DATA MANAGEMENT

1. **OBJECTIVES:** Outline the methods for collection and management of data for research studies

2. **DEFINITION:** A Case Report Form (CRF) is designed to collect data required by the protocol for each study subject. A CRF could be in paper or electronic form and the information collected may include but is not limited to: medical histories, physical exams, laboratory/test results, concomitant therapy, drug/device use, etc.

3. **PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES:**
   a) Responsible for accurate and complete collection of the data generated during a research study

   b) The PI may delegate data collection to the study coordinator

   c) Responsible for reviewing and interpreting the study data

   d) Ensure that study files are kept in a secured area and that confidentiality is maintained at all times

4. **PROCEDURES:**
   a) If delegated by the PI, the study coordinator interacts with study subjects and collects data accurately and completely in the CRFs, Data Collection Forms, or Database

   b) Complete forms with a black pen and complete all fields

   c) Use IRB-approved recruitment materials for the study

   d) A log should be maintained for effective and efficient screening of potential study subjects

   e) Maintain a log for all subjects enrolled in the study

   f) Keep the original signed and dated Informed Consent Form (ICF) with study files

   g) Keep a copy of emails and/or a telephone log for issues relevant to the study with study files

   h) Keep a flow chart of study activities to ensure that protocol requirements are completed for each subject (if applicable)

   i) If the study involves drugs or devices, maintain an accountability/dispensing log

   j) When required, post a "Clinical Research Flag" in the subject's medical record

   k) Record and report Adverse or Unexpected Events that may occur during the study

   l) If a subject withdraws from the study, obtain as much information as possible relevant to the study

   m) Make corrections in the CRF by drawing a single line through the error, then initial and date. Enter correct information next to it or a memo to file. Do not use eraser or whiteout

n) A copy of each completed CRF is retained at the study site

o) If corrections are needed after the sponsor has retrieved CRFs copies, make them as directed by the sponsor to ensure consistency

p) The study coordinator reviews the CRFs with the sponsor to ensure accurate data interpretation

5. SECURITY ISSUES

a) When using electronic data capture, the computer must be password secured

b) Study files must be kept at the VA and secured in a locked area or cabinet

c) Any subject identifying information or Protected Health Information must remain at the Atlanta VA Medical Center

d) Social security numbers should not be recorded in the CRFs

e) Laptops and flash drives must be encrypted by the VA if used for transporting data outside the VA. Contact the Information Security Officer (ISO) for information about security issues