

Expedited Review Categories

Expedited Category 1 - Drugs or devices not needing investigational new drug or device exemptions.

Expedited Category 2 - Venipuncture blood from ambulatory non-pregnant adults (<2x/wk, <450cc in 8 wks).

Expedited Category 3 - Collection of biological specimens by noninvasive means (hair, excreta, nail clippings, etc.).

Expedited Category 4 - Recording data from adults by non-invasive clinical procedures (e.g., weight, height, eye-color) and moderate exercise by healthy volunteers.

Expedited Category 5 - Study of existing data, documents, records, or specimens.

Expedited Category 6 - Study of voice, video, digital, or image recordings as the focal point of the research protocol (e.g., investigation of speech defects).

Please note any type of recording solely for the purpose of data documentation must have the appropriate safeguards in place to prevent any potential harm that may be a result of a breach in confidentiality. When the appropriate safeguards are present, research using this type of data documentation will fall under the exempt review category.

Expedited Category 7 - 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; (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; (iii.) the human subjects are elected or appointed public officials or candidates for public office; or (iv.) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.