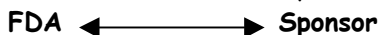


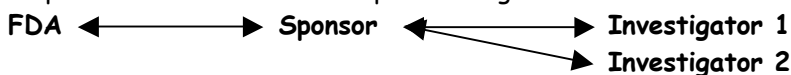


The three traditional major relationships in a clinical investigation are linear.

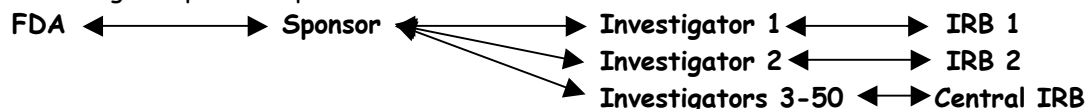
- The FDA works with the Sponsor to work out an investigational plan.



- The Sponsor selects one or multiple investigators.



- Each investigator puts the protocol before their IRB.



There are, however, a wide variety of other parties such as CROs, coordinators, monitors, consultants and DSMBs and various sub-contractors. With each additional entity there are more possible relationships and more distance between the end points. This can lead to a game of "telephone" or "gossip" in which each person repeats what another person allegedly said until no one knows what is real.

**RULE:** If you engage in a game of telephone, do not be surprised by misinterpretation. .  
IRC reserves the right to go back to the source, if necessary.

### IRC and the Client

IRC may contract directly with the sponsor or the CRO who may submit information on behalf of the investigator. IRC may contract with an institution or an investigator directly.

### The IRB and the Principal Investigator

The regulations all presume a 1:1 relationship between IRB and PI as if they were both within one site. Regardless of who IRC's client is, the basic relationship remains between the IRB and the investigator. The approval letter will be issued to the investigator. The sample consent form negotiated with the client may be individualized for each investigator.

IRC holds the investigator responsible for assuring that studies are conducted according to the approved protocol and for all actions of the staff and sub-investigators with regard to the protocol.

### The IRB and "Hidden" Parties

In order to have a better understanding of the organization of the study, IRC asks that all the active parties involved in the study be disclosed. These might include the SMO, the CRO, recruiters, surveyors, marketers, etc.

