



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: How do I get an Investigator Brochure?

PMB handles all requests for Investigator Brochures (IBs) where CTEP holds the IND and distributes the agent. Our company collaborators consider the information contained in these documents confidential. We can only release IBs to registered, active investigators with an approved LOI, concept, or protocol. While CTEP has received approval from collaborators to distribute the information electronically, the agreement does not allow recipients to post these documents on any web site, nor does it allow secondary distribution. (That is, when we give it to you, you can't pass it along.)

- ▶ You must provide
 - your own name, phone number, the investigator's name and NCI number (and this must be active, not pending or suspended)
 - the NCI LOI, concept, or protocol number, and
 - the NSC or name of the study agent.
- ▶ Once your site orders study agent, all investigators who have ordered the study agent will automatically receive updated versions of the IB to submit to your IRB.

All requests for IBs should be e-mailed to ibcoordinator@mail.nih.gov. This ensures that we receive a complete, correct e-mail address. You may call the IB Coordinator at 301-496-5725 in the rare instance where you cannot use e-mail.

- ▶ If you call (rather than e-mail), you must leave an e-mail address in addition to all the information listed above. When you leave your e-mail address, please speak slowly and clearly, and repeat it TWICE.
- ▶ PMB usually responds to requests for IBs within two business days.
- ▶ Keep in mind that IB attachments are very large; the average is 2MB, and a few are larger than 5MB. Check your mailbox to make sure you are able to receive big attachments. If not, please note this in your e-mail or voice mail and provide a suggestion for an alternate delivery method. (For example, we can mail the IB as a CD.)
- ▶ If you do not receive the IB electronically within two business days, please e-mail or call to follow up.

Please note that PMB does not provide IBs to non-US sites for submission to non-US regulatory authorities. These must be obtained directly from the drug company.

September 11, 2008

*Prepared and distributed by the Pharmaceutical Management Branch, CTEP, NCI.
Please do not re-distribute or post without permission.
Information in this FAQ is subject to change without notice; check periodically for updates.
Please contact PMB at (301) 496-5725 if you have questions.*