Standard Operating Procedures

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<th>SOP #302.4 Revision 4</th>
<th>TITLE: Exempt Review</th>
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<tr>
<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 8/31/2016</td>
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<td>Approved By: IRB Chair</td>
<td>Signature</td>
<td>Date 9/1/16</td>
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PURPOSE
To define policies and procedures for the exempt review process.

REVISIONS FROM PREVIOUS VERSION
Clarification added to category 5

POLICY
Research protocols that meet the categories set forth by the federal regulations [45 CFR 46.101(b), 21 CFR 56.104(d)] may qualify for exemption. An IRB member or qualified staff member reviews and approves all exempt research conducted at UNM or by employees or agents of UNM. The determination may not be made by any other party or office. Research activities are exempt from the human research protection regulations when the only involvement of human subjects falls within one or more of the following categories and the research is not regulated by the Food and Drug Administration (FDA):

1. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as:
   - Research on regular or special educational 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:
   - Surveys, interviews and observation involve children (unless the researcher does not participate in the activities being observed);
   - 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.

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 category 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:
   - The projects conducted pursuant to specific federal statutory authority such as programs under the Social Security Act, or other federal statutory public benefit (e.g. financial or medical benefits as provided under the Social Security Act) or services programs (e.g. social, supportive, or nutrition services as provided under the Older Americans Act);
   - 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.
   - Projects for which there is no statutory requirement for IRB review;
   - Projects that do not involve significant physical invasions or intrusions upon the privacy interests of subjects;
   - Authorization or concurrence by funding agencies that exemption from IRB review is acceptable.

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 FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Non-federally funded research involving no more than minimal risk that does not conform to a specific exempt category above. Examples include:
   - Collection of data from voice, video, digital, or image recordings made for research purposes;
   - Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk;
   - Behavioral games;
   - Studies requiring performance of a task that incur no risk;
   - Studies involving focus groups, oral histories, ethnographies or program evaluation.

Research must also meet the following ethical criteria in order to be approved, even if it falls into one or more exemption categories:
1. Research presents no more than minimal risk to participants;
2. Selection of participants is equitable;
3. If research involves interaction with participants:
   a) The circumstances of informed consent minimize coercion and undue influence.
   b) Participants will be informed that the study involves research, a description of procedures, that participation is voluntary and whom to call with questions;
   c) Provisions for protecting the privacy interests of participants are adequate.
4. If private identifiable data are recorded, provisions for maintaining confidentiality of data are adequate.

RESPONSIBILITIES
Execution of SOP: IRB Chairs, IRB Members, Researchers, OIRB Staff.
PROCEDURE
Submission and Screening
1. The PI submits a completed submission package to the OIRB through IRBNet. Instructions for preparing the application are available on the OIRB website. The researcher may call the OIRB with questions.
2. Upon receipt of the submission, OIRB staff conduct intake and pre-review activities as described in the Staff Intake and Pre-Review SOP. OIRB staff make a preliminary determination regarding study funding, whether the study meets the criteria for exempt review, including minimal risk, and identifies the research categories. If the application does not meet the criteria for exempt or expedited review, OIRB staff schedule the study for full board review according to the Initial Full Review SOP.

Assigning Reviewers
1. Qualified expedited reviewers (see SOP Initial Expedited Review) or qualified IRB staff may be assigned to conduct exempt reviews. All exempt reviewers undergo initial training with OIRB prior to conducting exempt reviews. Members who have served on the IRB for at least three months may qualify as an exempt reviewer.
2. The exempt reviewer notifies OIRB staff if he/she is not available to conduct exempt review during the assigned time period or has a conflict of interest as outlined in the IRB Member and Consultant Conflict of Interest SOP. OIRB staff document who served as exempt reviewer on the applicable reviewer form.

IRB Exempt Review
1. Exempt reviewers are provided all documents submitted by the researcher.
2. The exempt reviewer documents specific findings (e.g. exemption category, requirement for informed consent) by completing the Reviewer Checklists.
3. The reviewer is responsible for reviewing the application in enough depth to determine that all of the research procedures fit one or more of the exemption categories specified in this policy. The reviewer ensures that the research meets ethical principles and standards for protecting research subjects.
4. During review, the reviewer ensures that the research does not include any of the following:
   - Prisoners;
   - Survey or interview techniques which include children as subjects (federally funded research only);
   - The observation of children where the investigator participates in the activities being observed (exemption category #2 only);
   - FDA-regulated research.
5. If the reviewer is unable to respond within 7 days, OIRB staff forward the protocol to another reviewer.

Review Outcome(s)
1. The reviewer makes one of the following recommendations by completing the Reviewer Checklist and returning it to the OIRB as soon as the review is completed but, if possible, no later than 7 days from receipt:
   - Additional information needed to determine exempt status;
   - Required modifications needed to qualify study for exempt status;
   - Recommendation that it qualifies for expedited review or requires review by the fully convened IRB;
   - Exempt (general comments or suggestions may be included but not required for approval).
2. The reviewer can also recommend that the activities do not fall under IRB purview. In these cases the reviewer indicates this on the Reviewer Checklist, the review is complete and OIRB staff send a “does not apply” letter to the PI.
3. OIRB staff forward the reviewer’s recommendation in writing to the PI.
4. The PI is responsible for submitting any requested modifications to the OIRB who then forward them to the reviewer for review and approval if appropriate. The reviewer determines whether the modifications are sufficient for approval of exempt status, and, if so, OIRB staff send an exemption determination letter to the PI.
5. If the reviewer determines the modifications are inappropriate or insufficient, he/she may request that the PI make further modifications. This review and modification process continues until there is a resolution.
6. IRB records and letters for all exempt determinations include the citation of the specific category justifying the exemption.
7. When the IRB has certified a research study as exempt, the IRB does not require continuation reviews.
8. If the PI has concerns regarding the IRB decision/recommendations for changes in the study, he/she may submit the concerns to the IRB in writing, including a justification for changing the IRB decision. The request may be sent to the reviewer and/or the IRB Chair for final resolution. If the investigator is still dissatisfied with IRB decision, he/she may send the study to the full IRB for review.

REFERENCES
21 CFR 56.104(d)
45 CFR 46.101(b)
45 CFR 46.102(i)