

Are Meriter Pharmacists Engaged in My Drug Study at Meriter?

1. Typically, **Meriter pharmacists won't be engaged in research** if they are:
 - a. Storing study drug, keeping inventory, tracking study drug accountability, including returning unused drug to the manufacturer or sponsor
 - b. Randomizing subjects
 - c. Holding the blinding key for a study (unblinding a subject if circumstances require)
2. Only people **engaged** in research need to be added to the **Meriter application** in the study personnel sections.
3. FDA doesn't have the same notion of engagement as OHRP.
4. For FDA we're using who the FDA thinks should be listed on the 1572 as those who are engaged in research. See the [2010 Frequently Asked Questions – Statement of Investigator \(Form FDA 1572\) | FDA](#) question #33. This specifically addresses whether a pharmacist should be listed on the 1572. For more background on FDA's thinking on what research activities qualify a person as conducting (engaged in) research, see questions #31 – 32. FDA has a much narrower definition of "engagement" than HHS/OHRP.
5. Please solicit a **support letter** ([download template here](#)) from the Pharmacy Manager. Attach it to your Meriter Research Compliance Submission. The support letter should detail the resources Meriter Pharmacy agrees to give the study. For example, how many pharmacists may be involved, their duties related to the study, study specific training required, etc. The letter should cover the general terms and conditions of the Pharmacy Department's support of the study.
6. **Training** – Pharmacists will need study specific training on drug management/accountability, how randomization is done and any special instructions on blinding/unblinding a subject should circumstances require it.