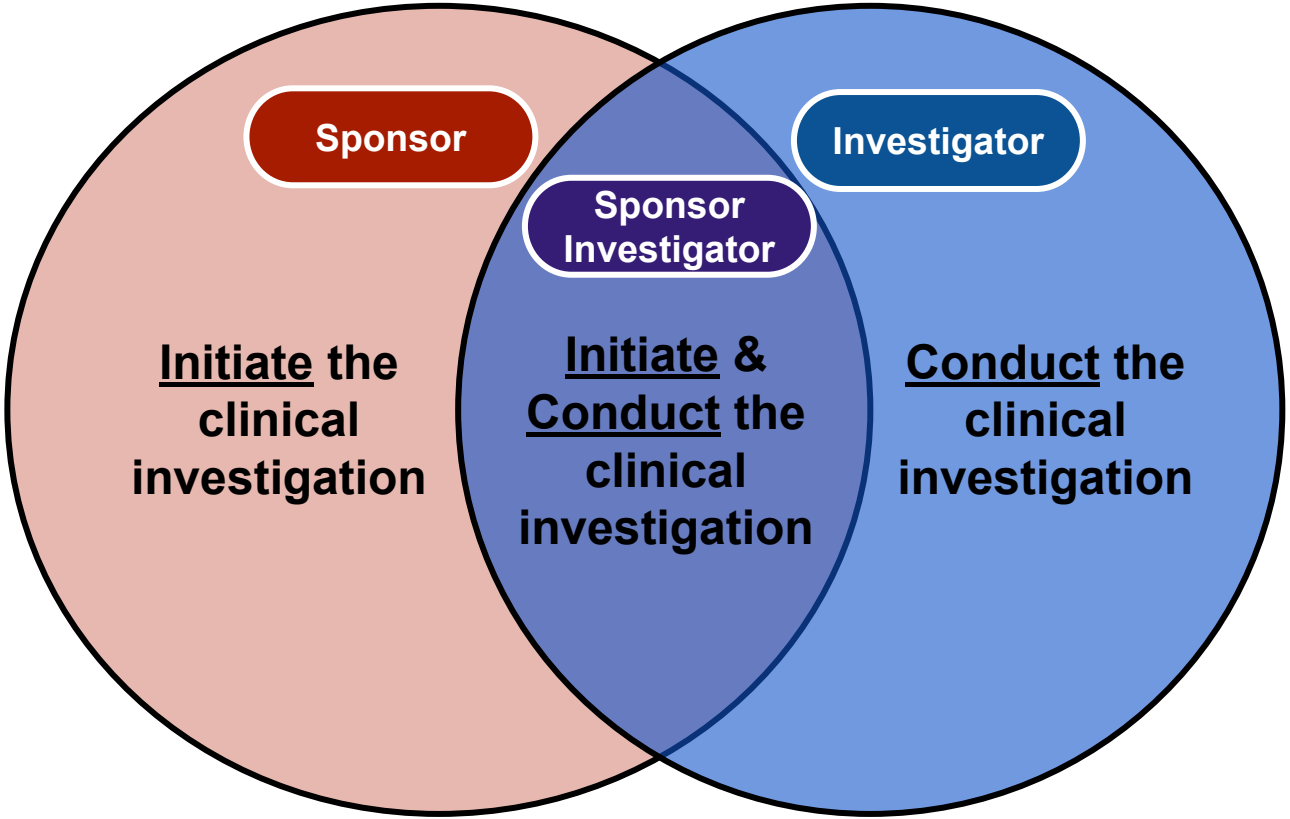
Definitions



Sponsor Responsibilities	Investigator Responsibilities
• **Select qualified Investigators, monitors**	• **Protect the rights, safety, and welfare of subjects under the investigator's care**
• **Obtain information from the Investigator** (e.g., signed Investigator's statement, Investigator's CV etc.)	• **Ensure that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations**
• **Inform investigators** (through IB, a current version of the IRB approved protocol, inform about the new observations/ SAEs, safe use of drug)	• **Provide assurance of IRB review by a qualified IRB for initial and continuing review and approval of the investigation**
• **Assure the compliance of investigators** (as per obligations addressed under the signed Statement of Investigator (i.e., FDA Form 1572), the general investigational plan, or applicable FDA regulations)	• **Investigator record keeping** (To accurately document the case histories and disposition of the drug including dates, quantity and use by subjects)
• **Ensure proper monitoring of the progress and conduct of the clinical investigation(s) at each of the involved study sites**	• **Investigator record retention** (To retain all correspondence relating to the use of human subjects in research, as well as copies of the IRB application forms, approval notices, and signed Informed Consent Documents (ICD)
• **Maintain an effective (i.e., up-to-date) IND** (i.e, will review & evaluate evidence relating to safety and effectiveness of the drug, submit Safety reports, Annual Reports, Protocol amendments to FDA)	• **Control of the investigational drug** (Ensures the investigational drug not given to any person not under the investigator's care)
• **Ensure that the FDA and all participating Investigators are promptly informed of SUSARs and/or other newly identified, significant risks related to the investigational drug.**	• **Inspection of investigator's records and reports** (Must allow FDA's authorized officer access to all records to verify the information)
• **Record-keeping and record retention requirements** (Maintain adequate & accurate records of the receipt, shipment/ disposal of the drug and Retain records for up to 2 yrs)	• **Delegate authority to qualified individuals**
• **Disposition of unused supplies of the investigational drug** (Assure safe return and disposal of unused investigational drug from each investigator who discontinued/ has been terminated)	• **Furnish all reports i.e, Progress reports, Safety reports and Final report to sponsor**
• **Inspection of the sponsor's records and reports** (Must allow FDA's authorized officer access to all records to verify the information)	• **Must take adequate precautions to ensure the safe and secure handling of the investigational drug if it is a controlled substance.**
• **Update ClinicalTrials.gov records (if a responsible party)** (when there is a change in recruitment status, protocol amendments, and results for an applicable clinical trial as per CT.gov's reporting requirements.)	• **Provide adequate medical care to trial subjects** (in case of AEs/ abnormal lab results related to trial)
• **May transfer of full/ partial obligations to CRO in writing** (shall be subject to same regulatory action as a Sponsor)	• **Promptly update the financial disclosure to sponsor as needed and for 1 year following study completion**

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