Clinical Research Management Plan
Duke – Site 1601

Duke Site Management Plan
Table of Contents

A. Clinical Site Administration

1. See organizational chart with job titles located on subsequent pages in this section

2. See Table of contents for Site SOP Manual located behind organizational chart

3. See Individual job descriptions located in each individual's personnel file

4. Continual review of staff workload and turnover in PDC data base with example included here.

5. Copies of licenses of site employees maintained in individual personnel files. Up to date CVs maintain in regulatory files

6. Annual review with business budget/fund accounting officer

7. Screening Logs – maintained in binder located in "The Nest" room 2390

B. Staff Education and Training

1. Job specific, clinic specific, AACTG orientations included in individuals personnel files.

2. Annual Research/GCP Education/Training via web at http://researchethics.mc.duke.edu/clinethics2.nsf/webpages/home

3. Occupational & Safety Education and Training via web at http://www.safety.duke.edu/

4. Ongoing and New Protocols – see minutes for specific protocol

C. Communication

1. Staff meetings – Monthly ACTU meetings. Minutes emailed to group and filed in SC office

2. Staff meetings – Weekly Clinic 2-J meetings. Minutes located in file in office managers office

3. Start up Protocol meetings – minutes mailed to all participants and copy retained in SC office

4. QA Meetings – Held monthly for routine chart audits. Individual audit tools are completed and given to respective CRNs for resolution of queries. Completed tools kept on file in SC office

5. Quarterly QA Meetings - minutes mailed to participants and a copy retained in SC office

6. DAIDS/AACTG – employees are placed on appropriated mail groups related to AACTG, SRO, DAIDS. Information that Site Coordinator identifies as essential is forwarded to individuals who may not be in mail group

7. Monthly FSTRF Reports – Distributed for review within the ACTU, discussed at monthly meetings, and filed in SC office

8. PPD Debriefing – ACTU group attends week end debriefing by monitor. Written report is kept on file in SC office for review as requested by staff

D. Quality Assurance (QA) and Quality Control (QC)

1. Joan Riddle, RN & Deitra Wade, RN Co Chair the QA Committee. Monthly QA Audits are announced by the co chairs and the Audit History Tool, recent randomizations and results of previous audits are all considered in selection of protocols/PIDs to be audited

2. The first two charts of a new protocol and the first two charts of a new nurse are automatically included in the audit selection for the upcoming month.

3. Each research nurse (including SC) is expected to audit 2 charts per month. There are 5 CRNs and the SC therefore a nurse can occasionally be excused from chart audits as needed and deemed appropriate by Co Chairs/Site Coordinator.

4. QA Audits –
    i. 100 % of all randomized subjects are checked against all inclusion/exclusion criteria by site coordinator or designee.
    ii. 100% of all consent forms are QA for correct version and subject signature/date/identification
    iii. Protocol specific audit tools (example included) are created by the QA committee that address the consent process, eligibility criteria, schedule of events, study drug, AE & SAE, endpoints and trends
    iv. After the chart is audited the completed tool is discussed with the research nurse and any addendums or source documentation that is needed is completed.
    v. The research nurse signs the tool and it is given to the Site Coordinator for compilation with the other charts audited for the month and a QA monthly chart audit report is generated, kept on file and distributed to the ACTU Staff

5. Copies of QC tools/aids that are used for implementing QC measures are included in this section.
    i. Monthly QA Tool
    ii. Monthly Accrual Report (Monthly, yearly, accrual year)
    iii. Monthly Data Management Report
    iv. Randomization Logs (Monthly, yearly, accrual year)
    v. Demographic spreadsheets
    vi. Specific Protocol spreadsheets

6. Reporting of QA results and documentation of QA audit findings.
    i. Monthly QA Audit Reports

ii. Quarterly QA Audit Reports (to identify trends)
iii. Monthly Audits are done as a group (a specific day is identified as a QA day and everyone blocks out their schedule). Lunch is provided by Dr. Bartlett and audits are often done in pairs especially with a new protocol or a protocol that needs a higher volume of auditing (rapidly enrolling or problems have been identified in past audits).
iv. Multiple visits are audited for each chart and if areas of inadequate source doc. or missed tests are identified a discussion real time will often result in an immediate change in the source doc. tool.
v. Audits that result in more than minimal deficiencies are flagged for audit in subsequent months.
vi. Monthly informal meetings with the SC and research nurses occur to encourage frequent dialogue between leadership and research nurse staff. Recent meetings have centered on discussion of sections of the DAIDS Source Doc. SOPs. Example of tool resulting from one of these meetings is included (Study drug documentation).

E. Regulatory Compliance

1. Title 21 and Title 45 CFR copies available in Site Coordinator's office, and on line. Some research nurses have their own copies

2. FDA Guidance for Industry and ICH Guidelines available in Coordinator's office and online

3. Janet Mueller, MT is our lead Regulatory Coordinator with Stuart Carr fulfilling Regulatory and Financial Duties within our unit. All Regulatory files are maintained within the regulatory offices of our clinic.

4. All regulatory documents are made available to site staff as needed.

5. Documentation of internal processes for IRB and SRO submissions and approvals as well as safety reports are house within the regulatory offices and their data bank

F. Pharmacy Compliance

1. Pharmacy Plan is located in the ACTU pharmacy files.

G. Management of Laboratory Specimens.

1. See Laboratory Management Specimen Plan located in Clinic 2-J lab

H. Community Advisory Board (CAB)

1. Quarterly CAB Meetings are held at First Presbyterian Church in downtown Durham.
    i. A light supper is served and minutes are taken and the last meetings minutes are approved.
    ii. The Chair and Co Chair of the CAB preside; an agenda is distributed at the beginning of the meeting.
    iii. Principle Investigator and Site Coordinator for AACTG are invited to, and attend, quarterly meetings. Their participation includes HIV/AIDS updates (local to international), and a brief description of open and soon to open protocols at our site. Discussion/feedback is encouraged and information is shared at a basic comprehension level.

2. CAB Sub-Committee Meetings
    i. Can occur monthly and more often if the group is working on a project (see examples below)
        1. HIV/AIDS Forum in March (Duke & UNC)
        2. Holiday Party for Clinic Patients
        3. Beyond the Forum in August (Duke PCP)

3. CAB member's percent representation of our catchment area see graph (next page).

4. CAB Participation at National Meetings.
    i. Until this year we have been able to stretch our allotted money to send 4-5 CAB members.
    ii. Changes in the dispersement of travel expenses will limit our future CAB participation to one at these events.

I. Outreach

1. Community meetings/lectures

    i. March Forum – Duke DART with UNC
    ii. Beyond the Forum – August , small group with PCP answering questions from interested participants
    iii. On site tour/visit to Durham Health Department and reciprocal tour/visit by Health Department to our site.
    iv. Weekly meetings with Henderson Outreach Site

2. Local Newspapers/radio Advertisement (included)

    i. *Front Page* – Gay Lesbian Paper
    ii. *Carolina Times* – African American Paper
    iii. *Medical Minutes* – Two minute radio interview with John Bartlett, MD

3. Chart Reviews – Weekly screening reports are sent to PI by Site Coordinator every Friday. PI in turn sends an accrual update to a PCP mail list. The update contains a brief synapse of open protocols. Subjects are then referred for chart review by PCP.

4. Websites

    i. DART website http://dart.medicine.duke.edu/IDclinic/index.html
    ii. World AIDS DAY http://www.worldaidsdaydurham.org/

J. Management Operations Evaluation

1. Evaluation of findings from internal QA and QC activity

i. Evaluations of findings from internal QA and QC activity is ongoing. Corrective actions often occur immediately following identification of deficiency. The tool used to collect the required data or the procedure may be revised or new tools may be developed.

ii. Identification of performance areas are discussed monthly (i.e. fstrf report results), Quarterly (i.e. QA meetings review of QA reports), yearly (SES Evaluations).

iii. Implementation of corrective actions occurs at time points identified in section ii. At times there may be corrective actions that occur on an individual basis. These are documented in individual employee files and are followed to resolution

iv. Periodic Review of Management Operations to ensure staff adherence.

1. Mid year planning sessions are held with each employee. Important highlights of the employee's performance are discussed and goals for growth and performance improvement are identified.

2. End of year Evaluation occurs in the late spring and each employee is evaluated using job description, SOP adherence, and performance plan expectations tools.

3. Annual Review of management operations for evaluation of effectiveness and needed change occurs in 2-3 meetings called by PI at the end of each budget year. Included in financial issues are accrual, scientific goals, staff retention, site overall evaluations (SESC, FSTRF etc).

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John A Bartlett, MD Date

Effective Date: 04.26.04
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