**Investigator-Sponsor Responsibilities**

*Call the IRB Office ext.* ***6-7512*** *with any questions*

*Refer to the* [*FDA Sponsor and Investigator Responsibility Checklist*](https://eirb.tuftsmedicalcenter.org/IRB/sd/Doc/0/UU2F5IMMHD847BK3RUV875SC35/Investigator-Sponsor%20Checklist.doc) *to clarify which documents can provide evidence that the Investigator-Sponsor has fulfilled his/her responsibilities.*

**Definitions:**

* Investigator
  + An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject).
  + In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team.
* Sponsor
  + A party who takes responsibility for and initiates a clinical investigation (21CFR312.3).
  + The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.
  + The sponsor does not actually conduct the investigation.
* Investigator-Sponsor
  + An individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed (21CFR312.3). The term does not include any person other than an individual.
  + In addition to the regular responsibilities of an investigator, the individual also has the responsibilities that are normally assigned to the sponsor and is responsible for maintaining an effective IND/IDE with respect to the investigations.

**General Responsibilities of an Investigator-Sponsor**

* Ensure that the investigation is conducted according to the investigational plan, applicable regulations, applicable local laws, and institutional policies.
* Ensure that the study is conducted according to sound research design and generally acceptable scientific methods
* Ensure the study is conducted according to the terms of the grant, contract and/or signed agreement(s)
* Protect the rights, safety, and welfare of subjects under the investigator’s care
* Apply to and obtain approval from the Food and Drug Administration (FDA) and an institutional review board (IRB) before administering the investigational product.
  + Complete and submit a [Form 1572](https://www.fda.gov/downloads/aboutfda/reportsmanualsforms/forms/ucm074728.pdf) to the FDA
* Secure funding for the clinical trial and apply for the appropriate insurance.
* Select qualified investigators and provide them with the information they need to conduct an investigation properly.
* Ensure all participating investigators provide sufficient and accurate financial information to allow the Investigator-Sponsor to submit complete and accurate certification or disclosure statements.
* Ensure proper monitoring of the investigation.
* Seek IRB approval for any amendments (study modifications) and for continuing review if the treatment use or study extends longer than one year.
* Obtain and document appropriate informed consent from the patient or legally authorized representative before 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.