Rev 05/10/18 ems

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.

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].