Note: For use by investigators, Research Compliance staff, and IRB members who question the ruling of “exempt” status for a proposal. Investigators are reminded that they must apply for and request exempt status—this decision can be made only by the Research Compliance Office/IRB. Please consult with Research Compliance staff as desired.

I. Does the project meet the definition for Human Subject Research?  
(SEE FORM Human Research Determination Checklist (DHHS and FDA) for Research Compliance Staff and IRB reviewers.)

| 1. NO. | Research Compliance: Notify PI IRB review is not needed. |
| 2. YES. | Proceed. |

II. Is an exemption prohibited?  
– The research involves prisoners as participants  
– The research involves Human Embryonic Stem Cells  
– For categories 1 through 5: The research is subject to FDA regulations

| 1. YES. | Exempt status cannot be granted. |
| 2. NO. | Proceed. |

III. Does the research fall into one or more of these categories?

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
   - research on regular and special education instructional strategies, or
   - 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:
▪ Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

▪ 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.

▪ If this research involves children, the procedures are limited to observation of public behavior when the investigators do not participate in the activities being observed and educational tests.

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:

▪ The human subjects are elected or appointed public officials or candidates for public office; or

▪ 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:

▪ Public benefit or service programs;

▪ Procedures for obtaining benefits or services under those programs;

▪ Possible changes in or alternatives to those programs or procedures; or

▪ 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,

☐ if wholesome foods without additives are consumed or

☐ 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.

INVESTIGATOR: IF your work falls into one of these categories, you may request exempt status. In the IRB application, specify which exemption category(ies) the work meets.

RESEARCH COMPLIANCE STAFF/IRB:

This application _____ DOES _____ DOES NOT qualify for exempt status.

Exemption Category(ies) ________________

Forward to Director of Research Compliance for final decision.