PAPM Screening fields

Protocol #

Protocol Title

Protocol Start and End Date

Department

1) Investigator information
    a. Name
    b. Completed training
2) Participant information
    a. Total participants enrolled at time of audit
    b. Total participants approved by the IRB
    c. Did the number exceed approved by the IRB?
    d. Were screening procedures performed per IRB approved protocol?
    e. Was the study conducted by IRB authorized personnel, as described in the protocol?
    f. Did each participant meet study inclusion / exclusion criteria?
    g. Were payments or renumeration made to participants?
3) Consent Document Information
    a. Total number of consent documents on file
    b. Number of consent documents signed and dated by the participant and by the investigator
    c. Number of consent documents NOT signed and dated by the participant and by the investigator
    d. Was informed consent obtained from each subject prior to the start of any study procedure
    e. Was the most recent approved versions of an IRB approved consent form (IRB approval stamp in footer) used to consent each subject?
    f. Did all subjects receive a copy of their signed and dated consent form?
    g. Are all pages of the consent form on file for each subject?
    h. Is there documentation to support that all subjects received a copy of their signed and dated consent form or they were consented -(i.e. oral consent)?
4) Data Storage and Security
    a. What type of data is being stored?
    b. What data security measures are used to protect data?
    c. Is a Data Use plan in place?
    d. How is data being stored?
    e. How is data transmitted and filed to storage medium (backed up) and how often is (was) this done?
    f. How often is data stored
    g. Who has access to data
5) Protocol file and correspondence
    a. Current IRB approved version of protocol in file
    b. Training certificates on file
    c. Approval correspondence on file
    d. Continuation reports on file
    e. Modifications on file
    f. IRB approved questionnaires/surveys/measures
    g. IRB approved recruitment/advertisements
    h. Reports of adverse events
    i. Reports of deviations
    j. Reports of unanticipated problems