Inova Fairfax Hospital/Inova Fairfax Hospital for Children
Department of Pharmacy Services

Investigational Drug Study
Pharmacy Set-Up Process **

To Start Work on a Study:

___ Protocol (latest version)
___ Pharmacy Binder (if available)
___ Physician Brochure - *This is the Investigators Brochure that comes with each study- this brochure contains the research data done on any humans or animals)* (especially if no pharmacy binder available; do not need pre-clinical study info, only human study info)
___ Name and contact information for study nurse and name of all prescribers approved by IRB
___ Anticipated enrollment in specified timeframe so pharmacy workload/reimbursement can be calculated

First Progress Point (meeting with Study Nurse):

Purpose: To determine how this study will be carried out specifically at IFH/IFHC and answer any questions that come up after initial reading of above documents.

___ Resolve any questions about how drug will be prepared
___ Determine what supplies sponsor supplied vs. hospital supplied
___ Determine how drug will be labeled (IFH/IFHC label with what comments, sponsor labels)
___ Determine how drug will be delivered to patient (regular pharmacy delivery, research nurse or other method)
___ Determine whether medication is to be charged or not
___ Determine whether 24 hrs/day x 7 days/week enrollment vs. daytime hours
___ Determine who/how randomization will be done (study nurse vs. pharmacist, system, and passwords for how many pharmacists)
___ Determine how medication is to be charted
___ Discuss any discharge or outpatient medication dispensing, if any.
___ Discuss specific information/elements (e.g. weight) that need to be on MD orders
___ Exchange information about site initiation visit date

Above information is used to request Lastword entry/charging parameters and pharmacy labeling capability from Information Systems (a minimum 2 week lead time is requested by IS if complex or IS in middle of big implementation)

Second Progress Point (meeting/call/email with Study Nurse):

___ Draft Pharmacy Guideline/Procedure is given to study nurse at this meeting for review and to identify or correct any errors.
___ Draft Pharmacy Guideline/Procedure is given to a 2nd pharmacist for review and to identify or correct any errors.
___ Draft Drug Information sheet is given to study nurse at this meeting for review.
___ Study Nurse: Draft Physician Orders written and given to IDS pharmacist at this meeting for review of medication orders and to identify or correct any errors.

Third Progress Point (meeting/call/email with Study Nurse):

___ Study nurse signs off on Pharmacy Guideline/Procedure and Drug Information sheet
___ 2nd pharmacist signs off on Pharmacy Guideline/Procedure
___ IDS pharmacist signs off on Physician Orders
___ Study start date determined
___ Contact information re: periodic audits anticipated, vacations, etc. exchanged to insure availability of IDS pharmacist

Study Initiation/ Patient Enrollment:

___ Physician Orders is required for initial drug to be prepared.
___ Consent Form (signed) is required for initial drug to be prepared.
___ Study nurse places copy of Drug Information sheet on patient's chart, if needed.
___ Periodic assessment of staff competence and provide in-services for new staff

Monitor Visits:

___ Schedule appointment with IDS pharmacist (allows preparation/self-audit prior to monitor visit)

Study Closure:

___ Need Letter indicating closure and any specific instructions for return of drug, final accountability sheets, saved vials or labels, etc.
___ Study binder removed from shelf and put into storage onsite/offsite
___ Notify staff of study closure (signs, email, etc.)
___ Notify Information Systems to de-activate investigational drug orders/entries
___ Complete final drug accountability audit and return drug to sponsor
___ Reconcile pharmacy reimbursement due with funds received
___ Document workload expended for internal tracking

**Note: Unique study requirements may require additional steps