**How to Create Study Coordinator Binder**

**Items to Include in Binder**

* Study Contact List (include contact information for key study representatives of sponsor, CRO, etc.)
* Study Protocol (flag important sections such as: schedule of events, investigational product information, study synopsis, inclusion/exclusion criterion, AE/SAE guidelines)
* IVRS information and help-desk contacts
* Visit checklist for each study visit to give guide for back-up coordinator in case of emergency or absence of primary coordinator. A visit checklist template is located in the Study Coordinator Trial Starter Kit.

• Copy of the most current Informed Consent Form

• Data Capture/EDC guideline manual and help-desk contact information