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FAQ: How do I obtain an investigator brochure?

Answer: Current versions of the Investigator Brochures (IBs) and related IB documents [Summary Of Changes, Appendix, Addendum, Erratum] where **CTEP holds the IND and PMB distributes the agent** will be provided through OAOP. All study PIs, site PIs, study grant PIs, investigators who received agent shipments or transfers, designated CTEP site coordinators for certain trials, NCTN/ETCTN/Consortium/Network Operations Office "Org-to-PMB IB" contacts, and CIRB "Org-to-PMB CIRB" contacts will be notified via email when new IB documents are posted in OAOP. These notifications will be sent from "NCI PMB Investigator Brochure Notification" with the email address <u>NCIPMBBrochure@mail.nih.gov</u>.

To access IB documents in OAOP you must have an active CTEP IAM account with a current password and active person registration status

- 1) Log into <u>OAOP</u> and select the "Investigator Brochures" tab.
- 2) If your role is Org-to-PMB IB contact or Org-to-PMB CIRB contact, skip to step 5.
- 3) Enter the matching NCI Investigator Number and Investigator Last Name associated with the approved Protocol, Concept, or LOI you are looking for.
- 4) Click "Get Info" and verify the information that is displayed. Then click "Verify Investigator."
- 5) Click on the NSC or Agent Name list of values icon and search for the agent by entering the NSC number or agent name.
- 6) Select the NCI Protocol/Concept/LOI number from the drop down menu.
- 7) Click "Search IB." The results will only display current IB documents related to the specific search criteria selected above.
- Repeat the search for each NCI Protocol/Concept/LOI and each agent involved in a particular Protocol/Concept/LOI. If the NCI Protocol/Concept/LOI involves a combination IB, it will display when searching for either agent.
- 9) To open the documents, double click on the file and sign the Statement of Confidentiality & Non-Disclosure by entering your own CTEP IAM username and password.
- 10) Click on the "Help" link at the top right corner of each page in OAOP for additional instructions.

Our company collaborators consider the information contained in these documents confidential. These documents cannot be posted on any web site or distributed to non-study related personnel.

Please note that you must contact PMB for more information if you are looking to provide IBs for submission to non-US regulatory authorities.

Questions regarding investigator brochures can be directed to the Pharmaceutical Management Branch (PMB), CTEP, NCI by calling (240) 276-6575 Monday through Friday from 8:30am to 4:30pm Eastern Time or by emailing <u>ibcoordinator@mail.nih.gov</u> at any time.

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