

# Augsburg College Institutional Review Board

## Full, Expedited, and Exempt Reviews

### Application Information

### Social and Behavioral Sciences

**APPLICATION INFORMATION** (pp. i - viii).  
Detach for your records. Do not submit these pages.

**NOTICE:**

**You must submit this application in the same page format as shown in this file. DO NOT** change the location of questions and pagination.

**If you need more space to answer any particular question, attach an additional sheet to the page where more space was needed. [For example, if your "lay summary" (Question 14 on page 4) requires more than one page, attach an additional sheet and number it "4A." ]**

**APPLICATION** - Social and Behavioral Sciences (pp. 1-8) - **Must be submitted in hard copy:**

For Full IRB review: submit one original and *ten (10) copies*;

For Expedited Review: submit one original and *two (2) copies*;

For Exempt (Chair only) review: submit one original and one copy.

Applications may be sent by mail addressed to:

Augsburg College Institutional Review Board  
c/o Norma Noonan, Ph.D., chair  
2211 Riverside Avenue, Campus Box 107  
Minneapolis MN 55454-1351

Telephone: 612-330-1198

Hand-delivered applications should be brought to Memorial 111 (the social science office).

Applications may not be sent by electronic mail or facsimile because the IRB original application requires original signatures of the applicant, advisor, and/or department chair and because email is not a confidential communications medium.



# Augsburg College Institutional Review Board

## Application Information

### Social and Behavioral Sciences

The ultimate responsibility for treatment of human research subjects rests with the researcher and with Augsburg College. The Augsburg College IRB exists as a safeguard to promote ethical and responsible treatment of subjects. Augsburg College and federal policies require that each project involving studies with human subjects be reviewed to consider:

- 1) The rights and welfare of the subjects involved,
- 2) The appropriateness of methods used to secure informed consent, and
- 3) The balance of risks and potential benefits of the investigation.

In conformity with Federal Regulations and Augsburg policy, there are three separate avenues (see below) for review of research involving human subjects. All three use this form.

- A. **Full IRB Review.** Research involving more than minimal risk to the subject requires review by the full IRB using risk/benefit analysis. Research using children or vulnerable populations requires review by the full IRB.
- B. **Expedited Review.** Research involving no more than minimal risk and in which the only involvement of subjects will be in one or more of the categories defined by Federal Policy 46.110 requires review by the chair and selected members of the IRB. See page ii for eligibility criteria.
- C. **Exempt Review.** Research of minimal or no risk as defined by Federal Policy 46.101b requires review by the IRB chair only. See pages ii-iii for eligibility criteria.

The following types of activities are not intended to fall under IRB review: Non-intrusive observation of subjects in public settings; data-gathering from class members solely for classroom purposes; and needs assessment or evaluation data intended to remain within the Augsburg community.

See Elements of Informed Consent for Social and Behavioral Science on pages v-vi and Sample Consent Form on pages vii-viii.

The final determination of level for review is made by the Chair of the IRB in conjunction with the IRB. Allow four weeks for review. No research may be initiated prior to formal written approval from the IRB.

Completed, *typewritten* forms should be returned to:

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c/o Norma Noonan, Ph.D., chair  
2211 Riverside Avenue, Campus Box 107  
Minneapolis MN 55454-1351

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**Detach instruction pages i through vii and retain them for your files.**

**Please note: All written documents submitted to the IRB must display college-level writing proficiency. Please attend carefully to grammar, spelling, and punctuation. Poorly written essays and inadequately organized applications will be rejected.**

# Augsburg College Institutional Review Board

## Application Information

### Social and Behavioral Sciences

#### **EXEMPT REVIEW CATEGORIES**

(Federal Policy 46.101b)

**THE FOLLOWING CATEGORIES ARE EXEMPT FROM FULL IRB REVIEW, BUT MUST BE REVIEWED BY THE CHAIR OF THE IRB.** The category number preceding each description is the number to claim on question number 13 on the application form.

#### 1. INSTRUCTIONAL STRATEGIES IN EDUCATIONAL SETTINGS

Research conducted in established or commonly accepted educational settings are exempt from full IRB review if they involve normal educational practices such as:

- i) research on regular and special educational instructional strategies, or
- ii) Research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

- [This category may be applied to research involving children. All other research on children requires full review.]

#### 2. SURVEYS/INTERVIEWS; STANDARDIZED EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, are exempt from full IRB review if:

- i) Information obtained is recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects, and
- ii) disclosure of the human subjects' responses outside the research could not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subject's financial standing, employability, or reputation.

- Surveys or interviews on sensitive or personal topics which may cause stress to study participants are not exempt from IRB review.

- Surveys or interviews with children are not exempt.

- iii.) Needs assessment or evaluation data intended to remain within the Augsburg community and not circulated on the website, in written documents, or in public presentations.

#### 3. PUBLIC OFFICIALS; SURVEYS/INTERVIEWS; EDUCATIONAL TESTS; OBSERVATION OF PUBLIC BEHAVIOR

Research involving the use of educational tests (cognitive, diagnostic, aptitude achievement), survey procedures, interview procedures, or observation of public behavior if:

- i) the human subjects are elected officials or candidates for public office; or
- ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.



#### 4. EXISTING DATA; RECORDS REVIEW; PATHOLOGICAL SPECIMENS

Research involving the collection or study of existing data, documents, records, and pathological specimens are exempt from full IRB review, if these sources are publicly available or if the information is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

- [Records considered private based on federal and state statute, including medical records and education records, require written release by the study subject or by the custodian of the record. Researchers are cautioned that review of private records involving access to and/or recording of identifiable information is not exempt from IRB review and requires written consent of the study subject. Existing public records do not require prior consent of subjects to review the records.]
- [Pathological or diagnostic specimens which are considered waste and are destined to be destroyed can be used in research and are considered exempt from IRB review if there are no patient identifiers linked to the specimen and if the data are not intended to be used in the diagnosis or treatment of a patient. (If either of these conditions apply, consent of the research subject is required and a higher level of IRB review is required.) Specimens retrieved as extra during a clinical procedure require review at a higher level and require written consent from the subject.]
- [Inclusion of fetal tissue in the pathological specimens category of exempt research is prohibited by regulation.]

#### 5. PUBLIC SERVICE PROGRAMS; DEMONSTRATION PROJECTS

Research and demonstration projects are exempt from full IRB review if they are conducted by, or subject to, the approval of department or agency heads, and which are designed to study, evaluate or otherwise examine:

- i) public benefit or service programs;
- ii) procedures for obtaining benefits or services under those programs;
- iii) possible changes in, or alternatives to, those programs or procedures; or
- iv) possible changes in the methods or levels of payment for benefits or services under those programs.

#### 6. TASTE TESTING AND FOOD QUALITY EVALUATION

Taste and food quality evaluation and consumer acceptance studies:

- i) if wholesome foods without additives are consumed (all food tested must be GRAS, or Generally Recognized As Safe); or
  - ii) 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 the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety Inspection Service or the U.S. Department of Agriculture.
- [This category may be applied to research involving children; however, written parental consent to include children in taste testing studies is required.]

# Augsburg College Institutional Review Board

## Application Information

### Social and Behavioral Sciences

#### **EXPEDITED REVIEW CATEGORIES**

(Federal Policy 46.110)

**RESEARCH IN THE FOLLOWING (MINIMAL RISK) CATEGORIES ARE ELIGIBLE FOR APPROVAL ON THE BASIS OF A REVIEW BY THE IRB CHAIR AND SELECTED IRB MEMBERS.**

The category number preceding each description is the number to claim on question 12 on the application form.

1. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth, and permanent 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 non-invasive 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 electromagnetic radiation outside the visible range (e.g., X-rays and microwaves).
4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8-week period and no more than two times a week, from subjects 18 years of age or older and who are not pregnant.
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 investigation of speech defects.
7. Moderate exercise by health volunteers.
8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens (e.g. where identifiers could link data to particular subjects).
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.

# Elements of Informed Consent, Requirements and Guidelines for Consent Forms

Informed consent is a process of communicating to the subject the purpose, risks, benefits, and voluntary nature of a specific study.

The consent form documents that the communication process took place. The consent form must contain all of the required “elements” of informed consent. The “sample consent form” should be used as a guide for writing a consent form. Rules and regulations are subject to change and revision. Standards for consent documents change over time. The investigator should be prepared to revise and update consent forms at the request of the Institutional Review Board (IRB).

The consent form should be written in lay terms; jargon and technical language should be avoided. If that language cannot be avoided, the terms should be defined parenthetically so that subjects can make an informed decision. The IRB recommends that researchers write the consent forms using simple declarative sentences, avoid technical language and have the final draft of the consent form reviewed by a person unfamiliar with the research to test for comprehension, prior to submitting it for review. Foreign language versions should be prepared for research with subjects whose English is limited.

## **Elements of Informed consent that must appear in the consent form:** (Federal Policy 46.116-111)

1. A statement that this is research, an explanation of the purpose of the research and the expected duration of the subject’s participation, (including an estimate of the total amount of the subjects’ time involved in participation ), a description of the procedures to be followed, and identification of any procedures which are experimental. The reason for the subjects’ selection must be included.
2. A description of any reasonably foreseeable risks or discomforts to the subject (including psychological risks such as stress, invasion of privacy etc.). If there is potential for the research causing emotional or psychological distress to the participants, prior arrangements must be made by the researcher for follow-up referral. This may not be the researcher. The name of the person/agency with phone number must be given on the informed consent instrument. If there will be a cost for the referral service, the subject must be informed of this.
3. A description of any benefits to the subject or others which may reasonably be expected from the research. If there is no benefit to participation to the individual subject, an honest declaration of that fact must be included in the text of the context form.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject. If any standard treatment is withheld as a result of participation, the subject must be informed.
5. An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights. A name and telephone number should be included. The researcher should not include a home phone number in communications with the subjects of the research. (If the researcher is a student, the advisor’s name and telephone number must be included on the form.)
6. A statement that participation is voluntary, the subject may refuse to participate, and may discontinue participation at any time without penalty or loss of benefits to which he/she is otherwise entitled. The consequences of a subject’s decision to withdraw from the research, if any, and procedures for an orderly termination of participation by the subject, should be included. Generally, use of friends, co-workers or clients makes voluntary participation impossible.
7. A statement describing the extent to which confidentiality of records identifying the subject will be maintained. If data obtained will be made available to any person or organization other than the subject, the investigator, and the investigator’s staff, or become part of a permanent record maintained in the subject’s name, the purposes of the disclosure, and the nature of the information to be furnished must be described. If audio or video tape recording, photographs, or movies will be taken, they should be described. The duration of time they will be retained before erasure or destruction should be specified. Use of such data for other purposes, including educational purposes, must be disclosed and permission obtained in a special portion of the consent form. Video or audio recording also requires separate consent in a special portion of the consent form.
8. An offer to the subject of a copy of the consent form.

9. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent, i.e., when in the investigator's opinion, it would be detrimental to the subject to continue.
10. Space for signature and date. (If applicable there should be a separate signature for permission to video-tape or audio-tape interviews.)
11. Space provided to document oral or written consent of minors. Parental consent for minors is required. However, the minor must also consent in writing if possible. If the child cannot provide written consent, oral consent is sufficient but must be documented by a witness whose signature is obtained. Mere failure to object should not be construed as consent.
12. If a subject will receive compensation or if there is an inducement or reward for participation, specific information concerning the terms of disbursement must be clearly described on the consent form, including consequences of subjects early withdrawal.
13. If there is the possibility of injury as a result of the research, information as to the medical treatment and compensation available should be included. (Note: if the research involves any invasive procedures, a "Health and Biological Sciences" application for approval form should be completed in lieu of the "Social Sciences Form.")
14. If consent is to be assumed by return of the survey instrument, this must be stated and the letter of introduction (cover letter) must contain all of the requirements of informed consent. If direct quotations will be used, this must be stated.

**Tips for completing consent form:**

- Write the form in second person "You", e.g., "You are invited to participate in a research project conducted by ". Avoid language like "you have been told..." or "you understand..." Numerous language and coercion pitfalls result when using those phrases;
- define or explain research terms such as "randomization" (like "the flip of a coin"), "double-blind" ("neither the researcher or the subject will know");
- quantities for blood drawing should be listed in lay term equivalents, not milliliters (teaspoon equivalents);
- headings for paragraphs are helpful and make the form easier to read;
- typeface should be a comfortable-readable size; avoid fine print. The form may not fit on to one page, additional pages are acceptable as long as they are essential.

**The sample consent form included in this packet (pages vii-viii) should be used as a guide for writing the consent form.**

*Note: All of the specific elements of this sample form represent crucial pieces in establishing informed consent. Use all relevant elements of this model form in your form. Please remove sentences that do not apply.*

**SAMPLE CONSENT FORM**  
[Insert Title of Study and "Consent Form"]

You are invited to be in a research study of [insert general statement about study]. You were selected as a possible participant because [explain how subject was identified]. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by: [Indicate College affiliation, e.g., "This study is being conducted by me as part of my master's project in Social Work/Leadership/Physicians Assistant Studies/Nursing, etc. at Augsburg College"]. My advisor is [insert name and title].

**Background Information:**

The purpose of this study is: [Explain research questions and purpose in lay language.].

**Procedures:**

If you agree to be in this study, we would ask you to do the following things. [Explain tasks and procedures; subjects should be told about assignment to study groups, length of time for participation, frequency of procedures, etc.] Explain fully.}

**Risks and Benefits of Being in the Study:**

The study has several risks: First, \_\_\_\_\_; Second, \_\_\_\_\_. [Risk must be explained, including the likelihood of the risk.]

[If there are significant physical or psychological risks to participation, the subject should be told under what conditions the researcher will terminate the study.]

The direct benefits to participation are: \_\_\_\_\_ [If no direct benefit (money, credit, etc.), state that fact here.]

[If applicable] You will receive payment at the start of the interview/focus group: \_\_\_\_\_ [Include payment or reimbursement information here. If subjects receive class points or some other token, also include that information here. Explain when disbursement will occur and conditions of payment **All rewards have to be given at the outset.**]

Indirect benefits to participation are \_\_\_\_\_ [Explain how subjects might benefit--e.g. Improved programs or policies; **possible** contribution to knowledge, etc.]

[If there is a physically invasive procedure exercise component to this research, or a sensitive personal issue where there is even a slight risk of injury, the following statement must be included in the consent form].

In the event that this research activity results in an injury, **a referral to** treatment will be available, including first aid, emergency treatment, counseling, and follow-up care as needed. However, payment for any such treatment must be provided by you or your third party payer, if any, (such as health insurance, Medicare, etc.). If there are psychological risks, provide a referral source (name of agency/organization, telephone number, and, if appropriate, contact person).

[Omit this section if there are no physical or psychological risks involved in a particular study objective.]

**Confidentiality:**

The records of this study will be kept confidential. {**indicate if and where you will present the results, such as a conference, symposium, colloquium, etc. If a thesis or project, indicate whether a copy will be in the library** If I publish any type of report (**if a thesis or project, you should say, if I publish any other kind of report**), I will not include any information that will make it possible to identify you. All data will be kept in a locked file [state where]; only my advisor, [insert Name], and I will have access to the data [and, if applicable, any tape or video recording].

If the research is terminated for any reason, all data and recordings will be destroyed. While I will make every effort to ensure confidentiality, anonymity cannot be guaranteed **due** to the small number to be studied. [ **This** phrase must be added when dealing with a small group].

[ If tape recordings or videotapes are made, explain who will have access, if they will be used for educational purposes, and when they will be erased. ]

[ If anyone besides the researcher will have access to the raw data, these persons must be identified. ]

[ Indicate one of the following:;]

- a. Raw data will be destroyed by (date). [Federal guidelines specify a minimum of 3 years for retention of data so the date should be three years from the end of your study.]
- b. Raw data will be retained but all identifying information removed by (date).

**Voluntary Nature of the Study:**

Your decision whether or not to participate will not affect your current or future relations with Augsburg College, (organization or agency - insert), or the researcher(s), [and/ or with other cooperating institutions--insert names ]. If you decide to participate, you are free to withdraw at any time without affecting those relationships. [ Explain here if monetary benefits will be adjusted due to early withdrawal. ]

**Contacts and Questions:**

The researcher(s) conducting this study is/ are \_\_\_\_\_ and \_\_\_\_\_. You may ask any questions you have now. If you have questions later, you may contact me/us at \_\_\_\_\_ . Phone: (Area Code) \_\_\_\_\_ .

[ If the researcher is a student, include advisor's name and telephone number . ex. My advisor is Dr. John Doe, Professor of Social Work. [doe@augsborg.edu](mailto:doe@augsborg.edu); 612 330-5555 ].

You will be given a copy of this form to keep for your records.

**Statement of Consent:**

I have read the above information or have had it read to me. I have received answers to questions asked. I consent to participate in the study. [For surveys which are to be anonymous, the signatures of subjects are not required.]

Signature \_\_\_\_\_ Date \_\_\_\_\_

[ Signature of parent or guardian \_\_\_\_\_ Date \_\_\_\_\_ ]

[ Signature of minor subject's assent \_\_\_\_\_ Date \_\_\_\_\_ ]

Signature of investigator \_\_\_\_\_ Date \_\_\_\_\_

[ If audiotaping or videotaping is used, add:]

I consent to be audiotaped (or videotaped):

Signature \_\_\_\_\_

I consent to allow my child to be audiotaped (or videotaped)

Signature \_\_\_\_\_

I assent to be audiotaped (or videotaped ) (minor)

Signature ( \_\_\_\_\_ Date \_\_\_\_\_

[ If direct quotations will be used in reports of study, add: ]

I consent to allow use of my direct quotations in the published thesis document.

Signature \_\_\_\_\_

I assent to allow use of my direct quotations in the published document (minors only)

Signature \_\_\_\_\_

I consent to allow of my minor child's quotations in the published document (parents/guardians)

Signature \_\_\_\_\_ Date \_\_\_\_\_

Note: Use relevant signature lines and delete the others..

[Revised 2/14/2008]

# Augsburg College Institutional Review Board

## REQUEST FOR APPROVAL FOR THE USE OF HUMAN SUBJECTS IN RESEARCH Social and Behavioral Sciences

1. **Project Title:** (use same title as grant application, if applicable)

\_\_\_\_\_

2. **Principal Investigator** \_\_\_\_\_  
(first middle last)

Telephone number (area code) \_\_\_\_\_  
College department name \_\_\_\_\_  
Investigator's address \_\_\_\_\_  
\_\_\_\_\_

(For IRB Use Only) Approval # _____ IRB Chair: _____ (Signature)
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Campus Box \_\_\_\_\_ Email address: \_\_\_\_\_

3. **Check one:**

- \_\_\_\_\_ Faculty / staff research
- \_\_\_\_\_ Fellow / post doctoral
- \_\_\_\_\_ Student Research
  - \_\_\_\_\_ Undergraduate
  - \_\_\_\_\_ Graduate

4. **If principal investigator is a student:**

Advisor's Name: \_\_\_\_\_  
Address: \_\_\_\_\_  
Department: \_\_\_\_\_  
Telephone: \_\_\_\_\_

**5. Applications for approval to use human subjects in research require the following assurances and signatures to certify:**

- The information provided in this application form is correct.
- The Principal Investigator (PI) will seek and obtain prior written approval from the IRB for any substantive modification in the proposal, including, but not limited to changes in cooperating investigators, agencies as well as changes in procedures.
- Unexpected or otherwise significant adverse events in the course of this study will be promptly reported.
- Any significant new findings which develop during the course of this study which may affect the risks and benefits to participation will be reported in writing to the IRB and to the subjects.
- The research may not be initiated until final written IRB approval is granted.
- Data collection may begin only after IRB approval is given.

This research, once approved, is subject to continuing review and approval by the IRB. The PI will maintain records of this research according to IRB guidelines.

If these conditions are not met, approval of this research could be suspended.

Signature of Principal Investigator \_\_\_\_\_ Date \_\_\_\_\_

**Student Research: As academic advisor to the student investigator, I assume responsibility for insuring that the student complies with College and federal regulations regarding the use of human subjects in research:**

Signature of Academic/Thesis Advisor \_\_\_\_\_ Date \_\_\_\_\_

**Note: If the faculty member supervising student research is not a full-time Augsburg employee, the proposal must be signed by the Department Chair, who, together with the part-time employee, assumes responsibility for compliance.**

Signature of the Department Chair \_\_\_\_\_ Date \_\_\_\_\_

**Faculty/Staff Research: As department chair, or designee, I acknowledge that this research is in keeping with the standards set by our department and assure that the principal investigator has met all departmental requirements for review and approval of this research.**

Signature of Department Chair \_\_\_\_\_ Date \_\_\_\_\_

## 6. Checklist for Investigators

(application will be returned if not complete)

- \_\_\_ (1) This application includes a lay abstract stating the purpose of the study.
- \_\_\_ (2) The application describes the study population, inclusion/exclusion criteria, process of identifying subjects, etc.
- \_\_\_ (3) The abstract includes a description of tasks the subjects will be asked to complete.
- \_\_\_ (4) The application includes a full description of anticipated risks and benefits of study participation.
- \_\_\_ (5) Provisions have been made to minimize risks and those procedures are outlined on the form.
- \_\_\_ (6) Provisions have been made and documented to care for subjects in case of accident or injury.
- \_\_\_ (7) Procedures to maintain confidentiality have been fully described.
- \_\_\_ (8) Provisions have been made to obtain informed consent from all individuals related to the study. (e.g., parents, subjects, cooperating institutions, etc.)
- \_\_\_ (9) All questions on the form have been completed.
- \_\_\_ (10) All supporting documents have been attached, including protocol, survey instruments, interview schedules, solicitation letters, advertisements, consent forms, etc. **Supporting documents must be in final form as you intend to distribute them. Your application will be returned if these documents are in outline or first draft form.**
- \_\_\_ (11) If this study requires approval of another committee or cooperating agency, documentation of approval or notice of application has been attached.
- \_\_\_ (12) Appropriate departmental signatures and signature of academic advisor for student research have been obtained on Pg 1.
- \_\_\_ (13) A copy of this application has been made for the investigator's records.
- \_\_\_ (14) I request blind review. I have omitted all identifiers from copies submitted. (Original copy contains all names for IRB file.)
- \_\_\_ (15) The application is in the same page format as shown in this electronic word processing file. The location of questions and pagination is the same as in the original.
- \_\_\_ (16) Any unanticipated problem involving risk to subjects or noncompliance with regulations regarding subjects must be reported immediately to the IRB.
- \_\_\_ (17) If the research period is longer than 11 months, the IRB must review the research project again.
- \_\_\_ (18) Some projects that are either complicated procedurally or are of a long duration may require verification that no material changes have occurred since the IRB review.
- \_\_\_ (19) Any changes in approved research protocols must be reported promptly to the IRB and may not be initiated until IRB approval except when necessary to address immediate hazards to subjects.
- \_\_\_ (20) I attach 10 copies for full review applications **or** three copies for expedited applications **or** two copies for exempt applications, including any attached instruments and materials.

**You must make a preliminary judgment about the level of review required for your application. The chair will then determine the level of review after submission and contact you if additional copies are required.**

Completed, *typewritten* forms should be returned to:

Augsburg College Institutional Review Board  
c/o Norma Noonan, Ph.D., chair  
2211 Riverside Avenue, Campus Box 107  
Minneapolis MN 55454-1351

Telephone: 612-330-1198

7. **Project title** \_\_\_\_\_

**Inclusive dates of project:** \_\_\_\_\_ to \_\_\_\_\_

8. **Project** (please circle): **has been / will be submitted to the following funding agency:**

\_\_\_\_\_

**Funding decision** (please circle): **is pending / has been awarded.**

Agency-assigned grant number (if known): \_\_\_\_\_

If this study is part of a program or center grant, provide the title and principal investigator:

\_\_\_\_\_  
\_\_\_\_\_

9. **Is this research subject to review by another internal committee of the College?**

No  Yes: If yes, attach documentation of approval.

Specify: \_\_\_\_\_

10. **Is this research conducted at another location or with a cooperating organization, e.g., schools, clinics, community agencies, etc.?**

No  Yes: If yes, provide written documentation of approval from that institution.

Specify: \_\_\_\_\_

**CHECK REVIEW CATEGORY BELOW:**

11.  This research requires **full review** by the Institutional Review Board.

12.  **Expedited Review** (see Application Information on page ii): This research fits the precise requirements of category \_\_\_\_\_ of the expedited review provision of 45 CFR 46.110." The research could be considered of "minimal risk" to participants based on those guidelines.

13.  **Exemption category:** (See Application Information on pages iii and iv.): This research fits the precise requirements of category \_\_\_\_\_ of the exemption categories of 45 CFR 46.101(b).

Exempt applications only categories 4-6:

Exempt Category #4: Pathological Specimens

All pathological specimens should be stripped of identifiable information prior to use. Describe the source of the specimens. How will they be obtained? If not obtained by the principal investigator, then by whom?

Exempt Category #5: Public Service programs

In addition to the information provided under *abstract*, above, provide documentation or cooperation from the public agency involved in the research.

Exempt Category #6: Taste Testing

Food ingredients must be at or below the levels found to be safe by federal regulatory agencies. Describe the food to be tested and provide assurance that these conditions are met.

#### **14. Lay Summary**

The purpose of this is to inform the IRB about your research in order to assess its risks and benefits. Describe your research project using lay language--language understood by a person unfamiliar with the area of research. Include your research question and methods to be used (hypothesis and methodology). Provide the justification for the research (what is the need or problem being addressed by the study, why this research should be done). Describe in detail the tasks subjects will be asked to complete/what subjects will be asked to do.

15. **Subject Population (Please note all items: a-d)**

a. Number: Male\_\_ Female\_\_\_\_ Total\_\_\_\_\_

b. Age Range: \_\_\_ to \_\_\_\_\_

c. Location of Subjects:

(Check all that apply)

\_\_\_ elementary / secondary schools

\_\_\_ outpatients

\_\_\_ hospitals and clinics

\_\_\_ college students

\_\_\_ other special institutions: specify:

\_\_\_ Family service agencies/social service agencies

\_\_\_ other: specify: \_\_\_\_\_

d. Special Characteristics:

(Check all that apply)

\_\_\_ children

\_\_\_ inpatients

\_\_\_ prisons/halfway houses

\_\_\_ patient controls

\_\_\_ adult volunteers

- e. If research is conducted off-campus, written documentation of approval/cooperation from that outside agency (school, clinic, etc.) should accompany this application. Be sure all levels with this authority within the agency/organization have given approval.

Agency: \_\_\_\_\_

Name and title of agency representative: \_\_\_\_\_

- f. Describe how subjects will be identified or recruited. Attach recruitment information, i.e., advertisements, bulletin board notices, recruitment letters, etc.
- g. If subjects are chosen from records, indicate who gave approval for the use of the records. If these are private medical recording agency records, or student records, provide the protocol for securing consent of the subjects of the records and approval from the custodian of the records.
- h. Who will make the initial contact with the subject? Describe how contact is made. **If recruitment is verbal, provide the specific script to be used.**
- i. Will subjects receive inducements before, or rewards after the study? If yes, explain how and when they will be distributed.
- j. If subjects are school children, and class time is used to collect data, describe in detail the activity planned for non-participants. Who will supervise those children? (This information should be included in the consent form.)

16. **Risks to participation:** (check all that apply)

- use of private records (medical, agency or educational records);
- possible invasion of privacy of subject or family;
- manipulation of psychological or social variables such as sensory deprivation, social isolation, psychological stresses;
- any probing for personal or sensitive information in surveys or interviews;
- use of deception as part of experimental protocol; the protocol must include a “debriefing procedure” which will be followed upon completion of the study, or withdrawal of the subjects. Provide this protocol for IRB review;
- presentation of materials which subjects might consider offensive, threatening, or degrading;
- other risks: specify: \_\_\_\_\_

Describe the precautions taken to minimize risks:

17. **Benefits to participation:**

List any anticipated direct benefits (money, or other incentives) to participation in this research project. If none, state that fact here and in the consent form. Also, list indirect benefits to participation (e.g., improved programs or policies; contribution to knowledge)

18. **Describe provisions made to maintain confidentiality of data:**

A. How will you disseminate results or findings? Who will receive copies of results and in what form?

B. Where will the raw data be kept and for how long? (Federal IRB guidelines suggest all data have to be kept a minimum of three years.)

Give the date for destruction of raw data. If raw data are retained, give date when identifiers will be removed.

(If tape recordings or videotapes are created, explain who will have access and how long the tapes will be retained.)

C. What security provisions will be used? Who will have access to the collected data? If tapes will be transcribed by someone other than the researcher, how will confidentiality be assured?

D. Will data identifying the subjects be made available to anyone other than the principal investigator, e.g., school officials, etc.?

No  Yes If yes, explain below and in the consent form.

E. Will the data be part of the subject's chart or other permanent record?

No  Yes If yes, explain.

19. **Informed consent process:** Prepare and attach a consent form or a consent letter:

A consent form is required for research involving risk, and for research where permanent record of results are retained (including videotapes). Signatures of subject (and parent) are required.

A consent statement or letter to participant(s) may be used in surveys but does not require the signature of the subject. Provide text of consent statements read to study subjects, distributed to participants prior to interviews or used as a cover sheet for a written survey.

20. **Consenting Process:**

A. Describe what will be said to the subjects to explain the research.

B. What specific questions will be asked to assess the participant's understanding?

C. In relation to the actual data-gathering, when will consent be obtained?

D. Will the investigator(s) be securing all of the informed consent? \_\_\_ Yes \_\_\_ No If no, name the specific individuals who will obtain informed consent.

E. The investigator should not use a home phone number in communications with subjects. A mobile, office, or departmental phone number may be used. (The IRB does need a home phone number on page 1 of this application form for its use.)