Protocol Drug Handling and Administration Guidance Document

Sections to include:

- Product description (i.e. tablets, vials, powder, etc…- if capsules of varying doses are supplied these should be described)
- Packaging (i.e. hard gelatin capsules in bottles, capsule s in blister packs, vials, etc…)
- Storage conditions
- Packaging and labeling *(must specify the contents of the label if the Sponsor-Investigator developed the agent: name of drug, quantity of drug, date of packaging, recommended storage temp, lot number)*
- *Manufacture (must specific if the Sponsor-Investigator developed the agent)*
- Administration (include reconstitution instructions – if applicable)

Note: if the protocol involves a placebo the sections listed above apply to all components of the protocol's treatment regimen (including placebo – if applicable)

DRUG HANDLING AND ADMINISTRATION EXAMPLE:

Investigational Product X

[Investigational Product X] will be provided by [drug supplier – if applicable]. [Investigational Product X] will be supplied as [dose(s), color, pill/vial/powder].

Medication labels will comply with US legal requirements and be printed in English. They will supply no information about the patient.

[Investigational Product X] should be stored at [x°C to y°C (x°F-y°F)]. All excursions should be brought to the Sponsor-Investigator's and [drug supplier's – if applicable] attention for assessment and authorization for continued use. Ensure that the drug is used before the retest expiry date provided by [drug supplier].

All protocol-specific criteria for administration of study drug must be met and documented before drug administration. Study drug will be administered only to eligible patients under the supervision of the investigator or identified sub investigator(s). During the study, [Investigational Product X] will be administered [route of administration] as [dose] every [frequency]. Patients should be instructed to take their [Investigational Product X] at [treatment regimen specifics – time of dosing / dietary specifics, etc…]. The investigator should instruct the patient to take the study drug exactly as prescribed (promote compliance). All dosages prescribed and dispensed to the patient and all dose changes during the study should be recorded.

If the patient forgets to take his/her dose [dose is made up / dose is not made up – specify details for making up the drug or clearly state when the patient is not to make up a dose].