**IMPORTANT: DO NOT CHANGE THE FORMAT OF THE FORM. ANY CHANGE OR MODIFICATION OF THE FORM WILL RESULT IN REJECTION OF THE APPLICATION BY THE CANDIDATE.**

|  |
| --- |
| If these human subjects study involves the use of any drugs or chemical or biological agents, the study is subject to CDSCO Guidelines. Researchers planning to use these agents in human subjects’ research must complete this form and include it with an original or amended New Protocol Application Form, as applicable.**Note: For drugs or biologics that are investigational, the consent document must clearly indicate that the agent is “investigational (experimental)” and that “an investigational drug is one that is not approved by the CDSCO/FDA for the use being studied.”** |

**Section A**

**A1. RESPONSIBLE PROJECT INVESTIGATOR/SUPERVISOR AT CHITKARA UNIVERSITY**

|  |  |  |
| --- | --- | --- |
| Last Name:       | First Name:       | Academic Degree(s):       |
| Dept. or Unit:       | Office Address:       | Mail Code:       |
| Street Address:       | City:        | State:    | Zip Code:       |
| Phone:       |  | E-mail:       |

**A2. Project Title**

|  |
| --- |
|       |

**B. Drug or Biologic**

|  |  |  |  |
| --- | --- | --- | --- |
| **Drug Name (Generic/Trade)** | **Manufacturer** | **Formulation** | **Route of Administration** |
|  |  |  |  |

1. Is the manufacturer of the drug sponsoring this trial?

**[ ]**  Yes

**[ ]** No. List the sponsor:

1. **Handling and Control of Drugs and Biologics**
2. Complete this section **only if seeking an exemption from the requirements of using the drug.**

**Please select the most appropriate exemption category and answer any questions associated with that category. (Tick your choice)**

**[ ]  Category 1:** CDSCO/FDA Determination of Exemption. Please attach a copy of the FDA determination letter.

 **[ ]  Category 2:** CDSCO/FDA-approved drug **and** the answer to all the following questions should be “y**es**”:

1. The drug is lawfully marketed in India or abroad?

[ ]  Yes

[ ]  No

1. The research is **not intended** to be reported to the CDSCO/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

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

[ ]  Yes

[ ]  No

1. 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. Justify:

[ ]  No

.

1. The investigation will be conducted in compliance with the CDSCO/FDA requirements for promotion and charging for investigational drugs.

[ ]  Yes

[ ]  No

**[ ]  Category 3:** *In vitro* diagnostic biological product **and** the answer to all the following is “**yes**”

.

1. The test article is an in vitro diagnostic biological product.

[ ]  Yes

[ ]  No

1. The *in vitro* diagnostic product is either blood grouping serum, reagent blood cells, or anti-human globulin.

[ ]  Yes

[ ]  No

1. The diagnosis made with the *in vitro* biological product will be confirmed by another, medically established, diagnostic product or procedure.

[ ]  Yes

[ ]  No

1. The in vitro diagnostic product will be shipped in compliance with CDSCO requirements

[ ]  Yes

[ ]  No

**[ ]  Category 4:** *In vitro* or animal use **and** the answer to all the following is “**yes**”.

1. The drug is intended solely for tests *in vitro* or laboratory research animals.

[ ]  Yes

[ ]  No

1. The drug is shipped in compliance with CDSCO guidelines.

[ ]  Yes

[ ]  No

**[ ]  Category 5:** Bioavailability or bioequivalence study **and** the answer to all the following is “**no**”:

1. A bioavailability or bioequivalence study involving a drug product that contains a new chemical entity, radioactively labeled drug product or cytoxic product.

[ ]  Yes

[ ]  No

1. A bioavailability or bioequivalence study involving a drug product containing an already approved, non-new chemical entity and is:
	* + - 1. a single-dose study in normal subjects or patients where either the maximum single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

[ ]  Yes

[ ]  No

* + - * 1. a multiple-dose study in normal subjects or patients where either the single or total daily dose exceeds that specified in the labeling of the drug product that is the subject of an approved new drug application or abbreviated new drug application.

[ ]  Yes

[ ]  No

* + - * 1. a multiple-dose study on an extended release product on which no single-dose study has been completed.

[ ]  Yes

[ ]  No

**[ ]  Category 6:** Clinical bioavailability or bioequivalence study for approval of an abbreviated new drug application or supplemental new drug application **and** the answer to all the following is “**yes**”:

1. Clinical bioavailability or bioequivalence study being conducted for approval of an abbreviated new drug application or supplemental new drug application other than studies described in Category 5.

[ ]  Yes

[ ]  No

1. Samples of the reference standard and test article will be are retained as described in 21 CFR 320.38 and 320.63.

[ ]  Yes

[ ]  No

**E. Handling and Control of Drugs and Biologics**

1. Select below the site(s) at which the research will be conducted and describe how the study drug will be handled at each site.

[ ]  **Chitkara University**

[ ]  The investigator will be responsible for the storage and handling of the study drug.

1. Describe how disposition of the study drug will be controlled, including procedures for storage, dispensing, limiting access to individuals listed as study personnel on the protocol and accountability.

|  |
| --- |
|       |

1. Indicate where the drug will be stored.

|  |
| --- |
|       |

 [ ]  Other:

[ ]  **Other site**

Specify:

|  |
| --- |
|       |

1. Describe how disposition of the study drug will be controlled, including procedures for storage, limiting access to individuals listed as study personnel on the protocol, dispensing, and accountability.

|  |
| --- |
|  |

1. Indicate where the drug will be stored.

|  |
| --- |
|  |

1. Provide a contact person at the site who can verify the institution’s approval of these procedures.

|  |
| --- |
|  |

**INVESTIGATOR ASSURANCES** The original, inked signature of the Project Investigator/Supervisor is required before this form can be processed. Other investigators are also responsible for these assurances and are encouraged to sign.

I certify that the information provided in this form and in all attachments is complete and correct.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| Principal investigator/Supervisor | Date |  | Researcher/Investigator (if any) | Date |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
| Investigator(if any) | Date |  | Investigator(if any) | Date |

**PLEASE NOTE: No form will be accepted without the signature of the Supervisor in case of PhD/Master/Bachelor students.**

**Any faculty who is an independent researcher must sign the form as the PI.**