Application for Exemption from IRB Approval

Research involving human subjects is ordinarily monitored by an Institutional Review Board (IRB) to ensure that the subjects are informed as to their risks and benefits of participation, that the research is designed to minimize risks and maximize benefits, and that participation is fully voluntary. Certain kinds of research involving human subjects are understood to be of sufficiently low risk or integral to the activities taking place that they need not be subject to full review under IRB regulations. Such **exempt** research needs to be judged as such by an independent authority, not the researchers themselves.

If you think your project can be considered exempt, please fill out this form. Select from among the 8 options below the one that seems to fit your project most closely, and provide a brief sentence or two in response to the questions, i.e. the research goal, the procedure to be used, assurance of voluntary participation. Most exempt research at Holy Cross falls into categories 1, 2, or 3.

Project title _____

Principal Investigator _____ **Dept** _____ **Phone** _____

Student Researcher* _____ **Year** _____ **Advisor** _____

***For student-initiated research only**

Number of subjects to be involved _____ **Dates of project activity** _____

1. Does this research involve normal educational practices not likely to adversely affect student learning or assessment of their professors? Such practices include research on instructional strategies, effectiveness of techniques, curricula, or classroom management methods.
2. Are the subjects asked only to perform educational tests, survey procedures, interview procedures, or observation and recording of their public behavior?
3. Does the research involve brief, harmless, painless, non-invasive behavioral interventions, not likely to adversely affect the subjects or offend or embarrass them? Does the subject agree in advance to such interventions along with collection of written or verbal data?

(for 2 and 3) Can at least one of the following be answered "No"?

   a. Can the subject's identity be readily ascertained?
   b. Would disclosure of the subject's responses outside the research place the subject at risk of liability, financial harm, employability, educational advancement, or reputation?
   c. Is any deception involved that is not agreed to in advance by the subject?

4. Does this research involve secondary research of identifiable private information or identifiable biospecimens?
5. Is this a project conducted by a Federal department or agency and subject to approval of the head of that department or agency (such as internal studies, contracts, or consulting arrangements)?
6. Does this research involve taste and food quality evaluation or consumer acceptance studies?
7. Does this research involve storage or maintenance of private information or identifiable biospecimens for secondary research?
8. Does this research involve secondary research for which broad consent is required? If you think this might be the case, consult the Chair of the Human Subjects Committee.

Signed: _____ Date: _____