

WORKSHEET: Additional Criteria for Approval EPA

| Document No.: | Edition No.: | Effective Date: | Page: |
|---------------|--------------|-----------------|--------|
| HRP-408 | 002 | 05 Apr 2019 | 1 of 1 |

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

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All criteria in 1 must be met

1. General Criteria *40 CFR §26*

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| 1.1 | <input type="checkbox"/> | The research does not involve consent of an LAR <i>40 CFR §26 Subpart A</i> |
| 1.2 | <input type="checkbox"/> | The research does not involve the intentional exposure of <Pregnant Women>, nursing women, or <Children> to any substance (see Footnote 2) <i>40 CFR §26 Subpart B</i> |
| 1.3 | <input type="checkbox"/> | One of the following is true: <input type="radio"/> The research does not involve <Children> as subjects (see Footnote 3) <input type="radio"/> The research meets the criteria in category (1) or (2) in "CHECKLIST: Children (HRP-310)" <i>40 CFR §26 Subpart C</i> |
| 1.4 | <input type="checkbox"/> | One of the following is true: <input type="radio"/> The research does not involve <Pregnant Women> as subjects (see Footnote 3) <input type="radio"/> The research meets the criteria in "CHECKLIST: Pregnant Women (HRP-305)" <i>40 CFR §26 Subpart D</i> |
| 1.5 | <input type="checkbox"/> | The research will be submitted to the EPA human subjects research review official for final review and approval before it begins <i>EPA Order 1000.17 A1</i> |

2. Notes

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3. Footnotes

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| 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. <i>40 CFR §26.1101(a)</i> |
| 3.2 | "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. <i>40 CFR §26.202(a) and §26.1102(f)</i> |
| 3.3 | "Observational research" means any human research that is not research involving intentional exposure of a human subject. <i>40 CFR §26.302 and §26.402(f)</i> |