

**START:** Does the research involve **no more than minimal risk** to subjects AND does the research involve procedures included in OHRP expedited review categories 1 – 7 below?

1. Clinical studies on drugs and medical devices if a) an INDA is not required for drug research, OR b) an exemption application is not required for a medical device or the device is cleared/approved for marketing;
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture a) from healthy, nonpregnant adults weighing at least 110 pounds, OR b, other adults and children with consideration for the age, weight, and health of subjects, and amount of blood to be collected;
3. Prospective collection of biological specimens for research purposes by noninvasive means;
4. Collection of data through noninvasive procedures not involving general anesthesia or sedation, and excluding X-rays;
5. Research involving materials collected or to be collected for nonresearch purposes (e.g. medical diagnosis);
6. Collection of data from voice, video, digital or image recordings; and
7. Research on individual or group characteristics or behavior

Expedited Review may also be permitted for minor changes to previously approved research.

NO

Is this research for which a limited IRB review is a condition of exemption under 45 CFR 46.104(d)(2)(iii); 45 CFR 46.104(d)(3)(i)(C); and 45 CFR 46.104(d)(7, 8)?

NO

YES

**STOP:** The research is eligible for Expedited Review.

**STOP:** The research is not eligible for Expedited Review. Full IRB approval is required.

YES

Is this research classified?

YES

**STOP:** The research is not eligible for Expedited Review. Full IRB approval is required.

NO

Could identification of research subjects put them at risk of criminal or civil liability, or of social or financial harm?

NO

**STOP:** The research is eligible for Expedited Review.

YES

Are measures in place to ensure that the risks to subjects are no more than minimal?

YES

**STOP:** The research is eligible for Expedited Review.

NO

References are based on the Revised Common Rule, effective 1/21/2019.

Decision Chart – Expedited Review