|  |
| --- |
| This checklist should be used to determine exemption of compounds using either stable or unstable isotopes. Please select the appropriate exemption pathway which applies to the product being used in the project |
| eBridge PRO Number:       | Drug/Biologic Product Name:      |
| [ ] 21 CFR 312.2(b) The project includes use of radioactive drugs (drugs containing unstable isotopes). To be exempt under this category, these sub-requirements must apply |
| 1. The research project involves basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product
 | [ ] Yes |
| 1. The use in humans is approved by a Radioactive Drug Research Committee (RDRC) that is composed and approved by FDA,
 | [ ] Yes |
| 1. The dose to be administered is known not to cause any clinically detectable pharmacological effect in humans
 | [ ] Yes |
| 1. 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 |
| 1. 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 |
| 1. The investigation is conducted in compliance with 21 CFR 312.7 (regarding promotion and charging for investigational drugs)
 | [ ] Yes |
|  |
| [ ] 21 CFR 312.2(b) The project includes use of cold isotopes (isotopes that lack radioactivity). To be exempt under this category, these sub-requirements must apply  |
| 1. 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 |
| 1. The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.
 | [ ] Yes |
| 1. The dose to be 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 |
| 1. The quality of the cold isotope meets relevant quality standards.
 | [ ] Yes |
| 1. 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 |