

REVIEWER DECISION WORKSHEET FOR EXEMPT STUDIES OR STUDIES APPROVED BY EXPEDITED REVIEW

IS STUDY EXEMPTED?

IS STUDY OK FOR EXPEDITED REVIEW?

REVIEWER NOTES:

<p>Exempt Category:</p> <p style="text-align: center;">Y N</p> <p><input type="checkbox"/> Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research or special educational instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.</p> <p><input type="checkbox"/> 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. For Veteran Affairs Medical Center (VAMC) research, damage to the subjects' insurability must also be taken into consideration.</p> <p><input type="checkbox"/> Research involving the use of education tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under category (b) 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.</p> <p><input type="checkbox"/> 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.</p> <p><input type="checkbox"/> 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 payments for benefits or services under those programs.</p> <p><input type="checkbox"/> Taste and food quality evaluation and consumer 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.</p> <p style="color: green; font-size: small;">*www.hhs.gov/ohrp/policy/exemptfaqsmar2011.pdf - 2011-05-11</p>	<p>Expedited Review Category:</p> <p style="text-align: center;">Y N</p> <p>Clinical studies of drugs and devices only when:</p> <p><input type="checkbox"/> Research on drugs where IND is not required. Research on drugs that increases risks or decreased acceptability of the risks associated with the use of the product is NOT eligible for Expedited Review.</p> <p><input type="checkbox"/> Research on devices where IDE is not required or the device is cleared for marketing and used in accordance with its cleared/approved listing.</p> <p><input type="checkbox"/> Collection of blood samples by finger stick, heel stick, ear stick or venipuncture:</p> <p style="padding-left: 20px;">Healthy, 110 lbs or more, may not exceed 550ml in an 8 week period, no more often than 2X/week.</p> <p style="padding-left: 20px;">If less than 110 lbs, may not exceed 50ml or 3 ml per kg in an 8 week period, no more often than 2X/week.</p> <p><input type="checkbox"/> Prospective collection of biological specimens for research purposes by noninvasive means.</p> <p><input type="checkbox"/> Collection of data through noninvasive means.</p> <p><input type="checkbox"/> Research involving materials (data, records, documents, specimens).</p> <p><input type="checkbox"/> Collection of data from voice, digital or image recordings.</p> <p><input type="checkbox"/> Research on individual or group characteristics or behavior (language, communication, cultural beliefs or practices, social behavior)</p> <p><input type="checkbox"/> Continuing review of research previously approved by convened IRB where:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Closed to enrollment <input type="checkbox"/> All subjects have completed all research-related interventions. <input type="checkbox"/> Research remains active only for long-term follow up. <input type="checkbox"/> Where subjects have never been enrolled. <input type="checkbox"/> Where study activity is limited to data analysis. <p><input type="checkbox"/> Continuing review where the other categories do not apply but that the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.</p>	<p>Signature of Reviewer _____ Date Reviewed _____</p> <p>Recommendations for informed consent:</p> <p>_____</p> <p>_____</p> <p style="text-align: center;">CONSENT ALTERATION/WAIVER CHECKLIST</p> <p>45 CFR46/116(D): An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirements to obtain informed consent provided the IRB finds and documents that:</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 15%;">YES</th> <th style="width: 15%;">NO</th> <th style="width: 70%;">MUST MEET ALL 4 CRITERIA</th> </tr> </thead> <tbody> <tr> <td style="height: 20px;"></td> <td></td> <td>The research involves no more than minimal risk to the subjects.</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> <td>The waiver or alteration will not adversely affect the rights & welfare of the subjects.</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> <td>The research could not practicably be carried out without the waiver or alteration.</td> </tr> <tr> <td style="height: 20px;"></td> <td></td> <td>Whenever appropriate, the subjects will be provided with additional pertinent information after participation.</td> </tr> </tbody> </table>	YES	NO	MUST MEET ALL 4 CRITERIA			The research involves no more than minimal risk to the subjects.			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