WCG FOUNDATION™

Improving lives by delivering on the promise of research

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.