**Supplement Form D**

**Research Involving Drugs or Biologics**

|  |  |
| --- | --- |
| **PI Name:** | **Date** |
| Protocol Title: | |

1. This research involves the following test articles (check all that apply and complete the appropriate sections below):

New investigational drug\* or biologic

Approved drug or biologic being used in accordance with its FDA-approved labeling

Investigational use of approved drug or biologic

\* *Dietary supplements, foods, and other substances may be considered drugs if they are being used to diagnose, cure, treat, mitigate, or prevent a disease or condition. Consult* [*FDA Guidance*](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf) *for more information.*

1. Who will assume primary responsibility for the storage, dispensing, and disposal of the drugs or biologics used in this study?

NJH Pharmacy

Investigator. Provide a plan for the storage, dispensing, handling, and disposal of the drugs or biologics including the procedures for inventory control and documentation (drug accountability). Also attach a copy of the approved waiver from use of the NJH Pharmacy for handling investigational drugs or biologics.

**Note:** *NJH Pharmacy is delegated responsibility by the Principal Investigator for storage, accounting for, dispensing, and compounding of investigational drugs and biologics used in research, whether conducted inpatient or outpatient. The manufacture/compounding of drug products not commercially available is coordinated by NJH pharmacy. Waivers from use of the NJH pharmacy’s policy of handling investigational drugs or biologics will be considered on a case by case basis by the Pharmacy director or designee, with review of required information from the PI regarding storage, accounting, dispensing etc. Documentation of waiver approval is forwarded to the IRB for placement in the study file.*

*The management of study drugs is guided by the Pharmacy Policy “Proper Control, Storage, Use and Handling of Investigational Drugs, Devices, and Biologics”.*

1. Does the sponsor of this research require investigator compliance with ICH-GCP E6?

Yes  No

If yes, the Principal Investigator must review “[International Conference on Harmonization (ICH) Good Clinical Practices (GCP) E6](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073122.pdf)” guidance and attest that they will comply with the requirements applicable to investigators.

Yes, I have reviewed the guidance and agree to comply with ICH-GCP E6

No, I am unable to attest to the above.

PI Name:  Date:

1. IND Evaluation
   1. List all drug(s)/biologic(s) to be used in this research (including those that are required per the protocol but not being studied):

* 1. Out of the above, list any drugs that are new investigational drugs **or** that will be used for an indication, population, or dosage that is outside of the FDA-approved labeling:

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **IND?** | **If yes, IND #** | **Holder of IND** |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |
|  | Yes  No |  |  |

* 1. If this research is being conducted under an IND, or one or more of the drugs used in the research is under an IND, **please include documentation verifying the IND number(s) with this submission**.

Type of Supporting Documentation Provided:

NA, there is no IND

Industry-sponsored protocol with IND number noted

FDA letter

Sponsor letter

Other. Describe:

* 1. Complete this section for each of the drugs/biologics identified above that are (1) being used outside of its labeling; and (2) that do not currently have an IND. If this section needs to be completed for more than one drug, please contact the IRB office for additional forms.

Drug/Biologic Name:

The FDA has determined that an IND is not required. *Provide a copy of the FDA letter with the submission.*

A copy of the FDA letter is included with this submission.

The sponsor has determined that an IND is not required.  *Provide a letter from the Sponsor indicating that an IND is not required and the basis for this determination.*

A copy of a letter from the sponsor is attached.

There is no documentation from the FDA or a sponsor stating that an IND is not required. Indicate which of the following categories for when an IND is not required applies to this research. *If you need to complete this section for more than one drug, contact the IRB office for additional forms.*

**Category One:** [21 CFR 312.2(b)(1)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for clinical investigations of a **drug product** that is **lawfully marketed** in the United States ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)). *All of the following must be true.*

The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug, and

The research is not intended to support a significant change in the advertising for the product, and

The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product, and

Justify:

The research will be conducted in compliance with the requirements for IRB review and informed consent (21 CFR Parts [56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56) and [50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50), respectively), and

The research will be conducted in compliance with the requirements concerning the promotion and sale of drugs ([21 CFR 312.7](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.7)), and

The research does not intend to invoke the FDA regulations for planned emergency research ([21 CFR 50.24](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24)).

**Category Two:** [21 CFR 312.2(b)(2)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for clinical investigations involving defined (blood grouping serum, reagent red blood cells, or anti-human globulin) **in vitro diagnostic biological products**.*All of the following must be true:*

The product is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and

The product is shipped in compliance with [21 CFR 312.160](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.160)

**Category Three:** [21 CFR 312.2(b)(5)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2) exemption for a clinical investigations involving the use of a **placebo** when the investigation does not otherwise require submission of an IND.

**Category Four**: [21 CFR 320.31](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.31)(b) and (d) IND exemptions for **Bioavailability** or **Bioequivalence** (BA/BE) studies ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)). *All of the following must be true:*

The drug product does not contain a new chemical entity ([21 CFR 314.108](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=314.108)), is not radioactively labeled, and is not cytotoxic.

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

The investigation is conducted in compliance with the requirements for review by an IRB ([21 CFR part 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)) and with the requirements for informed consent ([21 CFR part 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)).

The sponsor meets the requirements for retention of test article samples ([21 CFR 320.31(d)(1)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.31)) and safety reporting ([21 CFR 320.31(d)(3)](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=320.31)).

**Category Five**: [21 CFR 361.1](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=361.1) IND exemption for studies **involving radioactive drugs** ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)). *All of the following must be true:*

The research is basic research not intended for immediate therapeutic, diagnostic, or similar purposes, or otherwise to determine the safety and efficacy of the product.

The use in humans is approved by a Radioactive Drug Research Committee (RDRC) that is composed and approved by FDA.

The dose to be administered is known not to cause any clinically detectable pharmacological effect in humans.

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.

**Category Six**: IND exemption for studies involving **cold isotopes** ([FDA Guidance](http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM229175.pdf)). *All of the following must be true:*

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 standards.

The investigation is conducted in compliance with the requirements for review by an IRB ([21 CFR part 56](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=56)) and the requirements for informed consent ([21 CFR part 50](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=50)).

**Category Seven**: IND exemption for studies of **marketed drugs to treat** **cancer** ([FDA Guidance](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126837.pdf)). *All of the following must be true:*

The study is not intended to support FDA approval of a new indication or a significant change in the product labeling.

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

Based on the scientific literature and generally known clinical experience, there is no significant increase in the risk associated with the use of the drug product.

Justify:

The study is to be conducted in compliance with IRB and informed consent regulations, pursuant to 21 CFR 50 and 56.

The studies will not be used to promote unapproved indications, in compliance with 21 CFR 312.7.

**Additional Guidance for Investigator-Initiated Studies**

If this is not an industry sponsored trial, ensure that the protocol contains the following information for each drug or biologic used in this research.

* Name
* Dosage strength(s)
* Method/route of administration
* Mechanism of action
* Known drug interactions
* Known adverse effects
* Manufacturer/Sponsor
* Name of supplier
* Location of supply