Monday 4th November

Practical: Good Clinical Practice

1. What documents/records would serve to demonstrate that research staff are "fit for purpose" to conduct research related duties?

2. What activities can be undertaken/systems put in place to ensure clinical trial data can be accurately reported and verified?

3. Patient confidentiality: what actions should be taken to protect sensitive research data?

4. What is the purpose of a Data Monitoring Committee?

5. A patient diagnosed with dementia is eligible for a trial of a new treatment but is unable to speak English. There is no translation for the information sheet in existence. The patient's adult son is very keen for his mother to enter the trial and offers to act as an interpreter. How would you proceed?

6. A participant informs you that he wishes to prematurely withdraw from a trial. What information, if any, should you attempt to obtain regarding his withdrawal?