CSC Study Visit Checklist

The purpose of this checklist is to prompt or assist you in the tasks and responsibilities that occur during the course of a study visit. This document is not a required regulatory document. This checklist will vary depending on the nature of each study. You are therefore encouraged to use this only as a guide and to edit as is applicable to your study.

Set-up prior to the visit:

* Screen for eligibility
* Send contact letter to subject (IRB approved)
* Contact subject (via phone or in clinic)
* Schedule appt with subject, PI, and CSC
* Mail appointment letter. May want to include Informed Consent Documents and HIPAA documents.
* Order labs, radiology, etc.
* Order study medications
* Fax drug order to Research Pharmacy
* Verify that MD signed off on labs and study medication orders
* Fax payment request to AREF
* Call subject to confirm study visit and location

Day of visit:

* Informed Consent Document (ICD)/HIPAA signed
* Original filed in regulatory binder
* Copy of signed ICD/HIPAA and the unsigned Revocation Letter given to subject
* CPRS note entered within 72 hours
* Copy of required VA forms sent to Medical Records for scanning (this includes the 10-9012 and NOPP)
* Copy of optional VA forms sent to Medical Records for scanning if PI chooses to scan (this includes the ICD/HIPAA )
* Research Flag posted in CPRS if required by the R&D Committee
* Subject added to Master List in regulatory binder
* Accounting of Disclosures form updated if applicable
* Protocol Deviations reported per VA policy if applicable
* Reportable Events reported per VA policy if applicable
* Follow up appointment scheduled
* Visit entered in CTAR
* Sponsor reporting requirements:
  + Ekg faxed
  + eCRF completed
  + labs shipped
  + drug accountability