VANDERBILT UNIVERSITY

Investigational New Drug (IND) EXEMPT DRUG FORM

Principal Investigator:

Title of Study:

Drug Name:

For IND Exempt drugs used in research, VU researchers must complete this form and attach it to the submission in the electronic IRB system. (Reference: *HRP-306 – Worksheet – Drugs and Biologics*)

IND EXEMPTIONS (Check if "**Yes**". All criteria for one category must be "**Yes**" to be met. If none are met, the drug is not exempt from an IND.)

Category #1 - Lawfully Marketed Drugs (21 CFR 312.2(b)(1)) or Biologics

☐ The drug or biologic is lawfully marketed in the United States.

☐ 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.

☐ The research is not intended to support a significant change in the advertising for the product.

☐ 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.

☐ The research is conducted in compliance with the marketing limitations described in 21 CFR §312.7.

Category #2 - Serological Tests (21 CFR 312.2(b)(2))

☐ A clinical investigation for an in vitro diagnostic[viii] biological product that involves one or more of the following: (1) Blood grouping serum; (2) Reagent red blood cells; or (3) Anti-human globulin.

☐ 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.

☐ The diagnostic test is shipped in compliance with 21 CFR §312.160.

Category #3 - Placebos (21 CFR 312.2(b)(5))

☐ A clinical investigation involving use of a placebo when the investigation does not otherwise require submission of an IND.

Category #4 - Bioavailability/Bioequivalence Studies (21 CFR 320.31(b) and (d))

☐ The active moiety in the drug product is identical to that in an FDA approved drug.

☐ The drug product is not radioactively labeled.

☐ The drug product is not cytotoxic.

☐ The dose (single or total daily) does not exceed the dose in the labeling of the approved version of the drug product.

☐ The sponsor meets the requirements for retention of test article samples in 21 CFR 320.31(d)(1).

Category #5 - Radioactive Drugs for Research Use (21 CFR 361.1)

☐ The drug has been approved by Radioactive Drug Research Committee as a radioactive drug for certain research use under the criteria in 21 CFR 361.1(b)

Category #6 - Cold Isotopes for Research Use (FDA enforcement discretion [ix])

☐ 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.

☐ The research is not intended for immediate therapeutic, diagnostic, or preventive benefit to the study subject.

☐ 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.

☐ The quality of the cold isotope meets relevant quality standard.

[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.