

New Study Checklist

REGULATORY

- Regulatory documents received **Notes _____
- Regulatory documents sent to sponsor **Notes _____
- ICF sent to sponsor for approval **Notes _____
- ICF approved by sponsor **Notes _____
- Submitted to IRB
- Approved by IRB
- Received invoice from IRB
- Received invoice from pharmacy
- Sent invoices to sponsor

CONTRACT

- Contract received
- Contract requests sent to sponsor **Notes _____
- Revised contract received
- Revised contract signed and sent to sponsor
- Budget received **Notes _____
- Final contract and budget signed and filed
- Spreadsheet to record trial participants created

STUDY SUPPLIES & MISCELLANEOUS

- CRFs received (tabs created for AEs/SAEs, Patient Information, H&P-Procedures, etc.)
- Binders received (new tabs: general/new study regulatory binder tabs)
- Binders created (ICF binder, study drug, IB-AE-SAE-IND, etc.)
- IVRS and eCRF information received
- Drug received
- Other supplies received _____
- Yellow ICF-sub-study log created
- Brochure and subject drug card created and submitted to IRB
- Drug set up in Mysis EMR
- Protocol and IB scanned and stored on network and DocuShare
- Manuals-procedures scanned and stored on network and DocuShare
- Source documents created
- Starter packs created (include docs kept in "Starter Pack Forms")