**Coordinator Protocol Review Checklist**

Questions to ask yourself, items to consider on your first reading of the protocol:

* Have adhesive tabs to visually identify vital information for future reference (i.e., what to do in case of an adverse event during study drug administration?)
* Create a troubleshooting contact list with numbers/emails for CRO, Medical Monitor, IVRS, Investigational Pharmacy… (Who do I need to talk to when questions arise?)
* What are the reasons for conducting the current study?
* Can you define for a subject what an investigational drug study is? (The subject should understand that the drug has been previously used in humans, but additional human data are needed before the drug may be introduced to the marketplace)
* What are the inclusion/exclusion criteria?
* Can you briefly outline the details of the study to a potential subject?
* What are the potential benefits of the study drug?
* What are the potential side effects of the study drug?
* What is the time commitment required for the coordinator? For the subject?
* Are you familiar with any questionnaires that will be administered?
* Are you clear on the instructions for administering the test article?
* Are there potential barriers to recruitment, retention, and subject compliance?
* What is the length of the study?
* What is the number of on-site visits required? Virtual visits?
* What procedures will be performed at each visit?
* Do the details of the protocol match with the details of the ICF?
* Consider the protocol, Lab Manual, and Manual of Procedures for source document creation and subject visit planning (In what order do things need to be performed?)