



Single Patient IND Non-Emergent Compassionate Use Algorithm

First, **Request a Letter of Authorization (LOA)**, i.e. permission for the FDA to cross reference existing the IND or NDA of the drug being used for compassionate use from the pharmaceutical company. The LOA letter should state the company's **willingness to supply study drug free of charge to the patient or the patient's insurance and permission for you to revise the protocol for the patient, as necessary**. The letter should include the name(s) of the investigational product and existing IND number(s).



Create a **cover letter** from the PI/Sponsor addressed to the FDA

FDA address:

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document room
5901-B Ammendale Road
Beltsville, MD 20705-1266

What to include in the cover letter:

- State prominently at the top of the letter '**Request for a Single Patient IND for Compassionate Use**'
- **Informed Consent Statement** indicating that IRB-approval of the compassionate use with its associated consent will be obtained *prior* to initiating treatment.
- **Contact telephone and facsimile number; e-mail information**



Patient Information

- **Brief Clinical History** including diagnosis, disease status, prior therapy, response to prior therapy, relevant laboratory values and rationale for requesting the proposed treatment, including a list of available therapeutic options that would ordinarily be tried before the investigational drug or an explanation of why use of the investigational drug is preferable in this patient.
- Include a statement that **no drug treatment will be initiated prior to IRB approval & that the IRB approval and approved consent will be sent to the FDA once obtained**.
- **Proposed Treatment Plan** (you don't need to do a *formal* IND application like you would for a research study; sometimes the pharmaceutical company will have a single-patient protocol that they've used in the past, otherwise create one). It should include the dose, route, planned duration, monitoring procedures and modifications (e.g. dose reduction or treatment delay) for toxicity. Reference a published protocol or journal article if appropriate.
- This LOA will meet the requirement to provide information about chemistry, manufacturing & controls, pharmacology and toxicology.



Once the LOA is obtained, start Sinai Central and InfoEd processes



Get 1571 (serial# 0000; PI is the Sponsor) & 1572 signed by the PI



Submit cover letter, LOA, 1571, 1572 (all signed), protocol, & investigator CV to the **FDA** (originals plus 2 copies)



FDA will respond **30 days after the FDA receives the IND submission** & assign a new IND number, often by email. The IND is considered 'active' (i.e. treatment with drug 'may proceed', **provided IRB approval is conferred**). If treatment use is not allowed to proceed (i.e. a **clinical hold is placed**), FDA will notify the physician. Provide the IND# to the pharmaceutical company.



Create a consent with the subject's initials; the **pharmaceutical company must OK the consent**



Submit as a new project to the PPHS with all the requisite IRB forms