Complete Blood Count

1. Background and Rationale

At MrOS Visit 3 we will be obtaining a Complete Blood Count (CBC) with platelet and differentials for all participants that return to the clinic. This measure is standardized across labs and results will be comparable regardless of which lab completes the measure. Therefore, each MrOS clinic is responsible for establishing a contract with a local lab (such as Quest Diagnostic Laboratory) for obtaining this measure.

The following labs are being used:

Birmingham:	Quest Diagnostic Laboratory
Minneapolis:	Quest Diagnostic Laboratory
Palo Alto:	Stanford Outreach
Pittsburgh:	Quest Diagnostic Laboratory
Portland:	Quest Diagnostic Laboratory
San Diego:	Quest Diagnostic Laboratory

2. Equipment and Supplies

Please refer to the equipment and supplies needed based on the lab being used. Any needed labels should be provided by the lab being used.

3. Safety Issues, Exclusions and Measurement

Please see the MrOS Visit 3 Blood and Urine Collection Protocol for more information. Also, please refer to protocol specifics provided by the lab being used.

Please record if specimens were sent for the CBC measure on the Blood Collection TELEform. This value will be cross-checked with the data received.

4. Sending Data to the Coordinating Center.

If possible, clinics should try to obtain an electronic version (an excel spreadsheet) of the results to be sent to the Coordinating Center. Data should be transferred to the Coordinating Center on at least a monthly basis. Any personal identifying information should be removed from the file before it is sent to the Coordinating Center. The ID and Acrostic should be added to the file if possible. Before sending a file to the Coordinating Center, the file should be renamed so the file name is the participant ID followed by acrostic. For example, SF0001ABCD. Data will be transferred from the clinic to the Coordinating Center using the secure website designed for data transfer.

If electronic results are not possible, clinics should collect the lab report provided from the lab for each participant. A copy of the lab report should be made. The original should be stored with the participants file and the copy should be sent to the Coordinating Center. All personal identifying information should be blacked out or removed before sending the report. Clinics should be sure to record the participant ID and Acrostic on the copy that is sent.

Copies of the reports should be sent to the Coordinating Center to the attention of Liezl Concepcion on a monthly basis.

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5. Alert Levels

There are two levels of alert values for the CBC measurement: immediate referrals and alerts. CBC results requiring immediate referral are provided below; abnormal CBC results which do not fall within the values designated for immediate referrals will be considered alerts, as determined locally by site investigators. The specific protocols for immediate referrals and alerts will be determined locally, at each clinical site.

Immediate referrals are potential emergencies which may require immediate notification of the participant and (if so requested by the participant) his primary physician or other available health care provider. These are findings made upon reviewing the CBC results from the lab, following the clinic visit. Depending on the specific protocol for your site, the site staff may contact the MrOS study investigator for a clinical diagnostic assessment, determine whether immediate referral is indicated or may contact the participant directly with a referral to his physician or to an emergency room. Participants receiving immediate referrals are those who would be advised to go directly from home to their physician or to a hospital. With participant's consent (obtained verbally at the time of the immediate referral), the study physician would contact the participant's referring physician directly.

CBC results requiring ***immediate*** referral:

- Hematocrit < 30% or >60%
- Total White Blood Count > 20,000 $x10^6$/L (or > 20 $x10^9$/L)
- Absolute Neutrophil Count <1,000 $x10^6$/L (or > 1 $x10^9$/L)
- Platelet Count < 50,000 or > 1,000,000 $x10^6$/L (or <50 or >1,000 $x10^9$/L)

Non-immediate alerts are related to abnormal CBC results noted on the lab report that do not fall within the values designated for immediate referrals. These alerts may require medical attention but generally not on an emergency basis. In most cases, notification of the participant should be sent by mail within 10 days.