

## OHRs Information Sheet Expedited and Exempt Categories

Expedited Categories	Exempt Categories
<p><b>Category 1</b> Studies of drugs and medical devices only when (a) research on drugs for which an IND is not required, or (b) medical devices when (i) an IDE is not required; or (ii) the medical device is being used in accordance with its approved labeling.</p>	<p><b>Exemption 1: Normal Educational Practices and Settings</b> Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on effectiveness of or comparison among instructional techniques, curricula, classroom management methods.</p>
<p><b>Category 2</b> Collection of blood samples by finger/heel/ear stick or venipuncture (a) from healthy, non-pregnant adults <math>\geq 110</math> lbs, <math>\leq 550</math> ml in an 8 week period, not more frequently than 2 x per week; or (b) other adults and children, considering age/weight/health, collection procedure, amount of blood, frequency collected – may not exceed lesser of 50 ml or 3 ml/kg in 8 week period and not more frequently than 2 x/week.</p>	<p><b>Exemption 2: Educational Tests, Surveys, Interviews or Observations</b> Research involving use of educational tests (cognitive, diagnostic, aptitude, achievement), survey/interview procedures, observation of public behavior unless (i) information is recorded so humans subjects can be identified directly or through identifiers linked to the subjects, and (ii) disclosures outside the research could reasonably place subjects at risk of criminal/civil liability or be damaging to financial standing/employability/reputation.</p>
<p><b>Category 3</b> Prospective collection of specimens for research by non-invasive means – hair, nails, teeth, excreta/secretions, saliva, placenta, amniotic fluid, dental plaques, buccal scraping/swabs, sputum after saline mist nebulization.</p>	<p><b>Exemption 3: Identifiable Subjects in Special Circumstances</b> Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey/interview procedures, observation of public behavior, if (i) subjects are elected or appointed public officials or candidates for public office; or (ii) Federal statutes require without exception that confidentiality of information will be maintained throughout the research and thereafter.</p>
<p><b>Category 4</b> Collection of data through noninvasive procedure (no general anesthesia or sedation) routinely employed in clinical practice, excluding x-rays or microwaves. Examples: physical sensors applied to body surface with no input of significant amounts of energy, ECG, MRI, weighing or testing sensory acuity, EEG, US, blood flow.</p>	<p><b>Exemption 4: Research with Existing Data/Samples</b> Research involving the collection or study of existing data, documents, records, pathological or diagnostic specimens, if these sources are publicly available or if information is recorded so subjects cannot be identified directly or by identifiers linked to subjects.</p>

<p><b>Category 5</b> Research involving data/documents/records/specimens that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).</p> <p><b>Category 6</b> Collection of data from voice, video, digital, or image recordings made for research purposes.</p>	<p><b>Exemption 5: Public Benefit or Service Programs</b> Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which evaluate (i) public benefit/service programs (ii) procedures for obtaining benefits/services under those programs (iii) obtaining benefits/services under those programs (iii) possible changes in or alternatives to those programs/procedures (iv) changes in methods or payment for benefits/services under them.</p>
<p><b>Category 7</b> Research on individual or group characteristics or behavior (perception, cognition, motivation, identity, language, communication, beliefs or practices, social behavior) or research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, quality assurance methodologies.</p>	<p><b>Exemption 6: Taste and Food Evaluation and Acceptance Studies</b> Taste and food quality evaluation and consumer acceptance studies (i) if wholesome food without additives is consumed or (ii) if a food is consumed that contains a food ingredient at or below the level 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 EPA or the Food Safety and Inspection Service of the USDA.</p>
<p><b>Category 8</b> Continuing review of research previously approved by IRB (a) where (i) it's permanently closed to enrollment (ii) subjects have completed all research related interventions (iii) is active only for long-term follow-up; or (b) where no subjects have been enrolled and no additional risks have been identified or (c) the remaining research is limited to data analysis.</p>	<p><b>Category 9</b> Continuing review of research not under an IND or IDE where categories 2-8 do not apply but 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>