Application for Exemption from IRB Review

Please complete this form if one of the exempt research categories (see pgs. 2 - 4 of this document) applies to your study. The completed *Application for Exemption* may be submitted electronically to the Chair of the IRB Committee (irb@anselm.edu).

Research Study Title:

Proposed Start Date for Study:

Principal Investigator:

Institution, Organization, or Department:

Mailing Address:

Phone Number: Email Address:

Co-Investigator(s) If Student, then Responsible Investigator (Faculty):

Institution, Organization, or Department:

Mailing Address:

Phone Number: Email Address:

1. Are any of your research participants prisoners? Yes ☐ No ☐
   (If your answer is "yes," your research is **not** eligible for an exemption from IRB review.)

2. Referring to the explanations on the next page, please check the category (or categories) of exemption that describe(s) your research: 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐

3. Are any of your participants children (under the age of 18)? Yes ☐ No ☐

   (If your answer is "yes," your research is **not** eligible for an exemption from IRB review.)

4. Please provide a rationale for the category or categories you have selected. (*Note*: If you selected category 2, please be sure to indicate whether the data you collect is linked to participant names or other identifying information. Will unique identification codes be created? Who has access to information linking unique identifiers to actual participants' names? Where will such information be stored?)

5. Please describe your research project. Include information on research participants/human subjects, data collection procedures, and data collection instruments you plan to use in this study. Attach any data collection instruments.

IRB Exemption Categories

Research exempt from IRB review MUST only involve one or more of the following research categories. Research that contains elements of exempt *and* non-exempt activities is NOT eligible for IRB exemption.

1. **Research done in educational settings, involving normal educational practices that is not likely to have adverse impacts on students learning required educational content or assessment of educators who provide instruction. This research includes but is not limited to:**

a. Research on regular and special education instructional strategies
b. Research on the effectiveness of, or the comparison of, instructional techniques, curricula, or classroom management methods

Important: The following **fall outside the scope of research and do **not** require IRB exemption or approval:

- Student ratings of instruction;
- Institutional or program evaluation research or assessment that is directly tied to the employee's primary work or departmental duties (e.g., financial aid regularly examines student records; Institutional Research accesses student success data for learning outcomes assessment purposes; etc.);
- Employee performance evaluations;
- Studies conducted by students under the advisement of faculty for classroom instructional purposes only, when information gained is to be shared in the classroom setting only;
- Accreditation mandated assessment and/or evaluation;

2. **Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. In order for research to be considered exempt under this category one of the three following criteria must be met:**

- Information obtained is not identifiable
- Disclosure outside of the research would not put subjects at risk of harm (e.g., financially, employment, reputation).
- Information obtained can be identifiable but the IRB has done a limited IRB review in keeping with 46.111(a)(7), which relates to there being adequate provisions for protecting privacy and maintaining confidentiality

Important: Research on sensitive or personal topics which may cause stress to participants are **not exempt from review.

3. **Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects**

**Important: Deception is allowed if certain criteria are met. This exemption is only for benign behavioral research with adults and is not applicable to children.

4. **Secondary research for which Consent is Not Required. In order for research to be considered exempt under this category one of the three following criteria must be met:**

   a. Use of publicly available identifiable private information or identifiable biospecimens.
   b. Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.
   c. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA.
   d. Analysis of data on behalf of a federal agency or department – as opposed to an investigatorinitiate analysis of federally supplied data – if the requirements of certain federal laws are met. *These sources are publicly available* OR *if the information is recorded in such a manner that subjects cannot be identified, directly or indirectly, through identifiers linked to the participants*.

5. **Research involving taste and food quality evaluation and consumer acceptance studies This IRB exemption category applies to Federal research only.**

   If wholesome foods <u>without additives</u> are consumed OR *if a food is consumed that contains food ingredients, agricultural chemicals, and/or environmental contaminants <u>at or below the level and for a use found to be safe</u> by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture*.

6. **Storage or Maintenance for Secondary Use for Which Broad Consent is Required.**
   Broad consent must be or have been acquired first. This requires additional limited review by the IRB to determine there are adequate provision to protect the privacy of subjects and maintain the confidentiality of data.

   Broad consent includes at least seven and possibly nine elements of consent. It includes five standard elements of consent such as providing information to subjects (or legally authorized representatives) in languages understandable to the research subjects (or the legally authorized representatives). Broad consent also includes elements particular to secondary analysis, such as a general description of the data and of the types of research that may be conducted.

7. Secondary Research for Which Broad Consent is Required

Broad consent must be or have been acquired first. This requires additional limited review by the IRB to determine there are adequate provision to protect the privacy of subjects and maintain the confidentiality of data.

Under this category the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent.

Categories 2, 3, 7, and 8 may require additional **limited review.** Limited review is required when:

- The information obtained is recorded by the investigator in such a manner that the identity of the human subject can readily be ascertained, directly or through identifiers linked to the subjects,

AND

- Any disclosure of the human subjects' responses outside the research would reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, education advancement, or reputation.

For exempt categories 7 and 8, limited review is always required. It is also important to remember that exempt categories 7 and 8 are only available for use when broad consent will be (or has been) obtained.