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| The purpose of this worksheet is to provide support for IRB staff pre-reviewing research involving drugs. This worksheet is to be used. It does not need to be completed or retained. **Refer to UMB HRPP SOP on Emergency Use, Compassionate Use and Indiv Patient Expanded Access as needed.** | | | |
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| 1. Drug or Biologic Applicability | | | |
| Yes  No | | Does this activity involve any of the following?  ☐ In the United States: The use of a drug ii or a biological product (biologic) iii in one or more persons other than use of an approved drug in the course of medical practice iv.  ☐ Data regarding subjects or control subjects submitted to or held for inspection by FDA v.  If “Yes,” use the remainder of the worksheet; If “No,” FDA drug regulations do not apply. | |
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| 1. IND Requirements[[1]](#endnote-1) (One must be “Yes” If all are “No” IND information is not complete.) | | | |
| Yes  No | | The drug has a valid IND. (Complete Sections 3 and 4) | |
| Yes  No | | The drug is exempt from the IND requirements (Complete Section 5) | |
| Yes  No | | The research is conducted outside of the United States and is conducted under ICH-GCP. | |
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| 1. IND Validation[[2]](#endnote-2) (At least one must be “Yes” If all are “No” IND cannot be validated.) | | | |
| Yes  No | | Sponsor protocol imprinted with the IND number. | |
| Yes  No | | Written communication from the sponsor documenting the IND number. | |
| Yes  No | | Written communication from the FDA documenting the IND number. *(Required if the investigator holds the* IND*.)* | |
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| 1. Drug or Biologic Control (Must be “Yes” If “No” information regarding drug control is incomplete.) | | | |
| Yes  No | | The plan for storage, control, and dispensing of the drug is adequate to ensure that only authorized investigators will use the drug and that they will use the drug only in subjects who have provided consent.[[3]](#endnote-3) | |
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| 1. IND Exemptions (All criteria for one category must be “Yes” for a category to be met. If none are met, the drug is not exempt from an IND.) | | | |
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| **Category #1: Lawfully Marketed Drugs (21 CFR 312.2(b)(1))** | | |
| Yes  No | | The drug is lawfully marketed in the United States. |
| Yes  No | | The research is not intended to be reported to the FDA as a well-controlled study in support of a new indication for use nor intended to be used to support any other significant change in the labeling for the drug. |
| Yes  No | | The research is not intended to support a significant change in the advertising for the product. |
| Yes  No | | The research 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. |
| Yes  No | | The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7. |
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| **Category #2: Serological Tests (21 CFR 212.2(b)(2))** | | |
| Yes  No | | A clinical investigation for an in vitro diagnostic biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin. |
| Yes  No | | The diagnostic test is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure. |
| Yes  No | | The diagnostic test is shipped in compliance with 21 CFR §312.160. |
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| **Category #3: Placebos (21 CFR 312.2(b)(5))** | | |
| Yes  No | | A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND. |
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| **Category #4:** Bioavailability/Bioequivalence Studies (21 CFR 320.31(b) and (d)) | | |
| Yes  No | | The active moiety in the drug product is identical to that in an FDA approved drug. |
| Yes  No | | The drug product is not radioactively labeled. |
| Yes  No | | The drug product is not cytotoxic. |
| Yes  No | | The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product. |
| Yes  No | | The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1). |
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| **Category #5:** Radioactive Drugs for Research Use (21 CFR 361.1) | | |
| Yes  No | | The drug has been approved by Radioactive Drug Research Committee as a radioactive drugs for certain research use under the criteria in 21 CFR 361.1(b) |
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| **Category #6:** Cold Isotopes for Research Use (FDA enforcement discretion) | | |
| Yes  No | | 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  No | | The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject. |
| Yes  No | | 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  No | | The quality of the cold isotope meets relevant quality standards. |
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| 1. IND Oversight for investigators who hold the IND (One of the following must be “Yes”) | | | |
| Yes  No | | The investigator does NOT hold the IND. | |
| **Yes  No** | | The FDA requirements of a sponsor (including GMP when applicable) have been assumed by a contract research organization. | |
| **Yes  No** | | The investigator certifies in writing that they will be compliant with FDA sponsor requirements (including GMP when applicable). | |

1. i This document satisfies AAHRPP elements I.7.A, I.7.B

   ii The term ‘‘drug’’ means:

   (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

   (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and

   (C) articles (other than food and dietary supplements) intended to affect the structure or any function of the body of man or other animals; and

   (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).

   iii The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product,

   or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human

   beings.

   iv “Other than the use of an approved drug in the course of medical practice” refers to a practitioner providing an approved drug to a patient because the practitioner believes the drug to

   be in the best interests of the patient. If the protocol specifies the use of the drug, it is not in the course of medical practice unless use of the drug is completely up to the discretion of

   the practitioner.

   v. This is specific to submissions that are part of an application for a research or marketing permit. However, unless otherwise indicated, assume all submissions to FDA meet this

   requirement.

   vi. If there are questions about which category is appropriate, have the investigator apply for an IND following 21 CFR §312.23.

   vii. The investigator or other designated individual must maintain records of the product's delivery to the clinical trial site, the inventory at the site, the use by each subject, and the

   return to the Sponsor or alternative disposition of unused products. These records include dates, quantities, batch or serial numbers, and expiration dates (if applicable), and the

   unique code numbers assigned to the investigational products and trial subjects. The investigator must maintain records that document adequately that the subjects are provided

   doses specified by the protocol and reconcile all investigational products received from the Sponsor.

   viii An in vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the

   state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens

   taken from the human body. IVD products are devices as defined in section 201(h) of the Act and may also be biological products subject to section 351 of the Public Health

   Service Act.

   ix (FDA Guidance for Clinical Investigators, Sponsors, and IRBs Investigational New Drug Applications (INDs)) Determining Whether Human Research Studies Can Be Conducted

   Without an IND, September 2013: https://www.fda.gov/downloads/drugs/guidances/ucm229175.pdf. [↑](#endnote-ref-1)
2. [↑](#endnote-ref-2)
3. [↑](#endnote-ref-3)