

INITIAL FULL BOARD SUBMISSION

Eight packets of material should be submitted. Each packet should be completely collated and fastened so that each packet is ready for distribution to IRB members upon receipt. (Electronic submission is also available.) A checklist is available in the Forms section.

A cover letter is optional but is *often wise*. Actually, it is often the best way to present your submission to the board. It might highlight some facet of the study not obvious in the protocol such as an overview of the place of the study in a broader context. It could put into context the various players and their relationships. It should be considered a part of the record.

The IRC Application Cover Form is intended to provide an abstract of the protocol in standardized form for the reviewers and data manager; it is *not in lieu* of a good investigational protocol.

The Investigational Protocol may be in any format. Writers should recall that IRB members are diverse; members may not be knowledgeable about your field. Remember; the IRB should not need to make assumptions or intuit your needs. Extensive assistance is available in section 3.2 of this web site.

While excessive information is costly and could contain trade secrets, failure to provide sufficient information could result in the need to ask multiple questions, involve consultants, delay and further expense. If the protocol does contain trade secrets, those pages should be clearly marked.

(Grants do NOT make good protocols as they were written to fulfill a different purpose. Specific studies and a clear distinction between usual practice and what must be done for purposes of the study are required.)

Case Report Forms are considered to be part of the protocol and should be submitted. The board looks at whether confidentiality is maintained and whether there are procedures not mentioned within the protocol. This is also one way to see if the HIPAA "minimum necessary standard" is met.

Consent forms must have all required elements of consent unless justification for waiver from some or all of the elements is presented and accepted. These forms should be simple and literate. Compliance with California law requires that ten elements be described on any consent form for a "medical experiment" and that an Experimental Subjects Bill of Rights be appended. (See Consent Form) An electronic copy will assist IRC in sending mark-ups more rapidly.

Recruitment and Advertising information must be reviewed. This information refers to both process (on which protocols are often silent) and documents. The IRB needs to review the copy of any advertising. Advertising is becoming increasingly inventive.

Planned appearances to talk about research on talk shows and other forms of public relations, are considered to be advertising. (See, Advertising and Recruitment)

The Principal Investigator Application Form is unique to IRC's IRB and is admittedly long. Unlike institutionally based committees, our IRB is remote and requires additional documentation of site and investigator qualifications. This documentation should illustrate particular qualifications to conduct research as opposed to practice medicine. That is, it should illustrate research experience, sufficient personnel to complete case report forms, ability to react to whatever emergencies might be presented by the research, and GCP knowledge. The reviewers should be able to visualize the setting. Investigators need to specify all sites at which the research will take place and to satisfy local requirements.

This IRB will not knowingly approve a study to be conducted at a site at which a local IRB has prior jurisdiction. If the local facility has an IRB, that IRB must be consulted. IRC has a Waiver and Certification form to demonstrate local IRB agreement.

The Investigational Drug Brochure frequently contains proprietary information. If it does it should be clearly marked "Confidential." Two copies of the Brochure are needed.

An Investigational Device Exemption (IDE) must be obtained from the FDA for any significant risk device. An abbreviated IDE may be obtained under 21 CFR 812.2(b) if the IRB approves the protocol and agrees that the device poses no "significant risk" as defined in the regulation. IRC requires a separate document detailing why the sponsor and the investigator allege that the device is a non-significant risk device.

INITIAL EXPEDITED SUBMISSION

Two packets of material should be submitted. One packet is for the file and the second is for the reviewer. Should the reviewer ask for full board review, additional copies will be requested or made at IRC with the costs recharged to the client.

Although the IRB and investigator responsibility remains the same, the information needed may be in a format appropriate to the simpler nature of an expedited request.

Expedited Review Cover Page

This form is critical in establishing that the use of this process is warranted.

Protocol

This protocol should have the usual component parts of a protocol although the information may be much briefer.

Consent forms

Since expedited review is for simple procedures the consent forms should be simple.

Principal Investigator Application Form (expedited review)

The shortened form is available. It includes the waiver and certification information. Items mentioned in the header are also required.

