

## **Augsburg College Institutional Review Board**

### **Secondary Data Review Form 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 10 copies

For Expedited Review: submit one original and two copies;

For Exempt and secondary data (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) or placed on the chair's office door; Memorial 113.

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.

**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

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 four separate avenues (see below) for review of research involving human subjects. A, B, and C use the IRB form. D will use the secondary data 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 iii-iv for eligibility criteria.

**D. Secondary Data Review:** Research involving private secondary data with no personal identifiers requires review by the IRB chair only.

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; studies using existing public data exclusively; 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 three to four weeks for review. No research may be initiated prior to formal written approval from the IRB.

Completed, *typewritten* forms should be returned to:

Norma Noonan, PhD, Chair  
Augsburg College Institutional Review Board  
Augsburg College, 2211 Riverside Avenue, Campus Mail #107  
Minneapolis, MN 55454-1351  
(612) 330-1198

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

### **Exempt review: using secondary data**

#### **4. EXISTING PUBLIC DATA; RECORDS REVIEW; SECONDARY DATA; PATHOLOGICAL SPECIMENS**

Research involving the collection or study of existing data, documents, records, 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 is 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.]

### **Secondary Data Review**

Research involving the collection or study of existing private data, documents, and/or records are exempt from full IRB review, if the information is recorded in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects. Applicants will need to submit a secondary data review form.

**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 mi last degree)

Telephone number \_\_\_\_\_

College department name \_\_\_\_\_

Investigator's address \_\_\_\_\_

Campus Box \_\_\_\_\_

(For IRB Use Only)
Approval # _____
IRB Chair: _____ (Signature)

3. **Check one:**

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

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

Advisor's Name: \_\_\_\_\_

Address: \_\_\_\_\_

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 approval is granted.

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 \_\_\_\_\_

**Faculty/Staff Research: As department chair, or designed, 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) Procedures to maintain confidentiality have been fully described.
- \_\_\_ (4) All questions on the form have been completed.
- \_\_\_ (5) 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.**
- \_\_\_ (6) If this study requires approval of another committee or cooperating agency, documentation of approval or notice of application has been attached.
- \_\_\_ (7) Appropriate departmental signatures and signature of academic advisor for student research have been obtained on Page 1.
- \_\_\_ (8) A copy of this application has been made for the investigator's records.
- \_\_\_ (9) I request blind review. I have omitted all identifiers from copies submitted. (Original copy contains all names for IRB file.)
- \_\_\_ (10) 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.
- \_\_\_ (11) I attach 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:

Norma Noonan, PhD, Chair  
Augsburg College Institutional Review Board  
Augsburg College, 2211 Riverside Avenue, Campus Mail #107  
Minneapolis, MN 55454-1351  
(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 principle 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

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. **Type of data being used**

a. Location of data:

(Check all that apply)

- elementary / secondary schools
- outpatient data
- hospitals and clinics
- college students
- other special institutions: specify:  
 Family service agencies/social service agencies
- Corporate data
- other: specify: \_\_\_\_\_

b. Special Characteristics

(Check all that apply if known)

- children
- inpatients
- prisons/halfway houses
- elderly
- adults
- other vulnerable population:

c. If secondary data are owned by an institution, written documentation of approval/cooperation from that outside institution (school, clinic, etc.) to use their data, needs to accompany this application. Be sure all levels with this authority within the agency/organization have given approval.

d. Describe how the secondary data will be used.

16. **Confidentiality of Data:** (note that the consent forms should include this information.)

a. Describe provisions made to maintain confidentiality of data.

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

c. Where will the study data be kept and for how long?

Give the date for destruction of study data.

d. What security provisions will be used? Who will have access to the study data?