Pharmaceutical Management Branch/Cancer Therapy Evaluation Program/Division of Cancer Treatment and Diagnosis/National Cancer Institute
6130 Executive Blvd * Suite 7149 * Rockville, Maryland 20852
Phone: (301) 496-5725 * Order fax: (301) 480-4612 * Other fax: (301) 402-0429 * E-mail: pmbafterhours@mail.nih.gov

## FAQ: Why is my IRB asking all these questions?

"My IRB is driving me crazy! …Yesterday they wanted to know the IND number for an agent. Today, it's a question about the incidence of an adverse event. I can hardly wait for tomorrow!"

Institutional Review Boards can certainly add an element of "excitement" to anyone's day. These multidisciplinary panels ensure that the patient's rights and safety are addressed in advance and never violated. So, they have questions, and those questions can be difficult to answer.

One of the most common questions we receive is, "What is Agent X's IND number?" Because this question has become so common, we are now including the IND number for each CTEP IND agent on the cover page of every protocol. The NCI-supplied agent's NSC is also included. (Older protocols may still be missing the IND on the cover page.)

The most recent Investigator's Brochure (IB) will provide a good estimate of known adverse event incidence (see the FAQ on how to receive an IB), and some CAEPRs (included in the protocol document) do, too.

"What about Special Exception and Treatment Referral Center protocols? What type of IRB approval is needed?"

•"Special Exception" allows individual patients access to investigational agents. Thismechanism is the functional equivalent of a compassionate IND, but differs from it in that the investigator uses the CTEP IND rather than obtaining an individual investigator IND from the FDA. Special Exception protocols are patient-specific, available to qualified investigators, and must be IRB-approved for each individual patient.

•For certain high-priority diseases, the NCI identifies patient populations and creates a Treatment Referral Center (TRC) Protocol for the NCI-designated Comprehensive Cancer Centers. TRC protocols require IRB approval at each participating institution.

So, go easy on your IRB, They are trying to protect patients from exploitation, confusion, or harm. Let us know how we can help.

September 9, 2008