

# Chronic Kidney Disease in Children Cohort Study (CKiD)

## QUESTION BY QUESTION SPECIFICATIONS

### EL: ELIGIBILITY FORM

THIS FORM MUST BE COMPLETED AND DATA ENTERED FOR ALL CHILDREN ENROLLED INTO CKiD

#### General Instructions:

- 1) Sites must obtain written consent from a parent or legal guardian and assent, if applicable, from the participant before performing any study related procedures or tasks, including the collection of data. Written consent/assent may be obtained prior to or on the day of the initial study visit.
- 2) The EL form must be completed and submitted to the CCC as follows:
  - a. If the site identifies an eligible child and they are able to obtain written consent/assent at that time, the EL form should be completed in its entirety and faxed to the CCC.
  - b. If the site identifies an eligible child but written consent/assent has **not** been obtained (i.e., family/child may be interested in participating in the study but they need more time to decide and provide written consent), an EL form must be partially completed with only the **interviewer's initials and the next consecutive KID ID number**. **No other data can be recorded on the form until written consent/assent has been obtained.** This partially completed form must be faxed to the CCC. The site should keep the partially completed form stapled to the fax coversheet. **Once written consent/assent is obtained, sites must complete the remainder of the EL form, fax it to the CCC and again keep a copy of the completed form stapled to the fax coversheet.**

If the site identifies an eligible child but the family/child does not agree to participate in the study (i.e., does not provide written consent/assent), a refusal form (REF) must be completed and that KID ID should not be reused.

If after providing written consent/assent, the family/child decides to withdraw from the study (even if before Visit 1A occurs), the Disenrollment Form (DSEN) must be completed and that KID ID should not be reused.

For children who refuse to participate or withdraw before Visit 1a has occurred, the lab kit must be returned to the Central Biochemistry Lab (CBL).
3. This form is designed to document whether a child is eligible for enrollment into the CKiD cohort study. If a potential participant has a response that falls in any of the shaded areas, he/she is ineligible for enrollment. Forms should not be faxed to the CCC for people deemed ineligible for enrollment into the CKiD study.
4. Once the EL form has been received by the CCC, study supplies with the KID ID will be sent to the site. After making a copy at the site, the original EL form must be sent to the CCC with the other Visit 1a forms for data entry.
5. Follow all specified instructions on the form. Statements in boxes or in italics are instructions and should **not** be read to the participants.
6. Although information may be obtained during medical record abstraction, the information collected on the form must be confirmed with the parent/legal guardian and the child, if appropriate.
7. Use form version dated 01/01/2007.

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The following are the steps in determining the next consecutive KID ID number.

- a. Enter “1” in the first box for participants who are enrolled during the first phase of enrollment and “2” for participants enrolled during the second phase of enrollment. The DCC will determine when the first phase of enrollment has ended.
- b. The next two digits indicate the site number. Values between “01” and “49” are reserved for sites coordinated by the Midwest clinical coordinating center, and “50” to “99” for sites coordinated by the east coast clinical coordinating center.
- c. The last three digits document the sequence of participants in a given site beginning with “001” for each site.

**Upper Left Corner:** The person who is interviewing the potential participant must document their initials.

Question 1: Record the date the form is completed when written consent/assent has been obtained. **Note:** The entire form should not be completed until after written consent is obtained.

Question 2: Sites must have a documented DOB for a participant to be eligible. For example, a copy of the child’s birth certificate or DOB documented in the child’s medical records. Without DOB verification, the participant is ineligible for enrollment into CKiD.

Question 3: Sites must have a documented gender for a participant to be eligible. The CKiD Steering Committee has agreed that eligible participants must have estimated glomerular filtration rate (GFR) measurements between 30 and 90 ml/min/1.73m<sup>2</sup>. GFR differs by age and gender of the participant. Therefore, gender must be documented in order to review the appropriate serum creatinine range on pages 3 to 5 of the eligibility form.

Question 4a: Sites must have a documented height for a participant to be eligible. In order to calculate GFR, height is needed. Therefore, a participant must have a documented height in order to review the appropriate serum creatinine range table on pages 3 to 5 of the eligibility form and determine eligibility for enrollment into CKiD. Date of most recent height refers to the date within the **last 6 months OR** closest to the **most recent** serum creatinine measurement. Document the date of most recent height.

Question 4b: Record height measurement in inches or centimeters for the most recent height. Round to the nearest inch or centimeter. If a participant is less than 17 inches or greater than 78 inches, the clinical site should contact their CCC to ensure that the appropriate eGFR is obtained.

Question 5a: Sites must have a documented serum creatinine measurement in order to review the serum creatinine range table and determine if the child is eligible for enrollment into CKiD. Date of most recent serum creatinine measurement refers to the date within the last 6 months the measurement was obtained.

Question 5b: The serum creatinine measurement must be obtained from laboratory results within the last 6 months prior to the form completed date indicated in Question 1. Record serum creatinine measurement in milligrams/deciliter (mg/dl).

Question 6a: A second height measurement must be obtained for all children. The second

height measurement must be within the **last 18 months OR** be closest to the **second** serum creatinine measurement. Some children may only have one height measurement per year. If the child only has one documented height measurement, enter the same date and height. Document the date of second height measurement.

Question 6b: Record height measurement in inches or centimeters for the second height measurement. Round to the nearest inch or centimeter.

Question 7a: A second serum creatinine measurement must be obtained for all children. Date of the second serum creatinine measurement refers to the date within the last 18 months (excluding the most recent measurement) prior to the form completed date indicated in Question 1.

Question 7b: The second serum creatinine measurement must also fall within the serum creatinine range that corresponds to an estimated GFR between 30 and 90 ml/min/1.73m<sup>2</sup> in order for the child to be eligible for enrollment into CKiD. A second serum creatinine measurement must be obtained from laboratory results within the last 18 months. Record serum creatinine measurement in milliliters/deciliter (mg/dl).

Question 8: Sites must use the tables on pages 3 to 5 of the eligibility form to determine if the child's serum creatinine measurements from questions 5b and 7b above correspond to an estimated GFR between 30 and 90 ml/min/1.73m<sup>2</sup>. The lower serum creatinine limit of the range corresponds to an estimated GFR of 90 ml/min/1.73m<sup>2</sup> and the upper limit corresponds to an estimated GFR of 30 ml/min/1.73m<sup>2</sup>. Calculations differ by age and gender of the participant. Although it is important that for all participants between the ages of 12 and 30 months that the clinical sites contact their CCC to discuss the age and height of the child to ensure that the appropriate K value is used, for children between the age of 12 and 18 months, sites should use Table A as a guide to determine study eligibility. For males 19 months to 13 years (before 13<sup>th</sup> birthday) and females 19 months and older, Table B should be used. Finally, for males 13 years and older (after 13<sup>th</sup> birthday), Table C should be used to determine study eligibility.

Question 9a: Sites must determine study eligibility based on age as of "most recent serum creatinine measurement" (the date documented in Question 5.) **Age should be calculated by subtracting the most recent serum creatinine date from the date of birth.** For example: if DOB = 11/03/2002 and Most recent SCr = 02/23/2005, then age = 2 years old. The Steering Committee has agreed that eligible children must be between the ages of 1 to 16 years old. Therefore, the child is eligible as long as he/she has not had his/her 17<sup>th</sup> birthday. Signed consent must be obtained before any study procedures are performed.

Question 9b: The participant is not eligible for enrollment into CKiD if his/her age, as determined by DOB and most recent SCr measurement (see 9a above), is not between the ages of 1 and 16 years old (before 17<sup>th</sup> birthday).

Questions 10-16: These questions are used to further determine eligibility. Although this information may be obtained through medical chart reviews, sites should verify the accuracy of the information in medical records by asking the parent/legal guardian of the potential participant during the clinic visit.

Question 17: This question is to determine if the child has had a history of severe to profound developmental delay (mental retardation). Severe to profound

developmental delay (mental retardation) is determined as having an IQ < 40, which is defined as a significant impairment in adaptive functioning and/or the inability to independently execute self-care skills.

Question 18: Check “NA” for male participants.

Question 19: This question is asked to determine if the child has had an allergic reaction to Iodine or Iohexol. If “Yes” is selected, contact the Central Biochemistry Laboratory for further clarification and instruction. They may be reached at (585-275-9784).

Question 20: Forms and questionnaires are available in English and Spanish. This question is asked to determine if the child is fluent in English or Spanish.

Question 21: Sites must document the language that the child speaks most frequently.

Question 22: Sites must document the language that the child’s parent speaks most frequently.

Question 23a: Sites must obtain written permission from a parent or legal guardian and assent, when appropriate, from the study subject before performing any study related procedures or tasks, including the collection of data. Signed permission/assent may be obtained prior to or on the day of the initial study visit.

Question 23b: This question documents the date consent form was signed by a parent or legal guardian.

Question 24a: Sites must document whether or not their institution requires child assent. If their institution does not require child assent, skip to question 25.

Question 24b: If applicable, sites must document the date assent was obtained from the child.

Question 25: Consent for genetic testing is optional. Participants who refuse to consent for genetic testing are still eligible for enrollment into CKiD. This question documents whether genetic testing consent was obtained from a parent or legal guardian.

Question 26: Consent to store biological specimen(s) to use for future ancillary studies is optional. Participants who refuse to consent to the storage of their biological specimen(s) are still eligible for enrollment into CKiD. This question documents whether consent to store the child’s biological specimen(s) was obtained from a parent or legal guardian.

Question 27: Sites must document the primary diagnosis of CKD. The study coordinator or MD may need to obtain this information from the participant’s medical record.

Question 28: Sites must document the race of the child by selecting yes (Code 1) or no (Code 2) for each race depicted from “a” through “f”. The site may select “Yes” for more than one race. If “Yes” is indicated for “other” category, then site must specify the race of the child. A response of “Yes”, “No” or “Don’t Know” must be selected for every race depicted.

Question 29: Sites must document the whether or not the child is of Hispanic or Latino/a origin by circling yes to Mexican-American, Chicano (Code 1), yes to Puerto Rican (Code 2), yes to Cuban (Code 3), yes to other Hispanic/Latino/a (Code 4), or no, not of Hispanic or Latino/a origin (Code 5). If unknown, the site should circle don't know (Code -8).