



Federally funded studies can present much more variety in the number of parties involved than in clinical studies. There is a funding source which could be government, personal, foundation or other. There may be an external data manager, statistician, surveyor, interviewer, recruiter, site or a myriad other groups and sub-contractors,

With a wide variety of parties there are more chances for a game of "telephone" or "gossip" in which each person repeats what another person allegedly said. IRC reserves the right to go back to the source, if necessary. **RULE:** If you engage in a game of telephone, do not be surprised by misinterpretation.

### **IRC and the Client**

Our client is generally the company represented by the person submitting an application. Often this is the company that was awarded a contract. Occasionally it is a sub-contractor that is actually carrying out the human subjects interactions while the contractor guides the process.

If there is federal funding involved, the company should have a federal wide assurance or FWA. This FWA is a promise the company has made to have appropriate policies and procedures for conducting human studies. IRC often asks to have assurance that those policies are in place.

The client company is responsible for the conduct of studies it supports.

### **The IRB and the Principal Investigator**

The regulations all presume a 1:1 relationship between IRB and PI as if they were equals within one site. Regardless of who IRC's client is, the basic relationship is 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.

Some studies have multiple sites and sub-investigators (e.g., school sites). IRC holds the investigator responsible for assuring that studies are conducted according to the 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.

