

## **Standard Operating Procedures**

- Do you, the investigator, have Standard Operating Procedures (SOPs) for your human subject research activities? The link to a template for Good Clinical Practices SOPs that you can modify for your site as appropriate is:  
[http://info.evms.edu/research/postdocs/goodclinicalpra\\_/gcpsop04/default.htm](http://info.evms.edu/research/postdocs/goodclinicalpra_/gcpsop04/default.htm)

## **Subject Consent Forms**

- Are personnel who are obtaining consent forms from subjects authorized and trained to obtain consent for this study? The link to IRB training requirements, which includes the consent process, is:  
<http://www.evms.edu/research/protections/training.html>
- Are you following the appropriate procedures for consenting subjects including consenting prior to the initiation of study procedures?
- Did you adequately document the consent process for each subject?
  - a. Signed and dated by subject or legally authorized representative?
  - b. Signed and dated by witness? Signed on the same day as subject?
  - c. Signed and dated by authorized consentor/investigator? Signed on the same day as subject and witness?
  - d. Used the current IRB approved consent form?
  - e. Was the consent form signed before the expiration date stamped on the last page?
  - f. Was an Employee/ Student addendum consent form signed (if applicable)?
  - g. Were additional consent requirements for vulnerable subjects, including children, wards of state, prisoners, and/or cognitively impaired individuals followed (if applicable)? Information can be found in IRB SOPs at:  
<http://www.evms.edu/research/protections/docs/sop.pdf>

## **Human Subjects**

- Are you fulfilling your IRB continuing review reporting requirement? Research projects must be reviewed at least once per year as required by the Federal government. The IRB may require more frequent review. Refer to your IRB approval letter for the specific date.
- If you need to make changes in your human subject protocol, have you submitted an amendment to the IRB office and received approval prior to initiating the change?
- Have you reported any adverse events or unanticipated problems to the IRB office? All unanticipated problems and adverse events, regardless of severity must be reported.
- If you have added personnel to your human subject research have they completed their research education requirements and have you submitted an amendment to the IRB? You must receive approval prior to allowing the new personnel to participate in study activities. Training requirements at:  
<http://www.evms.edu/research/protections/training.html>
- Did you assure that IRB approval has been granted before beginning the enrollment process of human subjects in the study?

## **Files Management**

- Do investigator files contain the following IRB documentation:
  - a. Protocol (all versions)?
  - b. Approval letter (initial) for initial protocol with original informed consent?
  - c. Amendment approval(s) with approved informed consent (if applicable)?
  - d. Informed consent forms (originals) for enrolled subjects?
  - e. Continuing reviews (if applicable)?
  - f. Adverse events (if applicable)?



## **Pharmaceuticals**

- If you are an investigator using an investigational new drug (IND) or an investigational device exemption (IDE), do you have:
  - a. a monitoring plan in place for routine review of research records?
  - b. Form FDA 1572 ( IND only)?
  
- If you are an investigator do you have case report forms to document adequate and accurate case histories recording all data pertinent to the investigations for each research subject? Source documents for each subject enrolled that document:
  - a. Subject met all inclusion/exclusion criteria
  - b. Exposure to test article
  - c. Concomitant medications
  - d. Clinical assessments of the subject during the course of the study
  - e. Laboratory reports
  - f. Diagnostic tests
  - g. Dose modifications
  - h. Adverse events/death
  - i. Protocol exemptions
  - j. Early termination
  
- Are you using proper procedures for drug accountability? Do you have a drug log to include:
  - a. Receipt of study product
  - b. Dispensing
  - c. Return
  - d. Terminal disposition of product

# IRB

  

# AUDIT

  

# CHECKLIST

### **Purpose:**

To provide guidance to investigative staff to help ensure compliance with EVMS IRB and federal policies as well as to assist investigative staff with self-monitoring. ***The components listed are part of the routine compliance audit conducted by EVMS.*** There may be additional requirements depending on the approved study.

For further information, please contact Research Compliance in the Office of Research at (757) 446-8480