Questions on ICH-GCP Guidelines

You may use the ICH-GCP guidelines E6 document and the FDA regulations for the conduct of clinical trials to answer the questions below

1. Discuss the Key elements of the Clinical Trial Regulations?

2. What are the expectations of PI responsibilities in the process of providing oversight at the clinic site?

3. Discuss the historical events that led to the institution of the Belmont Report? How has the Belmont Report shaped the practice of clinical trials?

4. Discuss the essential documents required by ICH-GCP to conduct a site initiation visit?

5. You are a new CRA required to qualify a clinical research site for a study in Follicular Lymphoma, FL, how will you satisfy the requirements to qualify the Principal investigator by education and training, and the clinical research site to conduct the study? Your considerations should include modalities to diagnose FL, such as Hematology sample collection, imagining modalities, consider standard of care, SOC for the management of FL disease, assessment for the response to treatment and the site resources to support the PI and conduct the study effectively

Your report is due by 9 PM on Thursday, 30 Jul 2020.