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Involvement of Collaborators in the Study Team

Scenario

Cancer Research Group LMN is embarking on an investigator-initiated non-therapeutic research study. The Principal Investigator (PI) of the study is Professor X. As part of the study protocol, breast tissue biopsy samples, pharmacogenetic and circulating tumor cell blood samples will be collected from treatment-naïve breast cancer subjects. The collected biospecimens will be sent to an external laboratory for analysis. Professor X will be collaborating with external laboratory Z for the processing and analysis of these biosamples.

In agreement with the PI, laboratory Z has appointed their staff members Mr A and Doctor B to be the collaborators in this research study. Mr A and Dr B will oversee a team of laboratory technicians within laboratory Z, who will be performing the physical processing and analysis of subjects' biosamples throughout the study.

As the study coordinator, what documentation relating to the study collaborators (Mr A and Dr B) must you ensure is in place before starting the study?

1. Both Mr A and Dr B must have their roles as collaborators indicated in the IRB application form.
2. As Mr A and Dr B are involved in the study conduct, they are required to complete their financial conflict of interest (FCOI) trainings and submit their FCOI declarations to DSRB.
3. Mr A and Dr B will be NOT be required to undergo CITI and GCP trainings for their roles as study collaborators.
4. A copy of the latest signed and dated CVs for Mr A and Dr B must be kept in the investigator file.
5. Both Mr A and Dr B must complete the necessary protocol-related trainings, and their training records must be kept on file.
6. After their trainings have been completed, the PI must include both Mr A and Dr B on the study delegation log prior to initiating any study-related activities.
7. As Mr A and Dr B are overseeing a team of lab technicians within external laboratory Z who will be processing the biosamples, Mr A and Dr B should ensure that appropriate training records and study-related documentation for these lab staff are maintained by laboratory Z. These documents should be accessible by the PI and/or his study team during the course of the study.

References:

1. *NHG PCR SOP 501-A02: Responsibilities of the Research Team*
2. *NHG PCR SOP 501-A03: Training and Education*
3. *NHG PCR SOP 501-B03: Study Initiation*
4. *NHG PCR SOP 501-B05: Documentation*

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