This guidance document is used to determine whether non-exempt <Human Research> subject to EPA regulations (see Footnote 1) can be approved.

### 1. General Criteria 40 CFR §26

1.1 The research does not involve consent of an LAR 40 CFR §26 Subpart A

1.2 The research does not involve the intentional exposure of <Pregnant Women>, nursing women, or <Children> to any substance (see Footnote 2) 40 CFR §26 Subpart B

1.3 One of the following is true:
   - The research does not involve <Children> as subjects (see Footnote 3)
   - The research meets the criteria in category (1) or (2) in "REGULATORY GUIDANCE: Children (HRP-310)" 40 CFR §26 Subpart C
   - To limit Children to category (1) in their respective Regulatory Guidance as this limits the criteria to subjects in observational research. The EPA requires application of 40 CFR 26. Subparts C and D to provide additional protections to children as subjects in observational research, i.e., research that does not involve intentional exposure to any substance.

1.4 One of the following is true:
   - The research does not involve <Pregnant Women> as subjects (see Footnote 3)
   - The research meets the criteria in "REGULATORY GUIDANCE: Pregnant Women (HRP-305)" 40 CFR §26 Subpart D
   - To limit Pregnant Women to category (1) in their respective Regulatory Guidance as this limits the criteria to subjects in observational research. The EPA requires application of 40 CFR 26. Subparts C and D to provide additional protections to pregnant women as subjects in observational research, i.e., research that does not involve intentional exposure to any substance.

1.5 The research will be submitted to the EPA human subjects research review official for final review and approval before it begins EPA Order 1000.17 A1

### 2. Notes

### 3. Footnotes

3.1 EPA regulates research that is conducted or supported by EPA. EPA also regulates research whose results are intended to be submitted to or held for inspection by EPA, regardless of whether the research is conducted or supported by EPA or any other federal agency. 40 CFR §26.1101(a)

3.2 For research not conducted or supported by any federal agency that has regulations for protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply, including:
   - EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

3.3 "Research involving intentional exposure of a human subject" means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject’s participation in the study. 40 CFR §26.202(a) and §26.1102(i)

3.4 "Observational research" means any human research that is not research involving intentional exposure of a human subject. 40 CFR §26.302 and §26.402(f)