DUKE UNIVERSITY HEALTH SYSTEMS
DUKE AIDS RESEARCH & TREATMENT CENTER
POLICIES AND PROCEDURES

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Title: Clinic Flow

PURPOSE: This document describes the clinic flow of a study participant at Duke AIDS Research & Treatment (DART) Center.

SCOPE: This SOP applies to the DART Research Associates, Research Nurses, Clinical Research Coordinator, Clinicians, and Principal Investigators.

RESPONSIBLITIES: The PI and Research Coordinator are responsible for ensuring that this procedure is followed.

PROCEDURES:

1. Study participant checks in with receptionist at Clinic 2J outpatient waiting area on the 2nd floor of Duke University Medical Center Clinic Building.
2. Receptionist verifies appointment and pages the appropriate coordinator and/or clinician.
3. Participant waits in waiting room.
4. Clinic intake nurse obtains vital signs of participant and returns them to the waiting room.
5. Study Coordinator receives encounter form with vital signs and meets with study subject prior to blood draw to ensure that consent has previously been obtained and to ensure no acute illness that would preclude obtaining blood samples.
6. Labs:
    a. Study Coordinator provides research phlebotomist with appropriate study visit kit, pre-labeled and with requisition completed except for draw time and fasting status.
    b. Study Coordinator and research phlebotomist consult prior to blood draw to verify if any additional blood samples may be needed. .
    c. Phlebotomist verifies subjects identity and completes time and fasting status (if applicable).
    d. Research Coordinator/Nurse completes drug dosing information for pharmocokinetic (PK) studies (if applicable).
    e. Phlebotomist draws required samples according to Duke University Medical Center Standard Operating Procedure for venipuncture and order of draw.
    f. Phlebotomist completes processing of study specific labs and prepares for shipment, including notification to receiving lab.
7. Study Coordinator meets with the study participant and updates medical history, any changes, medications and any other pertinent information and updates these findings on the study specific flow sheet.
8. Study Coordinator assesses patient. Abnormal findings are immediately referred to PI or Sub-Investigator for clinical exam. Study visits requiring physical exam are completed by the PI or Sub-Investigator.

9. Study Coordinator assesses patient for drug adherence (if applicable) and social needs, including: any emotional or psychological issues. Issues identified are immediately referred to Licensed Clinical Social Workers (LCSW) on staff after patient agreement.
10. Study Coordinator takes study medications that participant is returning (if applicable) and delivers them to the DART research pharmacy. The Study Coordinator signs out the pharmacist dispensed medication and gives it to the study participant. Any study medication questions are referred to the research pharmacist. All components of this process are documented on the study specific flow sheet by the Study Coordinator.
11. Study Coordinator talks with the participant about the next study visit and sets a dates and time with the participant, noting this date and time on the encounter form.
12. Study Coordinator provides the participant with travel reimbursement (as per study agreement) and has patient initial receipt which is returned to site Grants and Contracts specialist. Receipt of travel reimbursement is captured on the study specific flow sheet.
13. The study participant checks out with the clinic receptionist who enters the next scheduled appointment.