BRIEF GUIDELINES

FOR INSTITUTIONAL REVIEW BOARD

SOUTHWESTERN ADVENTIST UNIVERSITY

INTRODUCTION

Research is a key means by which understanding and the body of knowledge grow. Research, in fact, is a vital dimension of the mission of the educational process. It must be an integral part, then, of the mission of any university. Southwestern Adventist University strongly supports that mission and seeks to create a climate, through specific policies and procedures, designed, not only to stimulate research, but to create and maintain a system of ethics in which the human subjects of research are carefully protected.

The research policies and procedures in this document are patterned after 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 and Research Risks (OPRR) "Protection of Human Subjects" (*Code of Federal Regulations*, 45 CFR 46, March, 1983). These two documents provide the framework used in crafting Southwestern Adventist University's policies which are designed to:

1. Support the value of research
2. Give heed to the sanctity of human life
3. Provide a safeguard for basic human rights
4. Provide a learning opportunity

(Note: This document has been edited to represent the basic concepts and requirements to which we must give particular attention in Human Subjects 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 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 must guide research involving human subjects:

1. Research involving competent human subjects requires the person's **voluntary** and **informed** consent.
2. Special consideration and protection for subjects must be given in research involving persons who may lack full capacity to secure their own rights and interests, e.g. children, the elderly, the mentally challenged, the economically or educationally disadvantaged, and those who are in involuntary custody.
3. No person can be placed at risk as a research subject unless the risks are reasonable in relation to the anticipated benefits of the research.

4. The recruitment and selection of subjects must be reasonably related to the research and not impose inequitable risks and burdens on any segment of society.

B. INSTITUTIONAL REVIEW BOARD OF SOUTHWESTERN ADVENTIST UNIVERSITY

The Institutional Review Board (IRB) has been established to monitor all research involving human subjects, conducted by faculty, by staff, and by students at Southwestern Adventist University. The IRB 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 a minimum of faculty members, administrators, and off-campus professionals from a variety of disciplines.

C. AUTHORIZATION TO CONDUCT HUMAN RESEARCH

In both faculty and student research, involving human subjects, whether subject-risk is a possibility or not, **collection of data may not begin until WRITTEN APPROVAL has been given by the IRB**. The IRB has the authority to suspend or terminate research which does not meet its policies.

Students who engage in human-subjects research sponsored by non-university organizations and **for which the students so involved will register to receive Southwestern Adventist University credit** are expected to have the research **cleared in advance** by the IRB.

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 IRB chairperson, **both in writing**, as soon as possible, within 7 days of the injury.

The University physician has the authority in such cases to suspend the research project temporarily, until determination can be made concerning continuation. Consultation between the physician and the IRB chairperson (and other members, as necessary) will occur before a decision is made on continuation, revision of protocol, or termination of research. Any work with human subjects may resume only upon written authorization by the IRB chairperson. **The decision will be made, and response issued, within 14 days.**

D. APPLICATION PROCEDURE TO CONDUCT HUMAN SUBJECT RESEARCH

To apply for approval of research involving human subjects, the principal investigator must submit to the IRB (Institutional Review Board) – through the chairperson of the IRB – the following documents:

1. An ***Application for Approval of Research Involving Human Subjects***. (FORM A) Forms are available in the office of the chair of the IRB and on-line at

2. ONE of the following Research Protocol Documents:

   a. A ***Brief Research Protocol***. (FORM B) (Forms are available on-line at This document is to be used by students only 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.

   b. A ***Human Subjects Research Protocol***. (FORM C)

      Those individuals conducting research involving human subjects, either on or off-campus – whether faculty or students whose situations are not covered above or are planning to conduct thesis/dissertation research – are expected to submit protocols that address issues covered in Appendix C.

   c. A ***Thesis/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 required in the ***Brief Research Protocol*** or ***Human Subjects Research Protocol***. (FORMS B or C)

3. An ***Informed Consent Document***. (FORMS D,D1,D2,D3)

   For ethical and legal reasons, this document **must** receive particularly-careful attention.

4. Include any additional documentation that may be necessary to properly conduct the research, such as:

   a. A Cover-Letter of Explanation
   b. Questionnaires and other Instruments
   c. A Written Copy of Verbal Instructions
   d. Letters of Permission

E. HSRB REVIEW PROCESS

Please Note: The National Commission for the Protection of Human Subjects in Biomedical Research and the National Institutes of Health's Office of Protection and Research Risks have designated three categories of eligibility: (1) Exempt from Review, (2) Expedited Review, and (3) Full Review. (The IRB is opting for two categories by combining (2) and (3).)

1. **STEP 1** - The chairperson of the IRB will make an initial evaluation of the proposal and assign it to one of two (see explanation above) categories:

   a. **Exempt from Review** (FORM E)

      Studies which involve **no risk** to the subjects

      Protocols submitted under this category are screened by the chairperson of the IRB or a designee. If all application materials are complete and, if found to qualify as **"no risk"** research, these protocols will be approved without further review. Such protocols will receive a written response within five (5) working days.

   b. **Expedited and Full Review** (FORM F)

      All studies involving some risk to the subjects, even if the risk is minimal, or do not meet the criteria for Exempt-from-Review category.

      Such protocols will be reviewed by the entire IRB-in-session, and must receive approval of the IRB. Actions taken regarding such protocols may include one of the following four (4):

      (1) Full Approval
      (2) Conditional Approval (With monitoring of compliance and any needed revisions.)
      (3) Request for resubmission (With suggestions for modification)
      (4) Full Disapproval

      Protocols requiring Expedited and Full Review will take up to thirty (30) days for written approval by the IRB. (NOTE: Written approval for student-projects will be granted within fifteen (15) days.)

2. **STEP 2** - The chairperson of the IRB will notify the principal investigator and faculty advisor, in writing, of the decision regarding the protocol – within 30 days of the initial filing of the proposal.

   RESEARCH INVOLVING HUMAN SUBJECTS CANNOT COMMENCE UNTIL WRITTEN NOTIFICATION HAS BEEN RECEIVED.

3. **STEP 3** - IRB-approval is valid for one calendar-year. In the event that the investigator wishes to continue the research for a longer period of time, a request for an extension of approval must be submitted, no less than 30 days before the expiration date, to the IRB.

FORMS

FORM A Application for Approval of Research Involving Human Subjects

FORM B Brief Research Protocol

FORM C Human Subjects Research Protocol

FORM D Informed Consent

FORM D1 Documentation of Informed Consent

FORM D2 Preparing an Informed Consent Document
(Guidelines for Written Consent Forms)

FORM D3 Checklist for Review of Consent Forms

FORM E Eligible for Exempt Review

FORM F Eligible for Expedited/Full Review

SOUTHWESTERN ADVENTIST UNIVERSITY
INSTITUTIONAL REVIEW BOARD

FORM A

APPLICATION FOR APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

Instructions: Use this form as a cover-sheet and attach it to the following items: (1) The Appropriate *Research Protocol*, (2) An *Informed Consent Form*, (3) Additional Documentation, as needed – i.e. Cover Letter of Explanation, Sample Questionnaire, Written Copy of Verbal Instructions, and/or Letters of Permission. Please submit 2 full sets of the document (NOTE: For Expedited/Full Review, 6 copies are necessary.) to:

Chair, Institutional Review Board, Southwestern Adventist University, Keene, TX 76059
SWAU FAX Number (817 556-4744)
On-Campus Address: Findley Administration Building 100

SUGGESTED CATEGORY OF IRB REVEIEW:

The investigator(s) should read, carefully, the Brief Guidelines for Human Subjects Research and discuss with the research-advisor and/or the department chairperson, the relationship of the present research project to the policies and procedures contained in the above document. After this consultation, the investigator(s) need(s) to request that the research be considered by the Institutional Review Board (IRB) under one of the two categories listed below. Final assignment of the review category is made by the GSRB. The timeline of Board action is also noted.

_____Exempt from Review (5 working days)_____Expedited/Full Review (15-30 days)

DESCRIPTION OF RESEARCH PROJECT:

Project Title_____

Projected Date of Project Completion_____

Location Where Subject-Related Involvement Will Occur_____

_____

Application – page 2
SUPPORTING SIGNATURES:

"I have reviewed the above project with the investigator(s) and concur on the requested category of HSRB review."

(Name of Advisor, if student project)	(Signature of Supervising Advisor)	Date

"This project has been reviewed for research merit and has the academic endorsement of this department."

(Academic Department of Investigator)	(Signature of Department Chairperson)	Date

AGREEMENT OF INVESTIGATOR(S):

"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 only after written notification of its approval has been received.** Furthermore, I (We) agree that in cases involving research to be conducted at a non-SWAU site, such research will commence only after written authorization from an officer of the organization at each site involved has been filed with Institutional Research. Notification of any alterations in the attached protocol will be submitted to the Chairperson of the HSRB."

(Name of Principal Investigator)	(Signature of Principal Investigator)	Date

ANY ADDITIONAL INVESTIGATORS:

1. (Name of Coinvestigator) Print	(Signature of Coinvestigator)	Date
2. (Name of Coinvestigator) Print	(Signature of Coinvestigator)	Date
3. (Name of Coinvestigator) Print	(Signature of Coinvestigator)	Date
4.		

COMMENTS YOU MIGHT CONSIDER USEFUL TO THE HSRB:

ABSTRACT: In 100 words, or less, please provide a typed brief description of your research project.

SOUTHWESTERN ADVENTIST UNIVERSITY
INSTITUIONAL REVIEW BOARD

FORM B

BRIEF RESEARCH PROTOCOL
For use in Supervised Class Research Projects*

*Only students enrolled in research or methodology classes in which students are under the direct supervision of an instructor may consider using this data-collection or pilot studies may submit abbreviated protocols using this form. All other proposals (master's projects, theses, dissertations, and faculty research) require the submission of a complete protocol, as described within the document entitled Brief Guidelines for Human Subjects Research.

Name of Student_____

Advisor Signature_____ Date_____

Course #_____Course Title_____

INSTRUCTIONS:

1. Read the policies section of the Institutional Review Board (IRB), as outlined in the *Brief Guidelines* document. This document is available from the chair of the IRB or on-line at…..

2. TYPE responses to each of the items below, in the spaces provided, or attach extra printed pages.

3. Prepare any additional required documentation such as an *Informed Consent Form*, a typewritten copy of *Verbal Instructions*, a *Cover Letter with Instructions*, and/or *Letters of Permission*.

4. Complete an *Application for Approval of Research involving Human Subjects* form and have it signed by your instructor and by your department chairperson.

5. Attach the *Application* as a cover page to this document, along with any other supporting documents and submit to the chair of the IRB.

ITEMS REQUIRING A RESPONSE for **BRIEF RESEARCH PROTOCOL:**

1. Brief description of the purpose (the problem statement or hypothesis), the method, and the time-frame of the proposed research.

2. Description of how the research will benefit human subjects, as well as human and/or scientific knowledge.

3. Description as to how the subjects will be involved in the study and for how long.

4. Description of the subjects. (Give the number of subjects involved and list the criteria used in making the decision regarding their inclusion/exclusion. Indicate whether "minors" (under age 18) or other vulnerable populations will be involved.

5. If applicable, explain how the welfare and rights of minors or others with restricted competency to give informed-consent are to be protected.

6. Description of the risks and discomforts, if any, to the subjects.

7. Description of how personal privacy is to be protected and how confidentiality is to be maintained. **You must be specific.**

8. The subjects must be aware that their participation in the study is **completely voluntary** and that refusal to participate or complete the study will not have negative consequences to them. Explain, here, how the idea of "voluntary participation" is conveyed to the subjects. You must include information as to how you will deal with communication barriers -- the deaf, the blind, those with language barriers, and those with limited ability to understand your intent. (Submit a copy of the *Informed Consent Form*, or a copy of the *Letter of Instructions* for surveys distributed individually, or a *Written Copy of Verbal Instructions* which will be used in interview or classroom settings.

9. Description of information regarding the researcher's ethical responsibility to the subjects.

10. If off-campus sites (hospitals, schools, etc.) are to be used for data-collection, please attach letters of permission from an appropriate authority, at these sites, authorizing research.

SOUTHWESTERN ADVENTIST UNIVERSITY
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FORM C

Human Subjects Research Protocol
(Expedited/Full Review Requests)

The research protocol needs to contain each of 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) or otherwise are members of "vulnerable" populations who lack the full capacity to give informed consent, whether because of communication barriers or some lack of ability to understand or to be understood.

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 must 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 subject's personal privacy is to be protected and confidentiality of information is received and 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 D3.)

9. A copy of a signed permission-statement or letter for each off-campus site where research data will be collected regarding staff, clients, students, etc.. Approval will depend upon having such letters or permission-statements in the possession of the IRB.

10. Information as to the investigator's ethical responsibilities to the subjects.

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FORM D
Informed Consent

FORM D1
Documentation of Informed Consent

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

1. Required Content of the Written Informed Consent Document:

    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 subject's participation.

    c. A description of any reasonably foreseeable benefits, if any, to the subjects or others, which 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 subject(s).

    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 involves no penalty nor loss of benefit to which the subjects are otherwise entitled, and that the subjects may discontinue participation at any time without penalty of loss to which the subjects are otherwise entitled.

h. For research which may involve more than minimal risk of injury, the subject needs to be informed of the following statement, which must appear in the consent form:
(Statement is to be modified for off-campus research.)

"I understand that in the unlikely event of injury resulting from research procedures, Southwestern Adventist University, its agents, and its employees will assume whatever responsibility is required by law. Emergency medical treatment for injuries or illness is available in instances where the injury or illness is incurred in the course of an experiment."

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 person responsible for the subject. The relationship must be specified. In the event of a subject with whom there is a communication barrier—blind, deaf, language, inability to understand—there must be a means of obtaining appropriate signatures that assures the complete understanding on the part of that subject regarding the implication of participation.

2. Format of the Written Consent Form

a. The consent form should be either printed on a Southwestern Adventist University letterhead or, alternatively, the name of Southwestern Adventist University should be centered at the top of the consent form, together with the name of the investigator'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 to Southwestern Adventist University.

b. The consent form should clearly indicate the name, address, and telephone 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 must be returned to the subject or the person legally appointed to sign the consent form, to retain in her/his review and records.

    b. The responsibility for retaining signed copies of the consent form lies with the principal investigator(s). The consent forms must be kept in a secure depository, along with the investigator's other records for a reasonable period of time (normally, not to exceed three years from the date of project completion).

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 Presented (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 distributed 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 investigator. A written copy of the oral instructions which are to be read to the group must be submitted with the protocol. The items-list in Section 1, above, need to 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 FORM E, 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 the survey instruments in the classroom setting is not appropriate. Alternative methods of collecting forms completed at the discretion of the respondent, and which thus ensure the respondent's anonymity, should be employed.

    b. Anonymous Surveys or Questionnaires. In the case of research with no risk or minimal risk, 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. The cover-letter must be submitted with the protocol and must contain reference to the items mentioned in Section 1, above. The investigator must 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 e, Exempt Review, item 4), may submit an alternate form of written documentation in place of a consent form. Such documentation should describe how the interviewer will explain his/her research to the interviewee and how the investigator is prepared to ensure the interviewee's anonymity and the right to refuse participation in the interview.

5. Waiving of Signed Consent Documentation

The IRB 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 the subject wants documentation linking the subject with the research. 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 IRB may, under certain special circumstances, approve a consent-procedure which does not include nor which alters some or all of the elements mentioned above or may waive the requirement to obtain consent provided the IRB verifies and documents each of the following items:

a. The research involves no 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.

FORM D (continued) - **Informed Consent**

FORM D2
Preparing an Informed Consent Document
(Guidelines for Written Consent Forms)

Please check, as each item is completed:

☐ 1. UNIVERSITY HEADING
Type consent form on a Southwestern Adventist University letterhead or include Southwestern Adventist University and the name of the Department in the heading on the form.

☐ 2. CLEAR TITLE OF PROTOCOL
Keep the title simple and retain the same title in the consent form.

☐ 3. SIMPLIFIED LANGUAGE
Avoid technical jargon, using 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 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. PURPOSES 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 subject's participation.
d. Give a description of the location and procedures to be followed.
e. Identify any procedures which are experimental.

☐ 6. RISKS EXPLAINED
State the nature and degree of any reasonably foreseeable (or potential) risks, stress, discomfort, or invasion of 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 subject'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. PARTICIPANTS’ 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 nor 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. (If 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.” (If applicable)

☐ 11. ADDITIONAL COSTS

State any additional costs to the subject or a third party that may result from participation in the research.

☐ 12. REIMBURSEMENT OR COMPENSATION

Explain if there will be a reimbursement of costs 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 the following:

a. Plan for handling injury.
b. Nature of compensation, if any.
c. Name, address, and telephone numbers of persons to be contacted.

☐ 14. IMPARTIAL THIRD-PARTY CONTRACT

Example: “I have been told that if I wish to contact 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.” Or, give information on how to contact the investigator.

☐ 15. INFORMED CONSENT

Opportunities for the subject to ask questions must be given before subject-consent is granted. For instance, "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)."

☐ 16. COPY OF CONSENT FORM

Each person signing the consent form must be given a copy of that form. For example, "I have been given a copy of this consent form." If a copy is not given, state this in the actual 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 in (day/month/year) and involved . . .".

☐ 18. DATED SIGNATURES

Provide a signature and date-line for each subject, parent, or legal guardian (include relationship), witness, and investigator, as applicable.

Examples:

a. Competent Adult Subject

_____ _____
Signature of Subject Date

_____ _____
Witness Date

b. Subject is a Minor (Child must also sign if aged 7 years or older.)

_____ _____
Signature of Parent or Guardian Date

_____ _____
Signature of Child Subject Date

_____ _____
Witness Date

c. Subject is **NOT** able to sign.

Subject is unable to sign because_____

_____

_____ _____
Authorized Signature Date

_____
Telephone Number

d. Signature of Investigator

"I have reviewed the contents of this form with the person(s) signing above. I have explained potential risks and benefits of the study."

_____ _____
Signature of Investigator Date

_____
Investigator's Telephone #

____19. 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 she/he has knowledge of the research study.

____20. NUMBERING OF ADDITIONAL PAGES
If more than one page is used for the consent form, show pages numbered as "Page 1 of 3, Page 2 of 3, etc."

FORM D (continued) - **Informed Consent**

FORM D3
Checklist for Review of Consent Forms

Does the Consent form . . .	Yes	No
1. Include Southwestern Adventist University in the heading of the form?	☐	☐
2. Show clear title of the research protocol?	☐	☐
3. Use language that is minimally technical and appropriate to the reader in his/her primary language?	☐	☐
4. Describe the purpose, procedures, and duration of the study?	☐	☐
5. State the nature and amount of risk, stress, discomfort, or invasion of privacy?	☐	☐
6. Describe the potential benefits of the study to the subject and/or to humanity?	☐	☐
7. Describe the voluntary nature of participation and the freedom to withdraw at any time without penalty	☐	☐
8. State the appropriate alternative procedures that might be advantageous or available to the subject? (if applicable)	☐	☐
9. Indicate the extent of confidentiality or anonymity that will be maintained?	☐	☐
10. Describe additional costs, if any, to the subject as a result of participation?	☐	☐
11. Explain whether there will be reimbursement of costs or other inducement?	☐	☐
12. Include an injury compensation statement? (if applicable)	☐	☐
13. Allow the opportunity for the subject to ask questions before consenting and show the name, address, position, department, and phone number whereby the investigator(s) may be contacted if subject has further questions?	☐	☐
14. Acknowledge the subject's receipt of a copy of the consent form?	☐	☐
15. Provide a signature and date-line for each subject, parent, or legal guardian, and investigator, as applicable?	☐	☐

16. Avoid any implication that there is a liability release for negligence or waiver of subject's legal rights? ☐ ☐

SOUTHWESTERN ADVENTIST UNIVERSITY
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FORM E
Eligible for Exempt 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 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.

4. Research involving survey or interview procedures and research involving the observation of public behavior (including observation by an investigator who is also a participant in such behavior). Exceptions are noted below. (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.)

   Exceptions: Research described in section 4, above, shall **NOT** be eligible for inclusion in the exempt review category in situations where the following conditions exist:

   a. Responses are recorded in such a manner that the human subjects con be identified, directly or through identifiers linked to the subjects, and the subjects' responses, if they became known outside the research, could reasonably place 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 abuse, 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.

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FORM F
Eligible for Expedited/Full Review

1. Studies which, under full review, have previously been granted conditional approval if specific minor conditions are met, or where minor changes in procedures not affecting risk are proposed.

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

3. Collection of excreta and external secretions, including sweat, ungranulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

4. 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, thermography, electroencephalography, detection of "naturally-occurring" radioactivity, diagnostic echography, electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (e.g. x-rays, microwaves.)

5. 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.

6. 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.

7. Voice-recordings made for research purposes, such as investigations of speech defects.

8. Moderate exercise by healthy volunteers.

9. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

10. Research on individual or group behavior of 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 the subjects.