

Chronic Kidney Disease in Children Cohort Study (CKiD)

QUESTION BY QUESTION SPECIFICATIONS

MV: MISSED VISIT

The goal of this form is to gather information about specific efforts to locate participants who have missed their CKiD visits and to determine, if possible, the reason(s) for the missed visits. This form is to be completed only in cases where the participant never showed for the visit. Do not complete this form if the participant had a visit that was only partially completed.

Complete if the participant has progressed to the next study visit (i.e., the participant missed the visit and the site is moving forward with scheduling the next study visit.) Also, if a participant is being disenrolled or transitioned to the phone/in person follow-up protocol, the disenrollment (DSEN) form for disenrolled participants or the transitional form for PIP (TRS01) must be completed. In the event that the participant is being disenrolled or transitioned to PIP, and missed the study visit prior to disenrollment or transitioning to PIP, then the missed visit form should be completed. Do not complete a missed visit form for the same visit that the participant is being disenrolled or transitioned to PIP.

- A1. Record the participant's ID number or affix label in the space provided.
- A2. Record the number of the visit that was missed and for which you are recording information.
- A3. The form version is pre-printed. For the baseline visit use the form version dated 12/01/21
- A4. Record the visit number for the last completed visit.
- A5. Record the date in which the form is being completed - the month, day, and year.
- A6. Record the initials of the person completing the form.
Example: K I D
- A7. Document the type of visit. If regular study visit, then circle "0". If post-dialysis visit, then circle "1" and if post-transplant visit, then circle "2" and **Skip to B1**.
- A8. Document if the "MISSED" visit is an irregular (accelerated) study visit. Circle "Yes" (Code 1) or "No" (Code 2). Children who are scheduled to have renal replacement therapy will have their next study visit accelerated from 12 months to 3 months. The rationale for scheduling irregular study visits is to attempt to capture the clinically relevant changes in exposure at low levels of GFR, but before the onset of renal replacement. For children requiring an irregular visit, the irregular visit will be their last CKiD study visit.

SECTION B

- B1. Indicate the type of missed visit(s) by circling yes (Code1) or no (Code2) for each type of visit.
- B2. Circle all of the strategies used by the clinical site to contact the participant.
a – f It is recommended that at least three (3) calls are made to the participant's home. Circle yes (Code 1), no (Code 2), or not applicable (Code 3). Enter the number of calls, letters/postcards and field visits that were made or sent for each category circled. If no or not applicable is circled, skip to the next sub-question. If a strategy not listed in a - i was used, specify the other strategies that were employed to contact the participant on the lines provided. If no or not applicable is circled for sub-question "i", **skip to B3**.
- B3. Record the date of last contact with the participant - the month, day, and year.

SECTION C: REASON(S) FOR MISSED VISIT

- C1. Record the number of missed appointments made with the participant for this study visit. If none, enter "00". Record appointments made in the following ways: via telephone contact with participants, appointments scheduled at their prior study visits, sent letters (not returned) with appointments, or appointments made and confirmed through contact individuals.
- C2. Circle the reason(s) why you were unable to contact the participant. The selected reasons should correspond with the strategies used in question B2. Circle yes (Code 1) or no (Code 2) for each unsuccessful contact category. For example, if "phone disconnected" is circled in question C2, "telephone call(s) to participant's home" should be circled in question B2, with at least 01 call made. If yes (Code1) is circled for sub-question "k", specify the reason(s) on the lines provided. If no (Code 2) is circled, **skip to C3**.
- C3. Indicate the reason for missed visit/appointment(s) by circling yes (Code1) or no (Code2) for each reason that applies for the missed visit.

If "Yes" (Code 1) is circled for sub-question "a", **END** the form. Unknown should be selected when you have no idea why he/she failed to come for the visit. For example, this code could be circled in a situation where the participant's telephone number isn't correct or is temporarily disconnected, but the mail is not returned and the contact assures you that he/she gave the message to the participant. This should be circled only if you cannot circle any other reason, a presumably infrequent situation.

- Circle "Yes" (Code 1) for "Unable to contact participant" if you were unsuccessful in contacting him/her through telephone calls (including contacts) and letters or perhaps home visits.
- Circle "Yes" (Code 1) for "No show for multiple appointments" when you have either spoken with the participant to make appointments or are relatively certain he/she scheduled an appointment, but didn't show.
- Circle "Yes" (Code 1) for "Illness of participant" if he/she is too ill at home to tolerate coming in for his/her visit.
- Circle "Yes" (Code 1) for "Hospitalized" if you know the participant is hospitalized during the visit window and is unable to perform a study visit in the hospital.
- Circle "Yes" (Code 1) for "Moved/relocated" if the participant has moved and you have reason to believe he/she will return for a subsequent study visit. If there is no expectation he/she will ever return for a visit, fill out the disenrollment form instead of the missed visit form.
- Circle "Yes" (Code 1) for any and all of the following that apply if the participant indicates these as reasons for missing his/her study visit. In order to circle these reasons, you must have contact with the participant:

"Conflict with other studies an/or study visits"

"Family or home problems"

"Illness of family member"

"Transportation problems"

"Too much time required"

"Weather"

"Fear of study procedures"

"Worries about confidentiality"

If yes (Code 1) is circled for sub-question "o", specify the particular reason for the participant missing the visit that is not listed above. If no (Code 2) is circled, **skip to sub-question "p"**.

In sub-question "p", circle yes (Code 1) or no (Code 2) for "does not wish to participate at this time" if the participant indicates a willingness to consider a future visit. If yes, specify the reason for not wanting to come in for the current visit. In sub-question "q", circle yes (Code 1) or no (Code 2) if the participant indicates he/she wants to remain in the study. If Code 2 ("no"), then the participant indicates he/she does not want to remain in the study, **END FORM HERE AND COMPLETE THE TRANSITIONAL TO PIP FORM (TRS03)** for this visit instead of the missed visit form.