



Premise: A business relationship is commonly based on a signed agreement for provision of services.

Problem: Many potential clients are put-off or over-burdened by the idea of negotiating a contract through the system.

Solution: IRC has a short indemnification form that is the minimum possible unit acceptable to IRC. The current form(s) are in Section 4.5, Forms. The following sets out our expectations.

RELEVANT ISSUES - alphabetically

By placing a study with our IRB, you are agreeing to the following:

Confidentiality by the IRB: IRC makes every effort to maintain all materials as confidential. Members and staff are periodically reminded of this requirement. Auditors from the FDA and other regulatory bodies have the right to audit files and to make copies of them. Sponsors auditing the IRB will have access only to their own records. *Accreditation requires that the accreditation team have access to all records.*

Consent: See section 3.4 The obligation to obtain informed consent from subjects rests with the investigator, who is charged with considering fully the consent process as well as documentation of consent. The duty can be delegated but not with impunity.

Consultants: IRC retains the right to select consultants, when necessary, and to charge directly for such services. Consultants will give advice and counsel to the IRB but cannot vote.

Education: Investigators are charged with the ethical conduct of research for which they are responsible. All investigators will complete a recognized course of study regarding the Responsible Conduct of Research at least every three years. (Specialty courses, if approved in advance, may substitute.) Investigators must assure that their key personnel are adequately trained.

Fees: IRC's client is responsible for payment of all charges.

Good Clinical Practice - Good Research Practice: The principal investigator should be principled. All investigators are charged with knowledge and understanding of the conduct of research and protection of subjects. Clients conducting FDA regulated investigations are charged with knowing and following the GCP requirements.

Human Research Protection Program: Clients are expected to have a program with a written policy statement concerning protection of subjects.

Indemnification of IRC and its IRB: IRC requires indemnification from the applicant. If the applicant is an investigator, indemnification should come from the sponsor. If the applicant is a sponsor with multiple sites, the indemnification must apply to all sites reviewed for the study.

Indemnification is useless unless there is some assurance that the entity indemnifying has the ability to back it up. Applicants will have adequate means of backing their indemnification promise. IRC may ask for assurance of that ability.

Injury: IRC should be given a clear statement of the sponsor's and/or investigator's policy regarding compensation to subjects for harms incurred. Should a sponsor not include a statement, the relevant information on the consent document will apply.

Relationships: All human subjects requirements set by performance sites must be met. IRC must be informed of any changes required by institutional officials.

Reports: IRC clients are responsible for submitting complete and honest reports and responses. IRC must be informed of all adverse events or problems or device effects that are serious, related and unexpected, all serious or repeated protocol violations, FDA warning letters, and monitoring reports describing serious or continuing non-compliance.

Safety: IRB review is to assure compliance with federal human subjects protection standards and with ethical research practice; it *cannot assure* safety or freedom from harm. Investigators are expected to provide full and complete disclosure of all pertinent facts, including those which may not be specifically requested in the application but which are nevertheless relevant.

State and Local Law: IRC attempts to notify clients of applicable state or local law but makes no claims to provide legal counsel. Clients are advised to be aware of local and state laws.

SPONSOR Special Responsibilities: Sponsors are expected to select and train qualified investigators. Sponsors are presumed to have provided complete, honest and objective information. Sponsors will have a clear policy regarding compensation for injury that does not require a subject to resort to forceful measures. Sponsors shall assure that clinical studies undertaken meet ethical and regulatory standards for protection of human subjects. Sponsors will conduct appropriate on-site monitoring and will report any serious and any continuing non-compliance or problems.

Surveillance and Monitoring: The only regulatory requirement for IRB monitoring states, "An IRB shall conduct continuing review of research . . . and shall have authority to observe or have a third party oversee the consent process and the research." (21 CFR 56.109(c))

Continuing review is a committee process. IRC expects that sponsors will monitor the conduct of all investigations as required by FDA and ethical standards. The IRB has the right to conduct on-site review of a random sample of sites and of selected sites. IRC's clients will be responsible for the direct expenses plus a percentage.

