



## Ethical guidelines for research involving human subjects

Most of the research conducted at Bates Technical College will be conducted within the categories defined in the Federal Policy for the Protection of Human Subjects. However, all persons planning to conduct research should evaluate their research plans to ensure that their work falls under one or more of the criteria below. All research requests to the Office of Institutional Research will be reviewed against these criteria. If your project does not fall within these criteria, you must ensure that you contact the Office for Institutional Research for advice on appropriate ethical practice.

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

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

*Note: this exemption does not apply to research involving prisoners or research directed toward pregnant women as subjects, and the following types of research involving children are not exempt:*

- a. Survey
- b. Interview
- c. Observation of public behavior when the investigator is a participant.

*Confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise.*

(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

*Note: When a study uses subjects who are **MINORS**, category (2) only applies as follows:*

- *Studies using educational tests involving minors as subjects are exempt. Studies using survey or interview procedures with minors as subjects are **NOT** exempt.*
- *Studies using observations of public behavior involving minors are **NOT** exempt unless the investigator does not participate in the activities being observed.*

*Confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise.*

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, or observation of public behavior that is not exempt under (2), 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.

*Note: this exemption does not apply to research involving prisoners or research directed toward pregnant women as subjects.*

*Confidentiality of identifiable information must be maintained without the express permission of the subjects to do otherwise.*

(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.

*Note: The requirement for consent of the subjects is waived if the data, documents, records, or specimens, etc., are publicly available. The authorization of the custodian of the data, etc., can serve in lieu of specific subject consent for access to data, etc., which are not publicly available. In such cases, the investigator must be satisfied that the custodian is authorized to release the data, etc., for research purposes. This exemption does not apply to research involving prisoners or for research directed at pregnant women.*

(5) Research and demonstration projects which are conducted by or subject to the approval of federal 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.

*Note: Such work cannot be exempted if prior review is specifically required by statute, or if a research or demonstration project presents a danger to the physical, mental, or emotional well-being of a participant or subject of the research or demonstration project.*

*This exemption does not apply to research involving prisoners or to research directed toward pregnant women.*

(6) Taste and food quality evaluation and consumer acceptance studies,

- (i) if wholesome food 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: This exemption does not apply to research involving prisoners or to research directed toward pregnant women.*

**Any questions regarding research ethics and human subjects should be directed to the Office of Institutional Research before any research activity is undertaken.**