1.0 **Purpose**: The purpose of this standard operating practice (SOP) is to establish guidelines for the recognition, review and certification of human research activities that are exempt from federal regulations.

2.0 **Persons Affected:**
2.1 Individuals engaged in human research activities
2.2 UMCIRB Chairperson (or designees) and members
2.3 ORIC staff and administrators

3.0 **SOP**: Determination of whether human research activities can be certified as exempt is made by the UMCIRB Chairperson (or designee), acting on behalf of the UMCIRB. Human research determined to be exempt shall be conducted in a manner consistent with the ethical principles set forth by the Belmont Report, the Nuremburg Code, and all state laws and institutional policies, rules, and regulations. The UMCIRB does not require any routine exchange of information related to exempt research, nor is routine continuing review performed.

4.0 **Definitions:**
4.1 Listed below are the DHHS criteria for protocols classified in the exempt status unless otherwise directed:

**4.1.1** Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:
- (a) Research on regular or special education instructional strategies or
- (b) Research on the effectiveness or comparison among instructional techniques, curricula, or classroom management methods;

**4.1.2** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
- (a) Information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the individual, e.g. coding numbers, AND
- (b) Any disclosure of the participants’ responses outside the research could reasonably place the individual at risk of criminal or civil liability or be damaging to the person’s financial standing, employability, or reputation;

**4.1.3** Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or the observation of public behavior that is not exempt under #4.1.2 above if:
- (a) Participants are elected or appointed public officials or candidates for public office, OR
- (b) Federal statutes require, without exception, that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter;

**4.1.4** Research involving the collection of 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 individual participants cannot be identified, directly or through identifiers linked to the person, (i.e., no names, or code numbers recorded for the participant; no follow-up studies possible on a particular participant);

4.1.4.1 This information must be existing on the date the IRB application is submitted; and
4.1.4.2 The data collection tool may not have an identifier or code that links data to the source of the information; and
4.1.4.3 Amendments to extend dates of collection may not be accepted after the initial exempt application;

4.1.5 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 if:
(a) Public benefits or service programs (specifically, Social Security, Medicare, and Medicaid programs);
(b) Procedures for obtaining benefits or services under those programs;
(c) Possible changes in or alternatives to those programs or procedures; and
(d) Possible changes in methods or levels of payment for benefits or services under those programs;

4.1.6 Taste and food quality evaluation and consumer acceptance studies if
(a) Wholesome foods without additives are consumed or
(b) Food is consumed that contains a food ingredient at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the USDA.

4.1.7 The above exempt categories are applicable to Subpart D, which provides for additional protections of children involved as participants in research except for 4.1.2 above.

4.1.7.1 This exemption for research in children involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) does not participate in the activities being observed.

4.1.8 The above exempt categories are not applicable for human research activities involving prisoners.

4.2 Additional FDA exempt status requirements include:

4.2.1 Any human research activity which started before July 27, 1981 and at that time was subject to requirements for IRB review under FDA regulations, provided that the investigation remains subject to review of an IRB.

4.2.2 Any human research activity that started before July 27, 1981 and was not otherwise subject to requirements for IRB review under Food and Drug Administration regulations before that date.

4.2.3 Emergency use of a test article, provided that such emergency use is reported to the IRB within 5 working days. Any subsequent use of the test article at the institution is subject to IRB review.

4.2.4 Taste and food quality evaluations and consumer acceptance studies, if
4.2.4.1 wholesome foods without additives are eaten;
4.2.4.2 a food is eaten that contains a food ingredient at or below the level and for a use found to be safe by the Food and Drug Administration; or
4.2.4.3 a food is eaten that contains an 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.

5.0 Responsibilities:

5.1 Principal Investigators are responsible for:

5.1.1 Submitting an initial application for review to the UMCIRB.

5.1.2 Initiating certified exempt research after receiving written certification of concurrence from the UMCIRB.

5.1.3 Ensuring the human research involves no more than minimal risk and falls into an exempt category in order to receive certification of exemption.

5.1.3 Providing adequate provisions for protecting the privacy interests of subjects.

5.1.4 Equitable selection of participants.

5.1.5 Adhering to approved consent requirements, if applicable.

5.1.6 Submitting any changes e.g., confidentiality, consent, risk profile, etc. to the UMCIRB for review and approval prior to being initiated.

5.1.6.1 The research project may be elevated from exempt to expedited or full UMCIRB review after initial approval based on new information or regulatory guidance changes.

5.1.7 Submitting any serious and unanticipated risks to participants or others to the UMCIRB.

5.2 UMCIRB Chairperson (or designee) is responsible for:

5.2.1 Reviewing applications for exempt research to confirm the exempt category.

5.2.2 Raising any pertinent ethical, administrative or procedural issues surrounding the research.

5.3 ORIC is responsible for:

5.3.1 Pre-reviewing and raising any issues related to the research and communicating those issues to the investigator or other appropriate individuals.

5.3.2 Forwarding an official determination letter that the study has been confirmed to meet an exempt criterion.

5.3.3 Retaining records on exempt protocols for a minimum of 3 years after the certification date of the research.

5.3.4 Reporting all exempt certifications to the UMCIRB members by reporting these in the IRB minutes.

5.4 Studies that are determined to be exempt can still raise ethical concerns, and these should be considered. Potential areas of concern include methods of recruitment, communication with subjects, consent to participate in the exempt research, and use of the data. The UMCIRB is not required to exempt studies that appear to meet exemption criteria if they raise serious ethical concerns.

6.0 Revision History:

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<tr>
<th>Date</th>
<th>Revision #</th>
<th>Change</th>
<th>Reference Section(s)</th>
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<td>12.5.2013</td>
<td>1.0</td>
<td>Updated to stand-alone document.</td>
<td>All</td>
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References

FDA. Code of Federal Regulations:

DHHS, OHRP. Code of Federal Regulations:
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html