Responsibilities of a Sponsor-Investigator (Treating Physician)

- Apply to and obtain approval from the Food and Drug Administration (FDA) and an institutional review board (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 dose 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 adverse events 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 sponsor.
- Prepare and send summary report of treatment use to sponsor and FDA.
- Maintain confidentiality of the information both about the patient and the condition.
- Comply with applicable local laws and institutional policies.