

## EXPEDITED CATEGORIES for NEW RESEARCH

<b>1</b>	<p>Clinical studies of drugs and medical devices only when condition (a) or (b) is met.</p> <p><b>(a)</b> Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)</p> <p><b>(b)</b> Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.</p>
<b>2</b>	<p>Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:</p> <p><b>(a)</b> from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or</p> <p><b>(b)</b> from other adults and children<sup>2</sup>, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period &amp; collection may not occur more frequently than 2 times per week.</p>
<b>3</b>	<p>Prospective collection of biological specimens for research purposes by noninvasive means.</p> <p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• hair and nail clippings in a nondisfiguring manner;</li> <li>• deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;</li> <li>• permanent teeth if routine patient care indicates a need for extraction;</li> <li>• excreta and external secretions (including sweat);</li> <li>• uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;</li> <li>• placenta removed at delivery;</li> <li>• amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;</li> <li>• supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;</li> <li>• mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;</li> <li>• sputum collected after saline mist nebulization.</li> </ul> <p><b>Note:</b> On October 4, 2010, OHRP clarified that it agrees with the FDA's position that the following procedures are considered noninvasive:</p> <ul style="list-style-type: none"> <li>• Vaginal swabs that do not go beyond the cervical os;</li> <li>• Rectal swabs that do not go beyond the rectum; and</li> <li>• Nasal swabs that do not go beyond the nares.</li> </ul>
<b>4</b>	<p>Collection of data through <u>noninvasive procedures</u> (not involving general anesthesia or sedation) routinely employed in clinical practice, <b>excluding procedures involving x-rays or microwaves.</b></p> <p><b>Examples:</b></p> <ul style="list-style-type: none"> <li>• physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subjects privacy; weighing or testing sensory acuity;</li> <li>• magnetic resonance imaging;</li> <li>• electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;</li> <li>• moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.</li> </ul>

5	<p>Research involving materials (data, documents, records, or specimens) <u>that have been collected, or will be collected solely for non-research purposes</u> (such as medical treatment or diagnosis). <b>(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. <u>45 CFR 46.101(b)(4)</u>. This listing refers only to research that is not exempt.)</b></p> <ul style="list-style-type: none"> <li>• <i>This category includes materials that were previously collected for either non-research or research purposes, provided that any materials collected for research were not collected for the currently proposed research.</i></li> <li>• <i>The phrase "...or will be collected solely for non-research purposes" pertains to the origin of the materials. For example, blood samples that were collected for a clinical test or the results of a course driven exam given in a history class.</i></li> </ul>
6	<p>Collection of data from voice, video, digital, or image recordings made for research purposes.</p> <ul style="list-style-type: none"> <li>• <i>Expedited Review does not apply if identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.</i></li> </ul>
7	<p>Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. <b>(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. <u>45 CFR 46.101(b)(2)</u> and <u>(b)(3)</u>. <u>This listing refers only to research that is not exempt.</u>)</b></p>