|  |
| --- |
| The purpose of this checklist is to provide support for PIs and study personnel when submitting an expanded access application for IRB Review. This checklist must be used for all expanded access reviews. This checklist must be included in the submission. |
| **IRB Number:****Study Name:****Primary Investigator:****Entity:**  |                      |
|  |
| **Each expanded access submission must include the following items/forms:** |
|  |
|[ ]  Cover Letter |
|[ ]  Informed Consent |
|[ ]  Investigator’s Brochure (if available)  |
|[ ]  The FDA-issued individual patient expanded access IND |
|[ ]  Conflict of Interest (for each member of study personnel) |
|[ ]  Confidentiality Agreement (for each member of study personnel) |
|[ ]  PI’s CV |
|[ ]  Research Personnel List |
|[ ]  Thorough patient history and treatment plan (included in FDA Form 3926 or a separate document), including:* The proposed dosing schedule, route, and frequency of administration, duration of planned treatment, criteria for discontinuation of treatment, potential adverse events, and planned dose modifications in the event that there are adverse events;
* The planned monitoring for potential adverse events, response to treatment, and changes in clinical status, as well as proposed modifications to the treatment plan to mitigate risks to patients if appropriate;
* The key details of the patient’s history, including diagnosis and summary of prior therapy (including response to such therapy), as well as information regarding a patient’s relevant clinical characteristics (such as comorbid conditions and concomitant medications) that are necessary to assess the potential for increased risks of the drug;
* A summary of known risks of the drug (this information may be included in the consent form or the Investigator Brochure, rather than the treatment plan, as applicable), and
* An assessment that the probable risk to the patient from the investigational drug is not greater than the probable risk from the disease or condition. Note: The information provided to the IRB should match what was/will be submitted to the FDA.
 |
|  |
|  |
| Notes: |
|  |