

INVESTIGATIONAL DRUG(S) FORM

You must attach a PDF copy of the Investigator's Brochure/or package insert (including toxicity, previous animal/human studies, bibliography).

Please complete table below:

Planned Investigational Use	FDA-Approved Use
Study drug/treatment Generic name: _____ Commercial name: _____	
Indication:	Approved indication same as investigational use If different from investigational indication, Approved Indication:
Patient population(s):	Approved population same as investigational population If different from investigational population, Approved Patient population(s):
Dose(s):	Investigational dose approved If investigational dose not approved, Approved Dose(s):
Route(s) of administration (check all that apply): Oral Intravenous Intramuscular Ocular Subcutaneous Topical Other (Please list):	Investigational route(s) approved If investigational route(s) not approved, Approved Route(s) of administration are (check all that apply): Oral Intravenous Intramuscular Subcutaneous Topical Ocular Other (Please list):
Dosing regimen:	Investigational regimen approved If investigational regimen not approved, Approved Dosing regimen:

1. An FDA approved drug will be used for an unapproved purpose.

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IRB #:

Approval Date:

2. **An investigational (unapproved) new drug will be used.**

Name of the drug(s): _____
IND (investigational new drug application) number: _____
IND holder name (person/firm): _____
IND Holder Address: _____

IND holder is Principal Investigator (if checked, attach IND application to IRB submission)

This protocol is exempt from IND regulations. **Include FDA letter granting exemption.**

3. **Exemption from IND requirement (check all that apply):** The clinical investigation of a drug or biologic that is lawfully marketed in the United States may be exempt from IND requirements if all six of the following conditions are met [21CFR312.2(b)(1)]:

(i) It is not intended to be reported to FDA in support of a new indication for use of to support any other significant change in the labeling for the drug;

(ii) The drug is lawfully marketed as a prescription drug product and its proposed use is not intended to support a significant change in the advertising for the product.

(iii) It does not involve a route of administration of 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.

(iv) It is conducted in compliance with the requirements for IRB review and informed consent [21CFR parts 56 and 50, respectively];

(v) It is conducted in compliance with the requirements concerning the promotion and sale of drugs [21CFR312.7]; and

And exception from informed consent for emergency research will not involved [21CFR50.24].

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