**Template Cover Letter for Submission of a Single Patient Treatment Use Request to the IRB**

Please note: In a **non-emergency situation**, a written request (IND) for individual patient use of an investigational drug must be received by the FDA before shipment of and treatment with the drug may begin. These non-emergency requests are known as individual patient INDs.

**Please include the following information in your cover letter:**

- Statement that this is a request for an individual patient IND for treatment use

- Brief Clinical History of the patient including:
  - the diagnosis
  - the disease status
  - prior therapy
  - response to prior therapy
  - the 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

- Proposed Treatment Plan including (or provide a clinical protocol outlining the treatment plan):
  - the dose
  - route
  - planned duration
  - monitoring procedures
  - modifications (e.g. dose reduction or treatment delay) for toxicity

- Reference a published protocol or journal article if appropriate

- A brief summary of how the investigational drug is being obtained and from what Sponsor

- Informed Consent Statement that includes the proposed process to obtain consent from the patient for the single patient treatment use (see IRB consent template for Single Patient Treatment Use)

- An Investigator Qualification Statement that specifies the training, experience, and licensure of the treating physician

- Verification that an FDA Form 1571 has been completed and has been sent/will be sent to the FDA with the treating physician listed as the sponsor. (Please note: You can download Form 1571 and other forms from the FDA Web site. For forms and instructions please see: Information for Sponsor-Investigators Submitting Investigational New Drug Applications (INDs).)

- Provide confirmation that the patient or his/her family member did not provide a financial donation to the institution that is related to the experimental therapy being provided
The Principal Investigator (or appropriate delegate) must contact the Office of Planned Giving to assure that the patient in question has not given a gift to the Institution
  • Please note: if a gift was given, please contact the Director of the IRB, Tracy Ziolek, and a plan to address this will ensue

• Any relevant contact information needed