

Responsibilities of a Sponsor-Investigator (Treating Physician)

When you submit an individual patient IND or IDE request to FDA, you become both the sponsor and the investigator—and are expected to take on the following regulatory responsibilities associated with administering the product and overseeing treatment:

- Apply to and obtain approval from FDA and an IRB prior to administering the investigational product.
- Seek IRB approval for continuing review if the treatment use extends longer than one year or a second course of treatment is needed.
- Obtain and document appropriate informed consent from the patient or legally authorized representative prior to treatment.
- Maintain accurate case history records and observations related to provision of product, including adverse events.
- Report serious and unexpected adverse reactions that are believed to be related to the use of the investigational product, as required by FDA.
- Maintain accurate documentation of the disposition of investigational product, including dates, quantity, and use.
- Adhere to reporting obligations of IRB, FDA, and product manufacturer.
- Prepare and send summary report of treatment use to product manufacturer and FDA.
- Maintain confidentiality of the information both about the patient and the condition.
- Comply with applicable local laws and institutional policies.