research policies and procedures in this document were patterned after the following two publications: The Report of the National Commission for the Protection of Human Subjects in Biomedical Research (*The Belmont Report*, 1979) and the Report of the National Institutes of Health's Office of Protection from Research Risks (OPRR) "Protection of Human Subjects" (*Code of Federal Regulations*, 45 CFR 46, March 1983). These two documents provide the framework used in formulating Andrews University's policies which are designed to support the value of research, to give heed to the sanctity of human life, and to help safeguard basic human rights.

This document is an abbreviated form of the *Institutional Review Board Operating Policy*. The full policy document is available for review in the Office of Scholarly Research.

### A. ETHICAL PRINCIPLES FOR RESEARCH INVOLVING HUMAN SUBJECTS

Research involving human subjects should be carried out with a profound sense of the sacredness of the human will and existence, with respect and concern for the dignity and welfare of the people who participate, and with cognizance of federal and state regulations, University policy, and professional standards. The following principles should guide research involving human subjects:

1. Research involving competent human subjects requires the person's **voluntary** and **informed** consent.
2. No person should be placed at risk as a research subject unless the risks are reasonable in relation to the anticipated benefits of the research.
3. The risks and burdens to research subjects should not be unjustly distributed. The recruitment and selection of subjects should be reasonably related to the research and not impose inequitable risks and burdens on any segment of society. In addition, no segment of society -- by conscious exclusion from participation in a research study -- should be denied the benefits of research designed to benefit society at large.
4. Special consideration and protection for subjects should be given in research involving persons who may lack full capacity to secure their own rights and interests, e.g. children, the mentally infirm, the economically or educationally disadvantaged, and those in involuntary custody.
5. Special consideration should also be given to projects involving any aspect of life including, but not limited to, genetic study, environmental issues, and animal research.

### B. THE INSTITUTIONAL REVIEW BOARD

The *Institutional Review Board (I.R.B.)* has been established to monitor all research conducted by faculty, staff, and students at Andrews University. The Board also plays a role in educating the University community regarding the importance of safeguarding human subjects from any potential risks involved in research. It consists of 8 appointed faculty and administrators from a variety of disciplines.

## C. AUTHORIZATION TO CONDUCT RESEARCH

In both faculty and student research involving human subjects, collection of data may not begin until written approval has been given by the **I.R.B.** The **I.R.B.** has the authority to deny, suspend, or terminate research that does not meet its policies.

Students and faculty who conduct research involving human subjects that is sponsored by non-university organizations and **for which the students so involved will register to receive Andrews University credit** are expected to have the research cleared in advance by the **I.R.B.**

Permission must be obtained in advance from physicians or health professionals providing evaluation or treatment for project-related conditions to potential subjects. Individuals planning research projects which involve the use of invasive procedures should note the information in **Appendix E: Guidelines for Invasive Procedures.**

All events of injury to subjects during a research project (either on or off-campus) must be reported by the principal investigator to the University physician immediately, and to the **I.R.B.** chair or designee as soon as possible after occurrence, within 24 hours if possible, and 7 days at most. The incident must be documented in writing.

The **I.R.B.** physician has the authority in such cases to suspend the research project temporarily until determination can be made about continuation. Consultation between the physician and the **I.R.B.** chairperson (and other members if needed) will occur before a decision is made on continuation, revision of protocol, or termination of the research.

## D. IRB APPLICATION PROCEDURES

In applying for approval of research involving human subjects, the principle investigator must submit to the *Institutional Review Board*, through the Graduate Assistant of the *Office of Scholarly Research*, copies of the following documents:

1. ***Application for Approval of Research Involving Human Subjects*** Form.  
(Forms are available from the *Office of Scholarly Research* ~ you may: access this on our website; collect a hard copy from the **I.R.B.** office; or you may request that a copy be sent to you as an attached document via e-mail.
2. A ***Research Protocol Document***. Submission of one of the following types of documents will satisfy this requirement.
  - a. A ***Brief Research Protocol***. (Forms are available on our website or from the *Office of Scholarly Research*). To be used **only** by students under the direct supervision of an advisor in a research class or by students who are preparing protocols to do limited data collection or pilot studies. Allied Health, Nursing and Physical Therapy students should check with their research advisor regarding the correct type of protocol to submit to the **I.R.B.**
  - b. A ***Theses/Dissertation Proposal***. Relevant methodological portions of existing proposals may be used if they adequately address the issue of protection of human subjects from research risk as described below in Section G. A very brief but clear summary of the items listed in Section G should be submitted together with the *Thesis/Dissertation* proposal.

- c. A *Human Subjects Research Protocol*. Those individuals conducting research involving human subjects either on or off campus—whether faculty or students whose situations are not covered above—are expected to submit protocols that address those issues listed below in section G.
3. An *Informed Consent Form*. See section H.
4. Any additional required documentation: *Cover Letter of Explanation, Questionnaires, Written Copy of Verbal Instructions, Permission Documents*. Examples of this latter category include: {a} letters from an authorizing official at an off-campus site where research is to be conducted; {b} letters from a physician or other health care professional who is providing care, evaluation or treatment to a research participant for a condition related to the objective of the research study, and documentation and qualifications of personnel involved in invasive procedures.

## E. CATEGORIES OF IRB REVIEW

Screening and review of the protocol will occur at one of two levels. These levels are described in more detail in **Appendix A**.

1. *Exempt from Full I.R.B. Review*. Studies that involve no risk to the subjects and meet the criteria of **Appendix A** are exempt from full I.R.B. review. Protocols submitted under this category are screened by the chair of the I.R.B. or a designee. If all application materials are complete and if found to qualify as "no risk" research, these protocols are approved without further review. Such protocols normally receive approval within **one week** of the complete submission of all required documentation.
2. *Expedited/Full/Monitored I.R.B. Review*. All studies which involve some risk to the subjects or do not meet the criteria of Appendix A qualifying them as being exempt from review must be reviewed either by two members of the I.R.B. (**Expedited Review Category**) or by the full membership of the I.R.B. (**Full Review Category**). Such protocols must be approved by both reviewers (**Expedited Review**) or receive a majority vote of those I.R.B. members present (**Full Review**) to be approved. Actions taken regarding such protocols may include: full approval, conditional approval (with monitoring of compliance and any needed revisions), request for resubmission, or disapproval. Applications that receive expedited review can normally be processed within one month. Protocols receiving full review will usually take from four to six weeks to receive approval since they await the quarterly meetings of the I.R.B. Persons applying for I.R.B. approval should plan their schedule recognizing that adequate time must be allowed for the required approval process to be completed.

## F. PERIOD OF APPROVED RESEARCH

Once an application has been approved by the I.R.B. official written notification will be sent to the principal investigator(s) and faculty advisor, if applicable. Research involving human subjects cannot commence until such notification has been received. I.R.B. approval is granted for a period of one year. In the event that the investigator wishes to continue the research for a longer period of time, a written request (letter or e-mail) for an extension of approval must be submitted to the I.R.B. The I.R.B. will then respond to the researcher's request prior to the researcher being permitted to continue with such research.

## G. THE RESEARCH PROTOCOL

The protocol is a statement of the researcher's project design and a description of his/her responsibilities toward the human subjects involved in the research.

Every researcher planning to conduct research involving human subjects is required to submit a protocol describing the research to the **I.R.B.** The Board and/or a designee reviews the protocol and takes action regarding approval.

**One** copy of the protocol is submitted to the **I.R.B.** if the researcher expects exemption from review. If an expedited or full review process is expected or required, then five copies (**expedited**) or nine copies (**full**) are to be submitted.

The research protocol should contain the following elements:

1. A brief description of the purpose, methods, and time frame of the research.
2. A description of the subjects, indicating explicitly whether any are minors (under age 18 per Michigan law) or otherwise members of "vulnerable" populations **or other jurisdictions** who lack full capacity to secure their own rights and give informed consent.
3. A description of how subjects will be recruited and how they will be involved, including the criteria used for determining the inclusion/exclusion of subjects.
4. A statement of the benefits of the research to the human subjects, if any, and of the benefits to humanity and/or scientific knowledge.
5. A detailed explanation of how the welfare and rights of subjects whose competency to give informed consent is compromised are to be protected if such subjects are to be involved in the research.
6. A description of the risks and discomforts, if any, to the subjects. Such deleterious effects may be physical, psychological, or social. Some research involves neither risks nor discomforts but rather violations of normal expectations. Such violations, if any, should be specified.
7. A description of the means to be taken to minimize each such deleterious effect or violation, including the means by which the subjects' personal privacy is to be protected and the confidentiality of information received is to be maintained.
8. A copy of the consent form that is to be used with the subjects. A checklist for the review of consent forms is included in **Appendix C**. Sample consent forms are available for review on our website, on line or, at the *Office of Scholarly Research*.
9. A copy of a signed permission statement or letter (from the **I.R.B.** where applicable) of each off-campus (non-Andrews University) site where research data will be collected. Where appropriate, a permission letter(s) from an attending physician or other health care professional if such a professional's care, evaluation or treatment of the subject(s) is related to the object of the research study (See: Section D.4) as well as documentation regarding invasive procedures. Approval may be held up until such permission letters or other forms of documentation are on file with our **I.R.B.**
10. Any other information pertaining to the researcher's ethical responsibilities.

## H. DOCUMENTATION OF INFORMED CONSENT

Except as provided in sections 4, 5 and 6 below, informed consent shall be documented by the use of a written consent form approved by the I.R.B. and signed by the subject or the subjects' legally authorized representative. A copy shall be given to the person signing the form.

### 1. Content of the Written Informed Consent Form.

The full informed consent form must include:

- a. A statement that the activity involves research and a description of where the research activity will occur.
- b. An explanation of the scope, aims, and purposes of the research, and the procedures to be followed (including identification of any treatments or procedures which are experimental) and the nature of the expected duration of the subjects' participation.
- c. A description of any reasonably foreseeable benefits, if any, to the subjects or others that may result from the research.
- d. A disclosure of appropriate alternative procedures or courses of treatment (in instances where therapeutic procedures are involved), if any that might be advantageous to the subjects.
- e. A statement describing the extent to which confidentiality or records identifying the subjects will be maintained except in unusual cases.
- f. An offer to answer any questions the subjects may have about the research, the subject's rights or related matters, and the name of the person (together with address and telephone number) to whom the subjects may direct questions or must report an injury.
- g. A statement that participation is voluntary, that refusal to participate involves no penalty or loss of benefit to which the subjects are otherwise entitled, and that the subjects may discontinue participation at any time without penalty or loss to which the subjects are otherwise entitled if they had completed their participation in the research.
- h. For research which may involve more than minimal risk of injury the subject should be informed of the following statement which must appear in the consent form: (to be modified for off-campus research)

*“In the unlikely event of injury resulting from this research, Andrews University is not able to offer financial compensation nor to absorb the costs of medical treatment. However, assistance will be provided to research subjects in obtaining emergency treatment and professional services that are available to the community generally at nearby facilities. My signature below acknowledges my consent to voluntarily participate in this research project. Such participation does not release the investigator(s), institution(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to me.”*

- i. A space for the dated signatures of the subject, the principal investigator, and a witness. In the case of a minor (the child must also sign if seven years of age or older) or a person unable to sign, a second authorizing signature is required from the parent, guardian, or other responsible person. The relationship must be specified.

2. Format of the *Written Consent Form*.

- a. The consent form should clearly identify the relationship of the researcher to Andrews University. The name of Andrews University should appear centered at the top of the consent form together with the name of the department with which the researcher is affiliated. In cases where an anonymously returned questionnaire substitutes as a form of implied consent (**See Section 4.b. below**), the cover letter accompanying the questionnaire should clearly identify how the research is connected with Andrews University and one of its academic departments.
- b. The consent form should clearly indicate the name, address, and phone number of the investigator and an advisor or impartial third party whom the research subject may contact for additional information if desired.
- c. Places for the dated signatures of the subject (and/or parent/guardian, if applicable), investigator, and witness should be included at the bottom of the consent form.

3. Retention of the Signed Consent Form.

- a. A copy of the consent form should be returned to the subject or the person legally appointed to sign the consent form to retain for his/her review.
- b. The responsibility for retaining signed copies of the consent form lies with the principal investigator(s). These consent forms should be kept in a secure depository along with the researcher's other records for a reasonable amount of time (normally not to exceed three years).

4. Use of Alternate and/or Simplified Consent Forms.

Certain situations may justify the use of alternate and/or simplified consent forms. However, in all cases the investigator must demonstrate how the anonymity or confidentiality of the subject and his/her voluntary participation in the project will be assured and maintained.

- a. *Oral Instructions Read to a Group*. In the case of no risk or minimal risk research where instructions are read to a group of subjects (e.g. a questionnaire passed out in a classroom setting, with prior written authorization of the instructor), a short form to document the oral instructions presented to the subjects may be used. A witness who heard the oral instructions read to the group must co-sign the short form along with the researcher. A written copy of the oral instructions that are to be read to the group must be submitted with the protocol. The items listed in Section 1 above should be included in the oral instructions.

Research using surveys or questionnaires and dealing with sensitive areas of the respondent's own behavior (illegal conduct, drug/alcohol use, sexual behavior, etc. **See Appendix A, Exempt Review, item 4**) require special consideration. Although the purpose and use of surveys and questionnaires in such research may be explained in a classroom setting (with prior documented permission of the instructor(s) involved), requesting respondents to actually complete survey instruments in the classroom setting is not appropriate. Alternative methods of collecting forms completed at the discretion of the respondent and which thus insure the respondent's anonymity should be employed.

- b. *Anonymous Surveys or Questionnaires*. In the case of no risk or minimal risk research involving the use of surveys or questionnaires which are distributed individually and returned anonymously, the cover letter explaining the purposes and procedures of the research project may substitute for the consent form. Such a cover letter must be submitted with the protocol and should contain reference to the items mentioned in

section 1 above. It should state in the cover letter as well as on the survey form itself that the return of the survey or questionnaire serves as a form of implied consent.

- c. *Simple Oral Interviews*. Investigators conducting simple oral interviews, the content of which qualifies as exempt from review (see **Appendix A, Exempt Review**, item 4), may submit an alternate form of written documentation in place of an informed consent form. Such documentation should describe how the interviewer will explain his/her research to the interviewee and how the researcher is prepared to insure the interviewee's confidentiality and his/her right to refuse participation in the interview.

In all cases, the researcher is responsible for the filing of all proof of compliance with the above procedures and to keep them for a period of three years.

#### 5. Waiving of Signed Consent Documentation.

The **I.R.B.** may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that either of the following conditions exists:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

#### 6. Waiving the Consent Process.

The **I.R.B.** may under certain special circumstances approve a consent procedure which does not include or which alters some or all of the elements mentioned above or may waive the requirement to obtain consent provided the Board verifies and documents each of the following items:

- a. The research involves no more than minimal risk to the subjects.
- b. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
- c. The research could not practicably be carried out without the waiver or alteration.
- d. When ever appropriate, the subjects will be provided with additional pertinent information after participation.

#### 7. Consent from Attending Physician and/or Other Health Care Professionals.

In situations where an individual is currently being treated/evaluated by a physician and/or other health care professional for a condition related to the objective of the research study, the researcher is required to obtain the consent of the physician and/or health care professional prior to involving such research subjects in the study.

## APPENDIX

### A

#### CRITERIA FOR ELIGIBILITY IN THE THREE LEVELS OF IRB REVIEW

##### **EXEMPT FROM FULL IRB REVIEW:**

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as **(1)** research on regular and special educational instructional strategies, or **(2)** research on the effectiveness of, or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), if information taken from these sources is recorded in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
3. Research involving survey or interview procedures as well as that involving the observation of public behavior (including observation by an investigator who is also a participant in such behavior).  
**Exceptions:** **(a)** All research involving survey or interview procedures is exempt without exception, when the respondents are elected or appointed public officials or candidates for public office; **(b)** Research described in section 4 above shall **NOT** be eligible for inclusion in the category exempt from full **I.R.B.** review in situations where all of the following conditions exist:
  - a. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the subjects' responses, if they become known outside the research, could reasonably place the subjects at risk of criminal, or civil liability or be damaging to the subjects' financial standing or employability.
  - b. Responses are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects, and the research deals with sensitive aspects of the subjects' own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.
  - c. Respondents involved in survey or interview procedures (other than those associated with research described in section 1 above) are minors.
  - d. Investigator doing observation of public behavior of minors is also a participant in activities being observed.
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 the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - a. Public benefit or service programs;
  - b. Procedures for obtaining benefits or services under those programs;
  - c. Possible changes in or alternatives to those programs or procedures;

- d. Possible changes in methods or levels of payment for benefits or services under those programs.

***REQUIRING EXPEDITED I.R.B. REVIEW:***


1. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth if patient care indicates a need for extraction.
2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.
3. Recording of data from subjects 18 years of age or older using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electro-magnetic radiation outside the visible range (e.g. x-rays, microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an eight-week period and no more often than two times per week, from subjects 18 years of age or older and who are in good health and not pregnant. (See **Appendix F: *Guidelines for Invasive Procedures.***)
5. Collection of both supra- and subgingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.
6. Voice recordings made for research purposes such as investigations of speech defects.
7. Moderate exercise by healthy volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
10. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.
11. All studies which do not otherwise meet the criteria for exempt research.

***REQUIRING FULL I.R.B. REVIEW:***

All studies which do not meet the criteria for exempt or expedited review must be reviewed by the full **I.R.B.**

***REQUIRING MONITORED I.R.B. REVIEW:***

Studies which under previous full **I.R.B.** review have been granted conditional approval if specific minor conditions are met, or where minor changes in procedures not affecting risk are proposed.

Application for Approval      Andrews  University  
**Research Involving Human Subjects**  
**Research**

Institutional Review Board  
**Office of Scholarly**

Tel: 616-471-6360 ~ Fax: 616-471-6246

**INSTRUCTIONS:**

**Your application will not be processed unless ALL the relevant documentation has been submitted and is legible.**

Use this form as a cover sheet and attach to it the following items: (1) The appropriate *Research Protocol*, (2) An *Informed Consent Form* (if required), (3) And *Abstract* and, (4) Other documentation as needed—*Cover Letter of Explanation. Question Sample. Written Copy of Verbal Instructions*, and/or *Letters of Permission*. Submit the required number of full sets (**1 set for Exempt; 5 sets for Expedited; and 9 sets for Full Review**) to Andrews University, Office of Scholarly Research, Room 210 Administration Building, Berrien Springs, MI 49104-0355.

**SUGGESTED CATEGORY OF IRB REVIEW**

The investigator(s) should read carefully the *Brief Guidelines for Human Subjects Research* and discuss with his/her/their advisor and/or department chair the relationship of the present research project to the policies and procedures contained in the above document. After this consultation the investigator(s) should request that the research project be considered by the **I.R.B.** under one of the categories listed below. Final assignment of the review category is made by the **I.R.B.** The frequency of **I.R.B.** review action is noted by the respective review category.

- |   |  |  |
|---|--|--|
| <p><input type="checkbox"/> <b>Exempt from Full IRB Review [Weekly Review]</b><br/>         No risk/minimal risk research: fill out <i>Exempt Category Checklist</i> on page 2.</p> | <p><input type="checkbox"/> <b>Expedited IRB Review [Monthly Review]</b></p> | <p><input type="checkbox"/> <b>Full IRB Review [Quarterly Review]</b><br/>         Submit the appropriate documentation two weeks prior to the next Scheduled meeting of the IRB</p> |
|---|--|--|

**DESCRIPTION OF RESEARCH PROJECT**

**Project Title:**

.....  
 .....  
 .....

**Academic Department of Researcher:** .....

**Beginning and Ending Dates of Human Subjects Involvement in Research:** ..... to .....

**Place/Location of Human Subject Involvement in Research:** .....

**Target Population** (Description and Age Range): .....

**INVESTIGATOR(S) AGREEMENT**

*"I (we) hereby agree to abide by the terms and methodology as outlined in the attached research protocol. I (we) also agree to begin the implementation of this project—if not approved under the exempt category—only after written notification of its approval (valid for one year) has been received. Furthermore, I (we) agree that in cases involving research to be conducted at non-university site(s), such research will commence only after written authorization has been received from an officer of the organization at each site involved and filed with our Office of Scholarly Research. Notification of any alterations in the attached protocol will be submitted to the Director of the Office of Scholarly Research.*

**Name:** ..... **Name:** ..... **Name:** .....

**E-mail:** ..... **E-mail:** ..... **E-mail:** .....

**Address:** ..... **Address:** ..... **Address:** .....

.....

.....

**Tel:** ..... **Tel:** ..... **Tel:** .....

.....

(Principle Investigator's Signature) (Date) (Principle Investigator's Signature) (Date) Principle Investigator's Signature (Date)

**SUPPORTING NAME AND SIGNATURE**

*"I have reviewed the above project with the investigator(s) and concur in the requested category of I.R.B. review."*

.....  
Name of Advisor—Block Letters

.....  
Signature of Advisor Supervising Research

.....  
Date

—**ABSTRACT OF PROJECT**—

Please attach a separate sheet with the heading: **Abstract**

— **EXEMPT CATEGORY CHECKLIST** —

If your proposed research project does not place the subjects at **more** than minimal risk and is included in one of six categories of research which are exempt from full review under the provisions of the Cod of Federal Regulations for the protection of human subjects from research risk, indicate the category(s) that apply to the proposed project placing a check in the appropriate box below.

*Even if exempt from full IRB review, all research projects must make provision for compliance with published guidelines for obtaining informed consent and maintaining confidentiality. Some research listed below, if involving prisoners and/or directed toward pregnant women or other vulnerable populations groups, is not exempt.*

<b>1</b>	Research conducted in established or commonly accepted educational settings, involving normal educational practices such as: (a) Research on regular and special education instruction strategies, (or) (b) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or management only.
<b>2</b>	Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior UNLESS ALL of the following conditions exist: (a) Responses are recorded in such a manner that the subjects can be identified directly or through identifying links, and— (b) The responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation. <b>Note:</b> <i>The following types of Category 2 Exemptions do NOT apply to research where children (minors) are subjects: Survey Research, Interview Research, Observation of Public Behavior in which an investigator is a participant.</i>
<b>3</b>	Research of the type listed in Category 2 which under the above provisions is not exempt but qualifies for exemption if: (a) The human subjects are elected or appointed public officials or candidates for public office, or (b) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
<b>4</b>	Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens and these sources are publicly available, or if the information is recorded by the investigator in such a way that the subjects CANNOT be identified directly or through identifiers linked to the subjects.
<b>5</b>	Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: (a) Public Benefit or Service Programs (b) Procedures for obtaining benefits or services under those programs (c) Possible changes in or alternatives to those programs or procedures (d) Possible changes in methods or levels of payment for benefits or services under those programs.
<b>6</b>	Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe or agricultural, chemical, or environmental contaminant at or below the level found to be safe by FDA or EPA or USDA determination.

“In signing this form requesting exempt status, I (we) assure the Institutional Review Board that the only involvement of human subjects will comply fully with the criteria for one of the above exemption categories.”

.....  
Principle Investigator's Signature    Date                      Co-Principle Investigator's Signature    Date                      Co-Principle Investigator's Signature    Date

<b>APPENDIX B</b>
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**PREPARING AN INFORMED CONSENT DOCUMENT**

***GUIDELINES FOR WRITTEN CONSENT FORMS***

Check as completed:

- \_\_\_ 1. **ANDREWS UNIVERSITY/RESEARCHER'S DEPARTMENT IN HEADING**  
Include Andrews University and the name of the researcher's School/Department in the heading on the form. Label the document "Informed Consent" and include the title of the project.
- \_\_\_ 2. **CLEAR TITLE OF PROTOCOL**  
Keep the title simple and retain the same title in the consent form.
- \_\_\_ 3. **SIMPLIFIED LANGUAGE**  
Avoid technical jargon, use language appropriate to the reader, and understandable at about the eighth grade level. A separate explanation may be required in the subject's primary language. Compose the form using the first person and begin each explanatory paragraph with "I have been told..."
- \_\_\_ 4. **NO IMPLIED LIABILITY RELEASE**  
No informed consent, whether oral or written, may include any exemption clauses through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases, or appears to release the investigator, the sponsor, the institution, or its agents from liability or negligence.
- \_\_\_ 5. **PURPOSE AND PROCEDURES**
  - a. Provide a statement that the study involves research.
  - b. Give an explanation of the purposes of the research.
  - c. State the expected duration of the subjects' participation.
  - d. Give a description of the location and procedures to be followed.
  - e. Identify any procedures that are experimental.
- \_\_\_ 6. **RISKS EXPLAINED**  
State the nature and degree of any reasonably foreseeable (or potential) risks, stress, discomfort, or invasion or privacy. Risk is defined as the possibility of harm; physical, psychological, sociological or other that may occur as a consequence of any activity which goes beyond the application of the established and accepted methods necessary to meet the patient's needs.
- \_\_\_ 7. **BENEFITS DESCRIBED**

Describe the potential benefits of the study. Several examples follow: *“I have been told the benefits to me (to my child or to humanity) are...” “I have been told that because of the experimental nature of this study, it is possible that these benefits may not occur, and that complications and undesirable side effects, which are unknown at this time, including worsening of my condition, may result.”*

- \_\_\_ 8. **PARTICIPANT’S VOLUNTARY PARTICIPATION**  
Describe the voluntary nature of participation, the freedom to withdraw at any time without penalty, and the conditions of termination. Note the following example: “I have been told that refusal to participate in this study will involve no penalties or loss of benefits to which I am entitled and that I may still receive the following established form(s) of treatment.”
- \_\_\_ 9. **ALTERNATIVE TREATMENTS**  
State the appropriate alternative procedures or courses of treatment that might be advantageous or available to the subject (as applicable).
- \_\_\_ 10. **CONFIDENTIALITY AND/OR ANONYMITY**  
Indicate the extent of confidentiality or anonymity that will be maintained. “I have been told that my identity in this study will not be disclosed in any published document.” (As applicable)
- \_\_\_ 11. **ADDITIONAL COSTS**  
State any additional costs to the subject or a third party that may result from participation in the research (as applicable).
- \_\_\_ 12. **REIMBURSEMENT OR COMPENSATION**  
Explain if there will be reimbursement of cost or other inducement. “I have been told that I will be paid the sum of \$\_\_\_ for participating in this study.” If no compensation is to be given this should be stated.
- \_\_\_ 13. **RESEARCH RELATED INJURY**  
For research involving more than minimal risk state:
  - (a) Plan for handling injury
  - (b) Nature of compensation, if any
  - (c) Name, address and phone numbers of persons to contact
- \_\_\_ 14. **ADVISOR OR IMPARTIAL THIRD PARTY CONTACT**  
**Example:** “I have been told that if I wish to contact the researcher’s advisor or an impartial third party not associated with this study regarding any complaint I may have about the study I may contact (name, address, telephone number) for information and assistance. Also, give information on how to contact the investigator.
- \_\_\_ 15. **INFORMED CONSENT**  
There should be opportunity for the subject to ask questions before consenting. “I have read the contents of this consent form and have listened to the verbal explanation given by the investigator. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study (or for my child to participate in

this study). If I have additional questions or concerns, I may contact (investigator’s name, address, telephone number).”

- \_\_\_ 16. **COPY OF CONSENT FORM**  
Each person signing the consent form should be given a copy of that form. “I have been given a copy of this consent form.” If a copy is not given, state this in the consent form.
- \_\_\_ 17. **PREVIOUS RESEARCH PARTICIPATION**  
Use only if needed for your particular study. “I have \_\_\_/have not\_\_\_ participated in any research study in the past three months. My participation occurred on (day/month/year) and involved....”
- \_\_\_ 18. **INPATIENT STUDIES**  
For all inpatient studies, to ensure that patients receive coordinated care, the primary physician must sign and date (usually just below the investigator) this form as an indication that he/she has knowledge of the research study (if applicable).
- \_\_\_ 19. **NUMBERING OF ADDITIONAL PAGES**  
If more than one page is used for the consent form, show the pages numbered as “Page 1 of 3, page 2 of 3, etc.”
- \_\_\_ 20. **PARTICIPANT CONCERNS**  
You need to inform your subjects how they can contact either you or your advisor if they have any questions or concerns regarding their participation in the study.
- \_\_\_ 21. **DATED SIGNATURES**  
Provide a signature and date line for each subject, parent or legal guardian (include relationship), witness, and investigator as applicable.

**Examples:**

1. *Competent Adult Subject:*

_____	_____
Signature of Subject	Date

_____	_____
Witness	Date

2. *Subject is a Minor (Child must also sign if seven years of age or older):*

_____	_____
Signature of Parent or Guardian	Date

_____	_____
Signature of Child	Date

_____	_____
Witness	Date

3. *Subject is not able to sign:*

Subject is not able to sign because \_\_\_\_\_

\_\_\_\_\_

Authorized Signature

Relationship

Date

4. *Signature of Investigator:*

“I have reviewed the contents of this form with the person signing above. I have explained potential risks and benefits of the study.”

\_\_\_\_\_  
Signature of Investigator

\_\_\_\_\_  
Telephone Number

\_\_\_\_\_  
Date



# Andrews University

## *Institutional Review Board*

### ***CHECKLIST FOR REVIEW OF CONSENT FORMS***

[Also Instructions and Information Letters Given to Research Participants]

*{Prior to using this Checklist please review the document Summary of Research Protocol Form Requirements. Then sign this form on the reverse side and attach it to the IRB Application Form}*

<b>Does the consent form (instruction, letter). . . .</b>	<b>Yes</b>	<b>No</b>
1. Make reference to Andrews University in the Heading?	_____	_____
2. Identify in the heading the investigator’s relationship with an academic department of the university?	_____	_____
3. Show in the heading a clearly identified title of the research protocol that describes the type of research to be done?	_____	_____
4. Describe the purpose and procedures of the study in language that is minimally technical and appropriately informs the reader in his/her primary language?	_____	_____
5. Describe the potential benefits of the study to the subject, to the investigator’s discipline and/or to society?	_____	_____
6. Inform the subject of how the data and information collected during the conduct of the research will be used, disseminated and/or published?	_____	_____
7. Describe the location and duration of the subject’s involvement in the research study?	_____	_____
8. Describe the voluntary nature of participation and the subject’s freedom to withdraw at any time without penalty, prejudice, or denial of benefits to which he/she is entitled?	_____	_____

9. Indicate the extent of confidentiality or anonymity that will be maintained and what procedures will be used to safeguard them? \_\_\_\_\_

10. Explain whether there will be any form of payment, reimbursement of costs or other type of inducement for participation in the research? \_\_\_\_\_

**Does the consent form. . . .**

11. State the nature and amount of risk, stress, discomfort, or invasion of privacy, if any, which are anticipated during or as a result of the subject's participation in the study? \_\_\_\_\_

12. Avoid any implication that there is a release of liability for negligence or a waiver of the subject's legal rights? \_\_\_\_\_

13. Record the fact that the subject has had an opportunity to ask questions and receive satisfactory answers before consenting to participate in the study? \_\_\_\_\_

14. Show the name, position, department, mailing address and telephone number where the investigator(s) and advisor may be contacted if the subject has additional questions? \_\_\_\_\_

15. Acknowledge that the subject has received a copy of the consent form? \_\_\_\_\_

16. Provide a signature and date line for each subject, parent or legal guardian, witness and investigator, as applicable? \_\_\_\_\_

The following four items are to be included on the consent form only in those cases where the conditions described apply.

17. Describe any additional costs to the subject as a result of participation in the research (if applicable)? \_\_\_\_\_

18. State (if the research involves treatment or is therapeutic in nature) what appropriate alternative procedures might be advantageous or available to the subject (if applicable). \_\_\_\_\_

19. Include an injury compensation statement if invasive procedures are used or if subject is to be involved in physical activity, etc.? (if applicable) \_\_\_\_\_

20. Provide a list of exclusionary conditions and require the subject to disclose any any prior or existing conditions which would cause him/her to be excluded from the study? (if applicable) \_\_\_\_\_

I have reviewed the consent form for my research protocol based on the above questions. I find that it satisfactorily meets all of the above applicable criteria.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Dated

## APPENDIX D



### SUMMARY OF RESEARCH PROTOCOL AND CONSENT FORM REQUIREMENTS

#### RESEARCH PROTOCOL:

The protocol is a statement of the researcher's responsibilities toward the human subjects involved in the research. Every researcher planning to conduct research involving human subjects is required to submit a protocol describing the research to the **I.R.B.** The research protocol should contain the following elements:

1. A brief description of the purpose, methods, and time frame of the research.
2. A description of the subjects, indicating explicitly whether any are minors (under age 18 by Michigan law) or otherwise members of "vulnerable populations who lack full capacity to give informed consent.
3. A description of how subjects will be recruited and how they will be involved. Criteria for the inclusion/exclusion of subjects.
4. A statement of the benefits of the research to the human subjects, if any, and of the benefits to human or scientific knowledge.
5. A detailed explanation of how the welfare and rights of subjects whose competency is compromised are to be protected, if needed.
6. A description of the risks and discomforts, if any, to the subjects. Such deleterious effects may be physical, psychological, or social. Some research involves neither risks nor discomforts but rather violations of normal expectations. Such violations, if any, should be specified.
7. A description of the means to be taken to minimize each such deleterious effect or violation, including the means by which the subjects' personal privacy is to be protected and confidentiality of information received and maintained.
8. A copy of the consent form that is to be used with the subjects. Sample consent forms are available for review at the Office of Scholarly Research.
9. A copy of a signed permission statement or letter for each off-campus (non-University) site where research data will be collected. If required, a letter of permission from an attending physician/health professional and/or invasive procedure documentation. Approval may be held up until such letters of permission are in hand.
10. Any other information pertaining to the researcher's ethical responsibilities to the subjects.

#### DOCUMENTATION OF INFORMED CONSENT:

Except as provided in sections 4 and 5 below, informed consent shall be documented by the use of a written consent form approved by the **I.R.B.** and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form.

1. **Content of the Written Informed Consent Form.** The full informed consent form must include:

- a. A statement that the activity involves research and a description of where the research activity will occur.
- b. An explanation of the scope, aims, and purposes of the research, and the procedures to be followed (including identification of any treatments or procedures which are experimental) and the nature of the expected duration of the subjects' participation
- c. A description of any reasonably foreseeable benefits, if any, to the subjects or others that may result from the research.
- d. A disclosure of appropriate alternative procedures or courses of treatment (in instances where therapeutic procedures are involved), if any that might be advantageous to the subjects.
- e. A statement describing the extent to which confidentiality of records identifying the subjects will be maintained.
- f. An offer to answer any questions the subjects may have about the research, the subject's rights or related matters, and the name of the person (together with address and telephone number) to whom the subjects may direct questions or report an injury.
- g. A statement that participation is voluntary, that refusal to participate or a decision to discontinue participation at any time after research involvement begins will not involve any penalty or loss of benefit to which the subjects are otherwise entitled.
- h. For research which may involve more than minimal risk of injury the subject should be informed of the following statement which must appear in the consent form (to be modified for off-campus research):

*"In the unlikely event of injury resulting from this research, Andrews University is not able to offer financial compensation nor to absorb the costs of medical treatment. However, assistance will be provided to research subjects in obtaining emergency treatment and professional services that are available to the community generally at nearby facilities. My signature below acknowledges my consent to voluntarily participate in this research project. Such participation does not release the investigator(s), institution(s), sponsor(s) or granting agency(ies) from their professional and ethical responsibility to me."*

- i. A space for the dated signatures of the subject, the principal investigator, and a witness. In the case of a minor (the child must also sign if seven years of age or older) or a person unable to sign, a second authorizing signature is required from the parent, guardian, or other responsible person. The relationship must be specified.

## **2. Format of the Written Informed Consent Form.**

- a. The consent form should clearly identify the researcher's relationship with Andrews University and the name of Andrews University should appear centered at the top of the consent form together with the name of the researcher's department. In cases where an anonymously returned questionnaire substitutes as a form of implied consent (see section 4.b below), the cover letter accompanying the questionnaire should clearly identify that the research is connected with Andrews University.
- b. The consent form should clearly indicate the name, address, and phone number of an individual (the investigator and/or an impartial third party) whom the research subject may contact for additional information.
- c. Places for the dated signatures of the subject (and/or parent/guardian, if applicable), investigator, and witness should be included at the bottom of the consent form.

## **3. Retention of the Signed Consent Form.**

- a. A copy of the consent form should be returned to the subject or the person legally appointed to sign the consent form to retain for his/her review.
- b. The responsibility for retaining signed copies of the consent form lies with the principal investigator(s). These consent forms should be kept in a secure depository along with the researcher's other records for a reasonable amount of time (normally not to exceed three years).

#### 4. **Use of Alternate and/or Simplified Consent Forms.**

Certain situations may justify the use of alternate and/or simplified consent forms. However, in all cases the investigator must demonstrate how the anonymity and/or voluntary participation of the research subject(s) will be maintained.

- a. *Oral Instructions Read to a Group.* In the case of minimal risk research where instructions are read to a group of subjects (e.g. a questionnaire passed out in a classroom setting), a short form to document the oral instructions presented to the subjects may be used. A witness who heard the oral instructions read to the group must co-sign the short form along with the researcher. A written copy of the oral instructions that are to be read to the group must be submitted with the protocol. The items listed in section 1 above should be included in the oral instructions.
- b. *Anonymous Surveys or Questionnaires.* In the case of minimal risk research involving the use of surveys or questionnaires which are distributed individually and returned anonymously, the cover letter explaining the purposes and procedures of the research project may substitute for the consent form. Such a cover letter must be submitted with the protocol and should contain reference to the items mentioned in section 1 above. The anonymous return of the survey or questionnaire serves as a form of implied consent.
- c. *Simple Oral Interviews.* Investigators conducting simple oral interviews, the content of which qualifies as exempt from review (see **Appendix A, Exempt from Full Review**, item 4), may submit an alternate form of documentation in place of an informed consent form. Such documentation should be in the form of a written statement describing how the interviewer will explain his/her research to the interviewee and how the researcher is prepared to insure the interviewee's anonymity and right to refuse participation in the interview.

#### 5. **Waiving of Signed Consent Documentation.**

The **I.R.B.** may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that either of the following conditions exists:

- a. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether he/she wants documentation linking the subject with the research, and the subject's wishes will govern.
- b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

#### 6. **Waiving the Consent Process.**

The **I.R.B.** may under certain special circumstances approve a consent procedure which does not include or which alters some or all of the elements mentioned above or may waive the requirement to obtain consent provided the Board verifies and documents each of the following items:

- a. The research involves no more than minimal risk to the subjects
- b. The waiver or alteration of consent will not adversely affect the rights and welfare of the subjects.
- c. The research could not practicably be carried out without the waiver or alteration.
- d. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

#### 7. **Consent from Attending Physician and/or Other Health Professionals.**

In situations where an individual is currently being treated/evaluated by a physician and/or other health care professional for a condition related to the objective of the research study, the researcher is required to obtain the consent of the physician and/or health care professional prior to involving such research subjects in the study.

[Excerpted from the document *Brief Guidelines for Human Subjects Research*. Consult the entire document for a more detailed explanation]

**APPENDIX  
E**



**REVIEW REQUIREMENTS FOR HUMAN SUBJECT RESEARCH**

The Institutional Review Board (IRB) has been established to monitor all research conducted by faculty, staff, and students at Andrews University. Research involving human subjects should be carried out with a profound sense of the sacredness of the human will and existence, with respect and concern for the dignity and welfare of the people who participate, and with cognizance of federal and state regulations, University policy, and professional standards. The following guidelines should be used to assist researchers in determining at what level they should apply for approval of research involving human subjects which is to be either conducted at or sponsored by Andrews University

Review at each level is based on information submitted on the form available from the  
**Office of Scholarly Research**  
 Entitled  
**APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS**

<i>Type of Research Reviewed</i>	<i>Where Reviewed</i>	<i>Who Makes the Decision</i>
<p>1. <b>EXEMPT RESEARCH</b>                      This includes all research in which <b>only Involvement</b> of human subjects will comply full with criteria for one or more of the exempted categories listed under the <i>Exempt Status Criteria</i> on the reverse side of this document.</p>	<p>First in the department of the Researcher and then by the Office of Scholarly Research.</p>	<p>Responsible faculty investigator/student Advisor in consultation with the Departmental Review Liaison <b>and only then</b> is it submitted to the Office of Scholarly Research where the Graduate Assistant will process it.</p>
<p>2. All non-exempt research which is <i>externally</i> funded, regardless of the level of risk involved.</p>	<p>Central IRB (by full Board)</p>	<p><b>IRB</b></p>
<p>3. All non-exempt research which places subjects at <i>more than</i> minimal risk, regardless of the source of the funds.</p>	<p>Central IRB (by full Board)</p>	<p><b>IRB</b></p>
<p>4. All non-exempt research in departments which do <b>not</b> have IRB—approval guide lines for decentralized review, regardless of the level of risk involved or the source of funds.</p>	<p>Central IRB (by full Board)</p>	<p><b>IRB</b></p>
<p>5. Research which meets <b>all</b> of the following requirements:                      (a) Is undertaken in a department which has IRB—approved guidelines for Decentralized review, and                      (b) Is <b>not</b> externally funded, and</p>	<p>Selected Departments (in IRB—approved departments only)                      —or—                      Sub-committee of 3 IRB</p>	<p><i>Departmental Review Liaison</i> within a department which has received prior IRB—approval for its departmental review procedures governing human subject involvement in research.</p>

(c) Does <b>not</b> place subjects at more than Minimal risk, and (d) Is <b>not</b> otherwise exempt.	members.	—or— Three IRB members selected by the Graduate Assistant in the Office of Scholarly Research.
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## EXEMPT STATUS CRITERIA

### CATEGORIES OF RESEARCH QUALIFYING AS EXEMPT UNDER THE CODE OF FEDERAL REGULATIONS

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as:
  - a. Research on regular and special education instruction categories, (or)
  - b. Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey or interview procedures, or observation of public behavior **UNLESS ALL** of the following conditions exist:
  - a. Responses are recorded in such a manner that the subjects can be identified directly or through identifying links, and—
  - b. The responses, if they become known outside the research, could reasonably place the subject at risk of criminal or civil liability, or be damaging to the subject’s financial standing, employability or reputation.

**NOTE:** *The following types of Category 2 Exemptions do not apply to research where children (minors) are subjects: Survey Research, Interview Research, Observation of Public Behavior in which an investigator is a participant.*

3. Research of the type listed in Category 2 which under the provisions stated above is not exempt from review but which does qualify for exemption if:
  - a. The human subjects are elected or appointed public officials or candidates for public office, or
  - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, and these sources are publicly available, or if the information is recorded by the investigator in such a way that the subjects **CANNOT** be identified directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:
  - a. Public Benefit or Service Programs
  - b. Procedures for obtaining benefits or services under those programs
  - c. Possible changes in or alternatives to those programs or procedures, or
  - d. Possible changes in methods or levels of payment for benefits or services under those programs
6. Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed or 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 FDA or EPA or USDA determination.

**NOTE:** *Even if exempt from full IRB review, all research projects must make provision for compliance with published guidelines for obtaining informed consent and maintaining confidentiality. Some research listed above, if involving prisoners and/or directed toward pregnant women, is not exempt. Check with the Executive Secretary of the IRB for details.*

APPENDIX  
F



**Institutional Review Board**

**GUIDELINES FOR INVASIVE PROCEDURES**

1. **Basic Qualifications for Individuals Performing Invasive Procedures:**

- a. Credentials/License for Procedure Involved  
—or—
- b. Supervised Work Experience Doing Procedure (3 months minimum)  
—or—
- c. Graduate Training in Procedure Involved

2. **Documentation of Activity Involved:**

- a. The name and qualification of all participants (other than those involved in clerical activity) in the procedure *must be submitted with* the I.R.B. application form.
- b. The dates when the procedure will be conducted and the sites where the activity will be conducted *must be submitted with* the application.

3. **Situations Which Require the Termination of the Activity and Require that a Report of Such Termination be Submitted:**

- a. In the event of a procedure-related injury to any participant, the activity should be terminated.
- b. The university physician should be notified immediately of such an occurrence and a written report should be submitted to the chair of the I.R.B.