



What to include in a Compassionate Use (Non-Emergent) IND Application

1. **Cover letter:**
 - a. A statement that this is a request for an individual patient IND for treatment use (specifying that it is an “Individual Patient IND” at the top of the cover letter)
 - b. **Informed Consent Statement** indicating that IRB-approval of the compassionate use with its associated consent will be obtained *prior* to initiating treatment.
 - c. **Contact telephone and facsimile number; e-mail information**
2. **Brief clinical history including**
 - Diagnosis
 - Disease status
 - Prior therapy
 - Response to prior therapy
 - 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 to use of available therapeutic options.
3. **Proposed treatment plan**
 - Reference a published journal article if appropriate
 - Dose
 - Route
 - Planned duration
 - Monitoring procedures
 - Modifications (e.g. dose reduction or treatment delay) for toxicity
4. **Chemistry, manufacturing, and controls** information, and **pharmacology and toxicology** information. The requirement for this information may be met by providing a ‘Letter of Authorization’ (LOA) from the pharmaceutical company supplying the research product. The letter will allow the FDA to review previously submitted information in an existing IND or NDA for that product. The LOA should include the IND number, as well as the name of the product.
5. **FDA Form 1572: Investigator Qualification Statement** that specifies the training, experience, and licensure of the treating physician. This can be the first 2 pages of a CV which is usually sufficient.
6. **FDA Form 1571** completed with the treating physician listed as the sponsor.

If the request is approved, an IND number will be issued by the FDA. The IND is considered ‘active’ (i.e. treatment may proceed) 30 days after the FDA receives the IND submission or upon earlier notification of the physician by the FDA. **No study drug treatment will be initiated prior to IRB approval.** The IND# should be given to the drug supplier so the drug can be shipped to the treating physician.

If treatment use is not allowed to proceed (i.e., a *clinical hold* is placed on the application), the FDA will notify the physician of this decision initially by telephone, followed by a written letter providing the reasons for the denial of the request. You will be given the opportunity to respond by letter.

As the holder of the IND, **you are required to report SAEs directly to the FDA** using the **MedWatch form 3500a** or by telephone at 1-800-1088. You are also required to provide **annual reports**. All correspondence with the FDA should be accompanied by a new 1571, adjusting the serial # up each time (0001, 0002, etc).