



## University Senate

**Introduced by:** Council on Research

**Date:** April 24, 2006

### **Inclusion of “Exempt” Category in IRB Human Subjects Reviews**

IT IS HEREBY PROPOSED THAT THE FOLLOWING BE ADOPTED:

- I. That the UAlbany Human Subjects Institutional Review Board be permitted to treat the six categories of research listed in the Appendix as “exempt” research. “Exempt” means here that a project is not subject to, or is exempted from the Federal Department of Health and Human Services requirements spelled out in 45 CFR 46. To qualify as an exempt study, the research must fall within one of the specified regulatory categories *and* satisfy all UAlbany institutional requirements. Only the IRB may determine when research is exempt or requires a full or expedited review. Therefore, researchers must submit an application to the Office of Research Compliance to ensure that the research meets the criteria for an exemption.
- II. That the implementation be effective as soon as the proposal is approved by the President.
- III. That this bill be referred to the President for approval.

### **RATIONALE**

The Department of Health and Human Services (DHHS) regulations apply to all research involving living human subjects, but there are some categories of research that the government exempts from the regulations (see the Appendix below). The research that falls into these categories *remains subject to the institutional policies* of the UAlbany IRB.

Adoption of the “exempt” category would have several consequences for the review of proposals that fit the specified categories. These changes would include, but are not necessarily limited to:

- a. The application form for IRB approval would be much less lengthy, requiring only the most basic information (e.g. about who the investigator is, what the sponsoring agency is, if any, and so on).
- b. Individualized and signed consent forms would not be required.
- c. Investigators would not be required to submit renewal proposals unless there is significant change in the protocols involved.

*Note that use of the “exempt” does not mean the research is exempt from IRB review. “Exempt” means only that a project is not subject to the requirements of 45 CFR 46. However, the federal regulations, various funding agencies, and University at Albany policy prohibit investigators from making this determination on their own. Only the IRB may determine when research is exempt or requires a full or expedited review.*

Use of the “exempt” category should dramatically reduce both the complexity and time involved in meeting the requirements of the compliance process for many UAlbany investigators. If the task is less burdensome, the overall level of compliance may also improve.

## **APPENDICES**

### **The Six Categories of Exempt Research (specified in the DHHS regulations)**

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) 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), survey procedures, interview procedures or observation of public behavior, unless:

- (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; *and*
- (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

- (i) the human subjects are elected or appointed public 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) 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.
- (5) Research and demonstration projects which 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 methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies,
- (i) if wholesome foods without additives are consumed 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 and Inspection Service of the U.S. Department of Agriculture.

**NOTE the following limitations:**

When a research project is reviewed under exempt criteria, the review takes into consideration the level of risk involved as well as ethical concerns that may pose potential harm to a participant. If the reviewer finds that the ethical issues pose more than a minimal risk to the participant but the type of research falls within the exempt criteria, it is at the discretion of the IRB to determine that the project will be reviewed as either expedited or at a convened board meeting. Following are examples of research that is not or may not be eligible to be exempt:

- **Patients:** The decision as to whether a particular research project involving patients is exempt or may be expedited will be made by the IRB.
- **Children:** Children (under 18 years old) can be subjects of exempt research unless it involves survey or interview procedures (in which case, either expedited or full review will be required.)
- **Prisoners, fetuses, pregnant women, or human *in vitro* fertilization:** Exemptions do not apply. Expedited or full review is required.
- **Research in which the subjects are filmed or videotaped:** The decision as to whether a particular research project involving filming or videotaping of participants is exempt, or whether expedited or full review is required will be made by the IRB.
- **Focus group studies:** The decision as to whether a particular research project involving focus group studies is exempt, or whether expedited or full review is required will be made by the IRB.
- **Publicly available sources:** For purposes of University at Albany policy, "publicly available" means:
  1. Accessible by any adult person in the United States,
  2. Without any other conditions or restrictions, except the records may be limited to the use of faculty and students.
- Under UAlbany IRB policy, the fact that data are publicly available does not relieve the researcher or the University IRB from evaluating the data for risk to identified individuals or to classes of individuals. Final determination of whether expedited or full review is required, as well as whether the data may be used at all, rests with the IRB.