

IRB #

PI Name:

Drug, Dosage, Route of Administration:

IND EXEMPTION CHECKLIST

# 21 CFR 312.2(b)(1)

To be exempt under this category, all of these sub-requirements must apply:

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| --- |
| The clinical investigation involves a drug product lawfully marketed in the U.S.  Yes |
| The investigation is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use and is not intended to be used to support any other significant change in the labeling for the drug  Yes |
| If the drug that is undergoing investigation is lawfully marketed as a prescription drug product, the investigation is not intended to support a significant change in the advertising for the product  Yes |
| The investigation does not involve a route of administration or dosage level or use in a patient population or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. Please provide justification:  Yes |
| The investigation is conducted in compliance with the requirements for IRB review set forth in 21 CFR Part 56 and with the requirements for informed consent set forth in 21 CFR Part 50  Yes |
| The investigation is conducted in compliance with 21 CFR 312.7 (regarding promotion and charging for investigational drugs)  Yes |

# 21 CFR 312.2(b)(2)

To be exempt under this category, all of these sub-requirements must apply:

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| The clinical investigation involves one of the following in vitro diagnostic biological products (at least one box should be checked)  blood grouping serum reagent red blood cells  anti-human globulin |
| The product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure  Yes |
| The product is shipped in accordance with 21 CFR Part 312.160  Yes |

# 21 CFR 312.2(b)(3)

To be exempt under this category, all of these sub-requirements must apply:

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| The investigation involves a drug intended solely for tests in vitro or in laboratory research animals **and** the drug is shipped in accordance with 21 CFR 312.160  Yes |

# 21 CFR 312.2(b)(5)

To be exempt under this category, all of these sub-requirements must apply:

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| The clinical investigation involves a placebo **and** the investigation does not otherwise require submission of an IND (refer to the sections above)  Yes |

# 21 CFR 320.31(b) and (d)

To be exempt under this category, all of these sub-requirements must apply:

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| --- |
| The drug product does not contain a new chemical entity, is not radioactively labeled, and is not cytotoxic.  Yes |
| The dose (single dose or total daily dose) does not exceed the dose specified in the labeling of the approved version of the drug product.  Yes |
| The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR Part 56) and with the requirements for informed consent (21 CFR Part 50).  Yes |
| The sponsor meets the requirements for retention of test article samples (21 CFR 320.31(d)(1) and safety reporting (21 CFR 320.31(d)(3).  Yes |

# 21 CFR 361.1

To be exempt under this category, all of these sub-requirements must apply:

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| --- |
| The research is basic research not intended for immediate, therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product.  Yes |
| The use in humans is approved by a Radioactive Drug Research Committee (RDRC) that is composed and approved by FDA.  Yes |
| The dose to be administered is known not to cause any clinically detectable pharmacological effect in humans.  Yes |
| The total amount of radiation to be administered as part of the study is the smallest radiation dose practical to perform the study without jeopardizing the benefits of the study and is within specified limits.  Yes |

# Cold isotopes (FDA enforcement discretion)

To be exempt under this category, all of these sub-requirements must apply:

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| The research is intended to obtain basic information regarding the metabolism (including kinetics, distribution, and localization) of a drug labeled with a cold isotope or regarding human physiology, pathophysiology, or biochemistry.  Yes |
| The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.  Yes |
| The dose administered is known not to cause any clinically detectable pharmacologic effect in humans based on clinical data from published literature or other valid human studies.  Yes |
| The quality of the cold isotope meets relevant quality standards.  Yes |
| The investigation is conducted in compliance with the requirements for review by an IRB (21 CFR Part 56) and the requirements for informed consent (21 CFR Part 50).  Yes |

PI Signature Date

Version Date 9.20.2023