Investigational Study Checklist for Coordinators

\_\_\_ 1. Deliver Protocol, Investigator’s Brochure, Pharmacy Manual, MOP or other applicable study documents electronically to the Investigational Pharmacist.

\_\_\_ 2. Email the research pharmacy with the Principal Investigator’s name, coordinator’s name (if known) and billing contact. In lieu of providing the PI and coordinator’s name, the coordinator can complete the top section only of a blank Release of Drug Form and deliver it with the protocol electronically.

\_\_\_ 3. Provide any known limitations or concerns at time of protocol submission.

\_\_\_ 4. Allow the pharmacy adequate time (5-7 business days) to review the protocol, submit questions about procedures and return the signed release form.

\_\_\_ 5. Once pharmacy sends a signed Release of Drug Form, return the form with a signature from the Principal Investigator prior to study related requests/activity.

\_\_\_ 6. Verify with the sponsor if they need to visit the pharmacy prior to scheduling a Pre Site Visit. If so, schedule a date/time with pharmacy.

\_\_\_ 7. Verify with the sponsor prior to the Site Initiation Date if pharmacy personnel are requested for the Site Initiation Visit or if the sponsor will require a visit to the pharmacy. If so, schedule a date/time with pharmacy. If no, inform pharmacy when site is activated.

\_\_\_ 8. Once an IRB has approved a submitted protocol, email the approval to the Investigational Pharmacy and all subsequent renewals.

\_\_\_ 9. Email all amended protocols, pharmacy manuals, MOPs, IBs, etc to the pharmacy in a timely manner of receipt from the sponsor.

\_\_\_ 10. Contact the Investigational Pharmacy at least two business days prior to scheduling patients for a dispensing visit.

\_\_\_ 11. For each new patient enrolled, email the Investigational Pharmacist with the patient’s name, MRN, DOB and allergies or provide a completed prescription order form with the same information.

\_\_\_ 12. Schedule a date/time with the pharmacy for all pharmacy required monitoring visits.

\_\_\_ 13. Schedule a date/time with the pharmacy for Closeout Visits.

\_\_\_ 14. Contact the pharmacy when studies are closed out with the IRB.