Principal Investigator: **Date:**
Study Title:

Study Drug Form

For studies designed to test:

- **a drug**
- **a biologic**
- other **compounds or products** intended to affect structure or function of the body
- **dietary supplements** used to diagnose, cure, mitigate, treat, or prevent disease

please complete and attach this form under the Study Drug Information section of your E-IRB application. If your study involves multiple drugs, complete applicable sections (and attach additional forms if needed) for each drug being investigated.

Where instructions in this form indicate to attach additional materials (e.g., product information or FDA correspondence), please use the "Protocol/Products Attachments" button under the *Additional Information/ Materials* section of your E-IRB application to attach them.

Section A: Complete for EACH drug, biologic, or compound tested in this study.

DRUG NAME *(include generic and trade name if applicable):*	**STUDY DOSE** *(indicate if study dose exceeds maximum approved dose or maximum dose used in prior studies):*	**DOES INVESTIGATIONAL PLAN PERMIT DOSE ADJUSTMENTS?**	**ROUTE OF ADMINISTRATION** *(e.g., oral, topical, etc.):*	**APPROVAL STATUS**
		◯ No ◯ Yes *If yes, describe or reference protocol.*	☐ Check if combination drug/device product	☐ FDA Approved or legally marketed product ☐ FDA Approved/ Unapproved use ☐ Not FDA Approved ☐ Unsure

Attach a copy of the investigator brochure, approved labeling, package insert, and/or drug monograph (e.g., Micromedix, PDR).

Section B: 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 IND exemptions [21 CFR 312.2(b)].

Complete the following to document that the study is either:

1) Exempt from IND requirements, or

2) Subject to IND requirements and being conducted under a valid IND

Attach any applicable FDA correspondence.

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 or IND Exemptions for Studies of Lawfully Marketed Drugs or Biological Products for the Treatment of Cancer.

Principal Investigator: **Date:**
Study Title:

CATEGORY 1: STUDY IS 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.

Consultation with the FDA may be required at the discretion of the IRB.See FDA contact information below.

Indicate if the drug(s) used in this study meets any of the following IND Exemption categories and attach any available 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. ☐ **Study is exclusively collection of clinical outcomes (i.e., real world data) on an approved/cleared drug used in clinical care.** In order to meet this exemption, study must not affect treatment decisions *or how the drug is administered. Treatment must be based on medical practitioner's clinical judgment (e.g.., case-control study, clinical outcomes registry). This exemption would not apply if gathering data would influence treatment decisions.*

II. 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.

Pro-Tip: Use Adobe's "Undo" tool, or Ctrl-Z, to clear a radio button selection.

1. ◯ True ◯ False The drug is lawfully marketed in the United States.
2. ◯ True ◯ False 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.
3. ◯ True ◯ False The investigation is NOT intended to support a significant change in the advertising of a lawfully marketed prescription drug product.
4. ◯ True ◯ False 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 drug product*.

* *The study may involve an unapproved use as long as change does not significantly increase risk or decrease acceptability of risk. For guidance regarding FDA's interpretation of* ***dose, population, or route of administration changes that may significantly affect risk****, see the FDA Guidance regarding determining if research may be conducted without an IND or FDA IND Guidance for Marketed Cancer Treatments [PDF].*

5. ◯ True ◯ False The research is conducted in compliance with IRB review (21 CFR 56), informed consent (21 CFR 50), and marketing and promotion limitations described in 21 CFR 312.7.

Principal Investigator: **Date:**
Study Title:

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 IND guidance 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).

☐ Select Bioavailability or Bioequivalence Studies (see FDA IND guidance for dose limitations and required conditions).

☐ Select types of Cold Isotopes (see FDA IND guidance for types and required conditions).

☐ Dietary supplements, botanicals, or other substances designated as generally recognized as safe (GRAS) may be exempt from FDA IRB and IND regulations if study is intended only to reduce risk of a disease; evaluate effect on structure or function of the body; or support a new or expanded health claim and conducted in healthy individuals over 12 months of age. Studies designed to evaluate a supplement's ability to diagnose, cure, mitigate, treat or prevent disease are considered to be FDA regulated and are NOT exempt from IND submission requirements. See FDA IND guidance for revised information on which supplement studies require an IND. Refer to FDA Guidance Structure/Function Claims, Small Entity Compliance Guide for examples of structure/function effects.

☐ Electronic nicotine delivery systems (e.g., e-cigarettes) research may not require an IND if testing does NOT involve a therapeutic purpose. A study designed only to evaluate an effect on structure or function in the body may be exempt from IND requirements. An IND would be required if the intent of the study was to evaluate a product's ability to diagnose, cure, mitigate, treat or prevent disease. If the study examines the product's ability to cure nicotine addiction, or mitigate withdrawal symptoms, the sponsor-investigator should consult with FDA regarding need for an IND. See FDA and NIH Guidance.

III. If available, attach correspondence from FDA or commercial sponsor indicating that IND is not indicated for this study.

Principal Investigator: **Date:**
Study Title:

CATEGORY 2: STUDY IS SUBJECT TO IND REQUIREMENTS
Studies that do not meet an exempt category above require submission of an IND to FDA.

If study involves a drug product subject to IND requirements, indicate the status of the IND application and attach documentation as indicated.

☐ IND submitted and pending FDA approval or 30-day clearance period

☐ IND approved by FDA
Record IND number and IND holder on Study Drug Section of E-IRB Application and attach one of the following documents to validate IND number:

- Written communication from commercial sponsor printed with number
- Commercial sponsor protocol printed with number
- Written communication from FDA (required for investigator holding the IND★)

★ **Sponsor-Investigator Training**: IRB policy requires completion of Sponsor-Investigator Good Clinical Practice Training for investigators who hold an IND (see the Research Description Section of the IRB Application).

☐ Treatment or Individual Patient Expanded Access IND (include attachments listed in Drug Section of application)

☐ IND not applicable (e.g., study involves drugs exempt from IND requirements).

☐ Confirmation obtained from FDA or commercial sponsor indicating that IND is not indicated for this study.

FDA Contact Information –Contact the Chief, Project Management Staff, in the review division for the applicable therapeutic area if unsure about exemption from IND requirements. Organizational charts and contact information is available at:

- DRUGS
- CDRH Division of Drug Information: 888-463-6332, 301-796-3400, druginfo@fda.hhs.gov
- BIOLOGICS 301-827-2000
- CBER Manufacturer's Assistance 800-835-4709, 301-827-1800, Industry.Biologics@fda.hhs.gov

Section C: Study Drug Management Accountability, Registration, Training & Qualifications to Administer

[21 CFR 312.57]

(**MUST COMPLETE -** *attach additional pages if contents exceed space provided in below text fields*)

Note: Inpatient studies are required by Hospital Policy to utilize Investigational Drug Service (IDS) pharmacies (Oncology or Non-Oncology). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

1. Describe how drug(s) will be handled including policies and procedures for receipt, storage, control, dispensing, and accountability, unless you are utilizing IDS for all study drug(s) (put N/A below if this is the case):

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2. Describe any procedures in place to prevent drug dispensing and/or administration errors:

3. If the Principal Investigator (PI) or sub-investigator does NOT have training or experience related to the proposed study with this drug product, indicate plans to obtain or augment applicable qualifications or expertise:

4. For applicable clinical trials initiated after March 7, 2012, FDA regulations require the informed consent document to include a specific statement informing subjects about trial registration and availability of trial data on clinicaltrials.gov. If study is registered on clinicaltrials.gov, do all informed consent documents associated with the study include the specific statement?

◯ **Yes** ◯ **No** ◯ **N/A (e.g., not an applicable clinical trial)**

Definitions and Additional Resources

Drug (Food Drug and Cosmetic Act) = "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease . . ." and "articles (other than food) intended to affect the structure or any function of the body of man or other animals." Biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262) may also be considered drugs within the meaning of the FD&C Act. It is important to note that the *drug* definition is not limited to compounds intended for therapeutic purpose but also includes compounds intended to affect structure or function of the body without regard to influence on a disease process. [Source 2010 FDA Investigational New Drug Applications (IND) Guidance]
FDA Regulations - 21 CFR 312 (drug) & 21 CFR 600 (biologics)

2013 FDA Guidance - Investigational New Drug Applications (INDs): Determining Whether Human Research can be Conducted Without an IND

2004 FDA Guidance on IND exemptions for marketed products in cancer treatment

FDA information for Sponsor-Investigator's submitting an IND

ICH Good Clinical Practice (GCP) Consolidated Guidance, 4.6 Investigational products

FDA Botanical Dietary Supplements FAQ & Botanical Drug Product Guidance

Additional FDA resources including alternative medicine products, inspections, etc.