CHRONIC RENAL INSUFFICIENCY COHORT (CRIC) STUDY

Manual of Procedures Version 2, August 2007
Addendum #1
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These changes are to be implemented immediately and will be incorporated into the MOP upon finalization of additional changes

1. Changes to text regarding completion of the Demographic Information (DEMO) CRF

MOP currently reads:

Q7: CRIC study participant has the option of checking "Yes" for more than one racial category. If a participant checks "Black/African American" and any other category, the participant is identified as "Black/African-American" for eGFR calculation.

Updated MOP will read:

Q7: CRIC study participant has the option of checking "Yes" for more than one racial category. If a participant checks "Black/African American" and any other category, the participant is identified as "Black/African-American" for eGFR calculation.

Participants should be encouraged to respond to the race categorization questions by indicating affirmatively their membership in a race category. They should be advised that their ethnicity will be recorded as reported but that, for the purposes of NIH reporting, race is a distinct classification with separate reporting requirements.

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2. Change to anthropometric tape measure requirements to allow the option of using a longer, wider tape measure.

MOP currently reads:

9.B.1 Equipment:

- Gulick II 150c anthropometric tape measure

Updated MOP will read:

9.B.1 Equipment:

- Gulick II 150c or Gulick II *Plus* 120 inch anthropometric tape measure

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3. Additional guidelines to assist with the time frames for conducting follow up procedures and late clinic visits.

MOP currently reads (text to be changed highlighted in red):

3.G.3 Follow-up of Subcohort Participants

It is preferable to collect subcohort test data late, than to not collect it at all. If a participant has been difficult to schedule for follow-up tests, work with them to find the time that will suit their convenience, rather than miss the opportunity to conduct a GFR or EBT test. Whenever possible, schedule tests at approximately the same interval as would occur under ideal conditions. In the event that the baseline EBT/MSCT was obtained late, if the baseline test was done after year 2 (V7), the follow up EBT/MSCT should be completed at year 5 (13). In the case of a late baseline iGFR completion, subsequent testing should be done with at least one year between baseline and follow up iGFR testing.

IMPORTANT NOTE: Participants who begin dialysis should no longer have I-GFR testing if they have been part of this subcohort testing group. A GFRSTAT form should be completed to indicate that they are to be removed from this substudy.

Updated MOP will read (text highlighted in green will replace red text above):

3.G.3 Follow-up of Subcohort Participants

It is preferable to collect subcohort test data late, than to not collect it at all. If a participant has been difficult to schedule for follow-up tests, work with them to find the time that will suit their convenience, rather than miss the opportunity to conduct a GFR or EBT test. Whenever possible, schedule tests at approximately the same interval as would occur under ideal conditions.

In regards to the conduct of late EBT/MSCT or late Echo procedures, there must be a minimum of at least 2 years between measurements. For example, in the event that the baseline (V5) EBT/MSCT was obtained late (e.g., done after year 2 (V7)), the follow up EBT/MSCT should not be completed until after year 4 (V11); the same applies for Echo procedures. In the case of a late baseline I-GFR completion, subsequent testing should be done with at least 1 year between baseline and follow up I-GFR testing.

IMPORTANT NOTE: Participants who begin dialysis should no longer have I-GFR testing if they have been part of this subcohort testing group. A GFRSTAT form should be completed to indicate that they are to be removed from this substudy.

MOP currently reads:

3.1.1 Annual Visits

The RC should begin contacting participants 2 months prior to their annual visit. Visit windows are minus and plus 2 months of the target date, therefore, contacting participants early in the visit window allows the RC maximum flexibility in scheduling appointments or time to locate missing participants. The Data Management System provides Calendar Tools for Scheduling to assist in scheduling participants. The RC will arrange to forward the 24 hour urine specimen collection kit, instructions and when applicable, Diet History Questionnaire [DHQ] to the participant to be completed prior to the annual visit.

In the event the participant has relocated to an area from which it is no longer feasible to travel to the clinical center, the participant will be asked to permit study personnel to contact them annually by telephone. Every effort should be made to encourage continued participation. The RC should follow the format described for telephone contact.

Updated MOP will read (supplemental information added in green):

3.1.1 Annual Visits

The RC should begin contacting participants 2 months prior to their annual visit. Visit windows are minus and plus 2 months of the target date, therefore, contacting participants early in the visit window allows the RC maximum flexibility in scheduling appointments or time to locate missing participants. The Data Management System provides Calendar Tools for Scheduling to assist in scheduling participants. The RC will arrange to forward the 24 hour urine specimen collection kit, instructions and when applicable, Diet History Questionnaire [DHQ] to the participant to be completed prior to the annual visit.

If a participant has been difficult to schedule for follow-up clinic visits, work with them to find the time that will suit their convenience. It is preferable to conduct annual visits late, than to not conduct them at all. If an annual visit is conducted late, there must be a minimum of at least six months prior to conducting the next or subsequent clinic visit.

In the event the participant has relocated to an area from which it is no longer feasible to travel to the clinical center, the participant will be asked to permit study personnel to contact them annually by telephone. Every effort should be made to encourage continued participation. The RC should follow the format described for telephone contact.

4.B.1 Missed Visits

In the event that the RC is unable to schedule a clinic visit or make contact with the participant within the 4 month window, every effort should be made to complete the contact as soon as possible prior to the next scheduled clinic visit. A visit will be considered late if it occurs later than the 2 month window after the expected date. However, the RC should continue to attempt to complete this visit information up to 10 months after the anniversary clinic visit date. After the 10 month time window, the next visit window will begin and the RC should apply the clinic visit number of the next appropriate clinic visit. It is preferable to collect as much information as possible, even if this information is collected in the 'late' window, than to miss the opportunity to complete tests and questionnaires.

IMPORTANT NOTE: If an annual visit is conducted late, there must be a minimum of at least six months prior to conducting the next or subsequent clinic visit.

A visit is considered "late" when it is conducted outside the original window dates. A clinic visit is considered "missing" if it does not occur before the next clinic visit window has opened. Once the next clinic window opens if the prior visit has not been completed, a missed visit form must be completed (MISSVST).

For example, if the patient misses the year 1 visit window, but can come for a clinic visit at 19 months, that will be counted as a Year 1 visit, and the relevant Year 1 visit data should be obtained. But if patient can come at 23 months, then the Year 1 visit will be considered "missing" and the Year 2 data should be obtained. The patient is now in the window for the Year 2 visit.

Another example: If a patient misses a Year 1 visit, but when contacted over the phone for 18 month visit, is able to come in, an in person visit should be scheduled and Year 1 visit data should be obtained. The phone visit information need not be obtained separately in such circumstances, since the materials for the phone visit will be covered by the in person visit.

STUDY VISIT	VISIT DATE	ON-TIME RANGE		ALLOWED, BUT LATE	INFORMATION
Visit 1	Prescreening Visit	May 1, 2006	---	---	There are no time limits on the period between Prescreening and the Screening Visit
Visit 2	Screening Visit	May 20, 2006	---	---	Baseline visit must be completed within 3 months of the Screening Visit date.
Visit 3	Baseline Visit	June 15, 2006 **	Up to Aug. 20, 2006	Up to Aug. 20, 2006	**Calendar tool will calculate all subsequent dates and windows starting with June 15, 2006
Visit 4	6 Month Telephone Follow-up	Dec. 15, 2006	Oct. 15, 2006 to Feb.15, 2007	Feb. 16, 2007 to Apr. 14, 2007	The phone call window is 2 months before and 2 months after the expected date.
Visit 5	Year 1/12 Month Clinic Follow-up	June 15, 2007	Apr.15, 2007 to Aug.15, 2007 [- /+ 2 months]	Aug. 16, 2007 to Apr. 14, 2008 [- 2months, + 10 months]	In this example, visits conducted between Aug. 16, 2007 and Apr. 14, 2008, will be considered 'late.' If Visit 5 has not been conducted by Apr. 15, 2008, it is considered a missed visit.
Visit 6	18 Month Telephone Follow-up	Dec. 15, 2007	Oct.15, 2007 to Feb. 15, 2008	Feb. 16, 2008 to Apr. 14, 2009	The phone call window would be between months 16-20.
If Visits 5 and 6 have not been completed…				…Every attempt should be made to conduct Visit 5 until month 22. If after 22 months, the participant can be scheduled for a clinic visit, a Year 2 visit should be conducted.	
Visit 7	Year 2/24 Month Clinic Follow-up	June 15, 2008	Apr.15, 2008 to Aug.15, 2008 [- /+ 2 months]	Aug. 16, 2008 to Apr. 15, 2009 [- 2months, + 10 months]	The visit window begins at month 22 and continues until month 34. If Visit 7 has not been conducted by month 34 it is considered a missed visit. If after 34 months, a participant can be scheduled for a clinic visit, the data collected will be reported for Year 3, Visit #9.