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| **Section 1 – Complete One Form For Each Drug Being Tested In Research and used outside of the approved labeling or without a current or pending IND.**  *For each one, a drug record form is required* |
| **DRUG NAME** |
| Insert generic name here  Insert trade name here, if applicable  Check if [combination drug/device product](http://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm118332.htm) |

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| **Section 2 – Applicability of Investigational New Drug (IND) Regulatory Requirements** Under FDA regulations, research that involves use of a drug other than the use of a marketed drug in the course of medical practice, must have an IND, unless the study meets one of the exemptions from the IND requirement  [[21 CFR 312.2(b)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2)].  ***Complete the following to document that the study is exempt from IND requirements***  **To assist you in determining which category applies to your study, see** [**FDA guidance for determining whether human research studies may be exempt from IND requirements**](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) **or** [**IND Exemptions for Studies of Lawfully Marketed Drugs or Biological Products for the Treatment of Cancer**](https://www.fda.gov/downloads/Drugs/Guidances/UCM071717.pdf) | | | | | | | |
| **1. STUDIES EXEMPT FROM IND REQUIREMENTS**  **The following are categories of studies that may be “Exempt” from IND requirements. Specific criteria or conditions within each category must be met to qualify for exemption.** | | | | | | | |
| *Indicate if the drug(s) used in this study meets any of the following IND Exemption categories and attach any supporting documentation from the FDA or the Sponsor. Specific criteria or conditions within each category must be met to qualify for exemption from IND requirements. If unsure if a drug used in this study meets an exemption category, you are responsible for consulting category-specific guidance below or checking with the FDA in order to determine whether an IND is required.* | | | | | | | |
| **I. Confirmation from FDA or commercial sponsor indicating that IND is not indicated for this study.** | | | | | | | |
|  | | *Check here that applicable documentation is attached.*(see regulation for required conditions [21 CFR 312.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2)). IF CHECKED STOP HERE | | | |
|  | | N/A, go to **II. Other Potential Exemption Categories** | | | |
| **II. Other Potential Exemption Categories:**  *Each of the following exemption categories has specific conditions or criteria that must be met in order to qualify for exemption from IND requirements. If the study meets any of the following exemption categories, you are responsible for consulting* [*FDA guidance*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) *and/or checking with FDA to confirm the specific criteria are met in order to be exempt from IND requirements.* | | | | | | | |
|  | | Testing of select in vitro diagnostic biological products that meet the required conditions (see regulation for required conditions [21 CFR 312.2](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2)). IF CHECKED STOP HERE | | | |
|  | | Select Bioavailability or Bioequivalence Studies (see [FDA guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) for dose limitations and required conditions). IF CHECKED STOP HERE | | | |
|  | | Select types of Cold Isotopes (see [FDA guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) for types and required conditions). IF CHECKED STOP HERE | | | |
|  | | Dietary supplements, botanicals, or other substances designated as generally recognized as safe (GRAS) for use in food if study does NOT evaluate product’s ability to diagnose, cure, mitigate, treat or prevent disease (see [FDA guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) for required conditions). IF CHECKED STOP HERE | | | |
|  | | Radioactive drug or biological product if (1) it involves basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product, (2) the use in humans is approved by a Radioactive Drug Research Committee (RDRC) that is composed and approved by FDA, (3) the dose to be administered is known not to cause any clinically detectable pharmacological effect in humans, and (4) 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. (see [FDA guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)) IF CHECKED STOP HERE | | | |
|  | | N/A none of the above apply, go to **III. Study involves an FDA Approved drug product** | | | |
| **III. Study involves an FDA Approved drug product and ALL of the following are true.**  *If ANY of the following statements are “false”, you are responsible for consulting FDA to determine whether an IND is or is not required.* | | | | | | | |
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| 1. The drug is lawfully marketed in the United States. | | | | True | False | |
| 1. The results of the investigation are NOT intended to be reported to FDA as a well-controlled study in support of a new indication for use or intended to be used to support any other significant change in the labeling for the drug. | | | | True | False | |
| 1. The investigation is NOT intended to support a significant change in the advertising of a lawfully marketed prescription drug product. | | | | True | False | |
| 1. 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\*     *\*For guidance regarding what new indications relative to dose, population, or route of administration significantly affect risk, see the FDA Guidance regarding determining if research may be conducted without an IND* [[PDF](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)] *or FDA IND Guidance for Marketed Cancer Treatments* [[PDF](http://www.fda.gov/downloads/drugs/guidances/ucm071717.pdf)] | | | | True | False | |
| If True to #4, provide an explanation: Insert explanation here | | | | |
| 1. The research is conducted in compliance with the marketing and promotion limitations described in [21 CFR 312.7](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7). | | | | True | False | |