IRB Study Number:
Title:

Expanded Access IND (E.g. Single Subject IND, "Compassionate Use")

NAME OF DRUG OR BIOLOGIC TO BE ADMINISTERED	
CONDITION THAT WILL BE TREATED	
IND NUMBER	IND HOLDER

Confirmatory Statements:

☐ I confirm that the following statements are true:

- The patient or patients to be treated have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition;
- Providing the investigational drug for the requested use will not interfere with the initiation, conduct, or completion of clinical investigations that could support marketing approval of the expanded access use or otherwise compromise the potential development of the expanded access use**.**

NOTE: ***If both statements are <u>not</u> true, you must complete the full IRB application. If you intend to collect safety and effectiveness data for a use other than the IND-approved indication(s), you must comply with the IND regulations at 21 CFR Part 312 in addition to complying with the requirements for IRB approval (21 CFR Part 56) and protection of human subjects (21 CFR Part 50).***

Background

1. Provide a brief description of the drug (e.g. what does it do, is it approved to treat another condition/populaton, etc?):
2. What disease(s) or condition(s) will the drug be used to treat?
3. What alternatives are available to treat or diagnose the disease(s) or condition(s) described above?
4. Describe the patient or population who will receive the drug, including criteria for determining patient eligibility (i.e., screening procedures).

Commented [MM1]: May be approved and being used off-label. May be unapproved for anything, or unavailable in this country.

Commented [MM2]: Should be none. But should we have them describe

Commented [MM3]: Why do they need this specific drug? Do not meet criteria, no trials, etc. Why are other insufficient? Why do you think this might be the one?

Commented [MM4]: Should clarify if only one subject (ie. Single subject IND) or intermediate size. "Compassionate Use" is generally for N of 1-99. Higher and you start to get into clinical trial size.

Subject Population

Requested number of patients:
Notes:

- This is a specific number and you must not exceed this number. To increase the number of approved patients, a modification must be submitted to the IRB and approved prior to using the IND in additional patients.

Age Range (check all that apply):

☐ Newborn to 17 years of age*
☐ 18 or older

Procedures

1. Summarize the procedures/dose schedule for use of the drug, and any follow-up visits, tests or procedures.

2. Describe how the drug will be controlled, including the storage location, the procedures for storage, dispensing, and limiting access to the individuals listed as personnel on this application to prevent the inappropriate use of the drug or the use by non-approved health care practitioners.

3. Outline the schedule for monitoring the clinical use and safety of the IND, including follow-up patient visits, tests, or procedures.

4. What financial obligations will the patient incur as a result of receiving this drug?

Commented [MM5]: IDS or waiver.

Commented [MM6]: Who will pay for drug? If charged to subject, has FDA approved?
FDA must approve to charge the patient for an investigational drug under an IND.

Risks and Benefits

1. List the **possible risks, side effects,** and/or adverse events associated with the clinical use of the drug and how will risks be minimized:

2. List the **potential benefits** to the patient associated with the clinical use of the drug:

3. Please describe how you will monitor the safety of the patient.? :

Patient Identification and Informed Consent

1. How will potential patient(s) be initially identified?
2. Please describe the proposed consent process.
3. Please discuss whether there will be any waiting period between informing the prospective subject and obtaining consent, (e.g., does the indication for the IND require consenting of potential patients emergently?).

Commented [MM7]: Note if an LAR might be needed.

Commented [MM8]: Happens more often in HUDs but they could need to administer drug while patient is unable to give consent then consent after.

Notes:
- *If the PI plans to delegate the responsibility for obtaining informed consent, please ensure that all individuals are listed on the study personnel list in IRBIS.*
- *Please upload the consent document(s) that you intend to use.*

Required Attachments

1. FDA Approval
2. Investigator Brochure, Certificate of Analysis for Drug, or other document describing the substance(s) of the drug.
3. Informed consent form written for specific treatment (template available at _____)
4. Treatment protocol, if available

Commented [MM9]: Not all drugs under expanded access have an IB, but the Board should know what is in the drug being used.