

You are the PI of a multicenter clinical trial and you are confronted with the situation below

### **None Dispensed Study Drugs Scenario**

Participant number 10-000-31 came to the clinic for a study visit on 12<sup>th</sup> March 2009 and reported that he had last taken his study drug on 7<sup>th</sup> November 2008 since the last time he had drug dispensed to him was in October 2008 at an offsite visit by James. On checking the records it was found that he had been dispensed study drug in offsite visits by James Kiarie, a nurse at the site, in November and December 2008 and in January 2009, yet the participant reported that he was not visited.

This was reported to the assistant study coordinator on 12<sup>th</sup> March 2009 who informed the study coordinator and administrator on the same day. A meeting was scheduled with James on the 13<sup>th</sup> of March 2009. During this meeting the participant was called and confirmed he had not been given study drug since October 2008 and had not been visited at his home or place of work. He also pointed out that he was not given a return date to the clinic and was not reimbursed money during the offsite visit in October. James at this point denied participant claims.

The Principal Investigator was informed of this issue on 13<sup>th</sup> March 2009 and scheduled a meeting with James on 14<sup>th</sup> March 2009. During this meeting James further denied having not given the participant study drug or performed the visits.

### **Questions**

1. Why is it important to investigate this discrepancy?
2. What investigations would you carry out to find out what actually happened and why
3. How would you handle the data
  - a. Submitted by James from the offsite visits in November and December 2008 and in January 2009
  - b. Submitted by James from other offsite visits
  - c. Submitted by other nurses from offsite visits
4. Who would you report this occurrence to.
5. What possible corrective actions can be taken by the site to prevent recurrence
6. What possible actions can be taken on you as the PI after this error is reported