

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. If participant is 18 years or older, site must obtain written consent from the participant. 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 subject and they obtain written consent/assent, the EL form should be completed in its entirety, scanned and emailed to the CCC.
 - b. If the site identifies an eligible subject but written consent/assent has **not yet** been obtained (i.e., family/subject verbally expresses interest in participating in the study), an EL form must be partially completed with only:
 - the **next consecutive KID ID number** (refer to #9 for instruction on assigning a KID ID number),
 - **Participant's initials** and,
 - **Date of screening**. The screening date is defined as the date when the subject's diagnosis and medical record were reviewed to determine eligibility or the date when the site discussed the CKiD study with the family.

No other data can be recorded on the form until written consent/assent has been obtained. This partially completed form must be scanned and emailed to the CCC. The site should keep the partially completed form. **Once written consent/assent is obtained, sites must complete the remainder of the EL form, scan it, email it to the CCC and again keep a copy of the completed form stapled.**
 - c. An EL form should not be completed if the site identifies an eligible subject but the family/subject does not agree to participate in the study (i.e., is not interested and declines to provide written consent/assent). A refusal form (REF) must be completed instead. For eligible families/subjects who had previously expressed interest in the study (verbally agreed) but thereafter decline to provide written consent, a refusal (REF) must be completed. If an EL form had been partially completed and a KID ID was issued it should not be reused.
 - d. If after providing written consent/assent, the family/subject decides to withdraw from the study before Visit 1A occurs, a Disenrollment Form (DSEN) must be completed and that KID ID that was issued should not be reused.
 - e. For subjects who refuse to participate or withdraw before Visit 1a has occurred, the lab kit can be saved as a spare or returned to the Central Biochemistry Lab (CBL) with another shipment.

4. This form is designed to document whether a subject 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 scanned and emailed to the CCC for people deemed ineligible for enrollment into the CKiD study.
5. Once the EL form has been received by the CCC, study supplies with the KID ID may be ordered on the CKiD website. 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.
6. Follow all specified instructions on the form. Statements in boxes or in italics are instructions and should not be read to the participants.
7. 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 subject, if appropriate.
8. Use form version dated 09/01/24.
9. The following are the steps in determining the next consecutive KID ID number.
 - a. The first, second and third phases of enrollment has ended. Enter “4” in the first box for participants who are enrolled during the fourth phase of enrollment.
 - 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. Please note that if a site has previously enrolled subjects, then the three digits should continue starting from the last number recruited during the previous phase of enrollment (subjects enrolled in Cohorts 1, 2 or 3). For example, if a subject is enrolled during the fourth phase of enrollment but is the tenth subject recruited at site “01”, then the KID would be 4-01-**010** not 4-01-001.

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

Question 1: Record the screening date when the subject is identified. **Note:** The entire form should be completed **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 subject’s birth certificate or DOB documented in the subject’s medical records. Without DOB verification, the participant is ineligible for enrollment into CKiD.

Question 3: Sites must have a documented sex assigned at birth for a subject to be eligible.

This section captures data for subjects who have initiated kidney replacement therapy (KRT (dialysis or transplant))

Question 4: Site must document the subject’s KRT status. If the subject has not initiated KRT, then **skip to question 5 (the inclusion criteria section for subjects who are not currently on dialysis or have a transplant).**

Question 4a: Record the date of the subject’s most recent transplant – the month, day, and year.

Question 4b: Record the date chronic dialysis started – the month, day, and year.

For hemodialysis, indicate the date when the subject started treatment 2 or more days/week for at least 3 months. For peritoneal dialysis (PD), indicate the date when the subject started treatment 5 or more days a week for at least 3 months.

This section captures data for subjects who have NOT initiated kidney replacement therapy (KRT Naïve)

- Question 5a: Sites should document the subject's height so that GFR can be calculated for question 5e. A participant must have a documented height in order to use the U25calculator to calculate eGFR and determine potential eligibility criteria 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 the most recent height.
- Question 5b: 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 19.7 inches or greater than 74.4 inches, the clinical site should contact their CCC to ensure that the appropriate eGFR is obtained.
- Question 5c: Sites should document the date of the subject's most recent serum creatinine measurement.
- Question 5d: The serum creatinine measurement must be obtained from laboratory results. The results should correspond to date of the serum creatinine measurement. Record serum creatinine measurement in milligrams/deciliter (mg/dl).
If serum creatinine measurement is not available, check "NA" and END form.
- Question 5e: Sites should document the subject's eGFR.
Refer to page 4 for instructions regarding how to use the U25calculator to calculate the subject's U25eGFR.
- Question 6a: A second height measurement must be obtained. The second height measurement must be within the **last 18 months OR** be closest to the **second** serum creatinine measurement. Some subjects may only have one height measurement per year. If the subject 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 6c: A second serum creatinine measurement must be obtained. Date of the second serum creatinine measurement refers to the date within the last 18 months (excluding the most recent measurement) prior to the screening date indicated in Question 1.
- Question 6d: The second serum creatinine measurement must be obtained from laboratory results within the last 18 months in order for the subject to be eligible for enrollment into CKiD. Record serum creatinine measurement in milliliters/deciliter (mg/dl).
- Question 6e: Sites should document the subject's second eGFR using the U25calculator.
- Question 7: Sites must determine eligibility based whether the eGFR measurements from 5e and 6e fall below 60 ml/min/1.73m².

The remaining questions captures data for ALL subjects

- Question 8a: Sites must determine study eligibility based on age. **Age should be calculated by subtracting the screening date from the date of birth.** For example: if DOB = 09/23/2007 and screening date = 11/03/2024, then age = 17 years old. The Steering Committee has agreed that eligible subjects must be between the ages of 16 to 22 years old. Therefore, the subject is eligible as long as he/she has not had his/her 23rd birthday. Signed consent must be obtained before any study procedures are performed.
- Question 8b: The subject is not eligible for enrollment into CKiD if his/her age, as determined by DOB is not between the ages of 16 to 22 years old (before 23rd birthday).
- Question 9: Site must document if the subject is regularly seen by a pediatric nephrology.

- Questions 10-15: 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 16: This question is to determine if the subject has had a history of severe to profound intellectual disability. Severe to profound intellectual disability 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 17: Check “NA” for male participants.
- Question 18: This question is to determine if the subject is currently enrolled in a randomized clinical trial in which specific treatment is receiving in unknown. If “Yes” is selected, contact your respective CCC for further instruction.
- Question 19: This question is asked to determine if the subject has had an allergic reaction to Iodine or Iohexol. If “Yes” is selected, contact your respective CCC for further clarification and instruction.
- Question 20: Forms and questionnaires are available in English and Spanish. This question is asked to determine if the subject is fluent in English or Spanish.
- Question 21: Sites must document the language that the subject speaks most frequently.
- Question 22: Sites must document the language that the subject’s parent speaks most frequently.

DOCUMENTING INFORMED CONSENT

- Question 23a: Sites must obtain written permission from the participant, if they are 18 years old or older, OR a parent or legal guardian before performing any study related procedures or tasks, including the collection of data. Signed permission 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.
- Question 24a: Sites must document whether or not their institution requires subject assent. If their institution does not require subject assent, **skip to question 25.**
- Question 24b: If applicable, sites must document the date assent was obtained from the subject.
- Question 25: Consent for genetic testing is optional. Participants who refuse to consent to have samples collected and stored for NIDDK 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 collect and store NIDDK 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 collect and store the subject’s biological specimen(s) was obtained from a parent or legal guardian.
- Question 27: Consent for data linking is optional. Subjects who refuse to consent to have personal identifiers collected for the purpose of data linking with public national databases are still eligible for enrollment into CKiD. This question documents whether data linking consent was obtained from a parent or legal guardian.

- If all Yes/No responses are in non-shaded areas, then the subject is eligible for CKiD.
- **If the individual declines to participate (i.e., written or verbal Consent is NOT obtained), then complete the REFUSAL FORM.**

In some instances, the subject/family may be interested in the participating but need more time to consider it. If the subject verbally consents but written consent is not obtained, then the site cannot complete the entire form.

- **If only verbal consent is obtained, then partially complete EL form and email partially completed EL form to CCC.**
 - create CKiD study identification number “KID” and write KID below
 - document participant’s initials
 - document date of screening

If written consent is obtained, create KID and **email** the completed EL to the CCC to be entered into data management system.

Question 28: 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. The options are coded into categories. Glomerular causes of CKD and non-glomerular causes of CKD. Choose the appropriate diagnosis.

For sites that are able to perform a database search for N-G diagnoses, a list of ICD9 and ICD10 codes are provided below to assist in identification of potential participants.

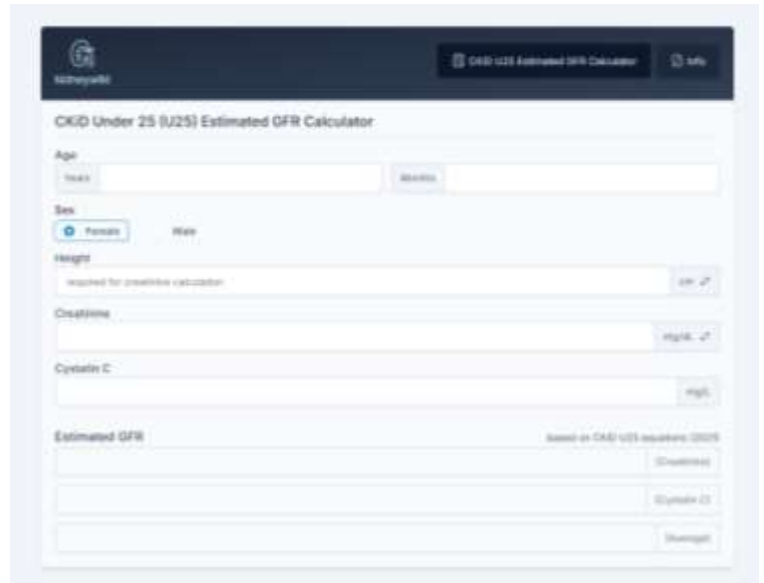
NG Kidney Disease Dx Codes		
Type of Disease	ICD-9 Code(s)	ICD-10 Code(s)
Aplastic/hypoplastic/dysplastic kidneys *	753.13	Q61.4
hypoplastic kidneys	753.0	Q60.5, Q60.3, Q60.4
Branchio-oto-Renal Disease/Syndrome *	759.89	Q878.8, Q87.0
Bilateral Hydronephrosis	591	N13.30, N13.2
Congenital Urologic Disease (Bilateral Hydronephrosis) *	73.0	
Cystinosis *	270.0	E72.04
Medullary cystic disease/juvenile nephronophthisis *	753.16	Q61.5
Methylmalonic Acidemia *	270.3	E71.120
Obstructive uropathy (Posterior urethral valve (PUV)) *	599.6	N13.9
Oxalosis *	271.8	E72.53
Perinatal Asphyxia *	768, 768.5, 768.6, 786.9	P84
Polycystic kidney disease (Autosomal dominant) *	753.13	Q61.2
Polycystic kidney disease (Autosomal recessive) *	753.14	Q61.19
Pyelonephritis/Interstitial nephritis	580.89, 581.89, 582.89, 583.89	N10, N11, N12
Reflux nephropathy *	593.73	N11.0, N13.7, N13.9
Renal infarct	593.81	N28.0
Syndrome of agenesis of abdominal musculature (Eagle Barrett, prune belly syndrome) *	756.71	Q89.4
Vactrel or Vater Syndrome *	759.89	Q87.2
Wilms’ tumor	189.0	C64.9
Other		
Infections of the Kidney	590	

For eligibility, individuals must be ≥ 16 to < 23 years old with an eGFR < 60 ml/min/1.73m². Use the U25eGFR calculator to calculate estimated GFR measurements based on the individual's SCr and height measurements.

DO NOT enter cystatin C results.

The calculator derived from Pierce CB, Munoz A, Ng DK, et al.. Kidney Int 2021 Apr;99(4):948-956. PMID: 33301749

To access **U25eGFR calculator**, go to <https://kidney.wiki/gfr-calculator/>
Enter age, sex, height (in cm), and serum creatinine (in mg/dL).



The image shows a screenshot of the CKiD U25 Estimated GFR Calculator interface. The form includes fields for Age (Years and Months), Sex (Female and Male), Height (cm), Creatinine (mg/dL), and Cystatin C (mg/L). The Estimated GFR result is displayed as 58.7 mL/min/1.73m² based on CKiD U25 equations (2021).

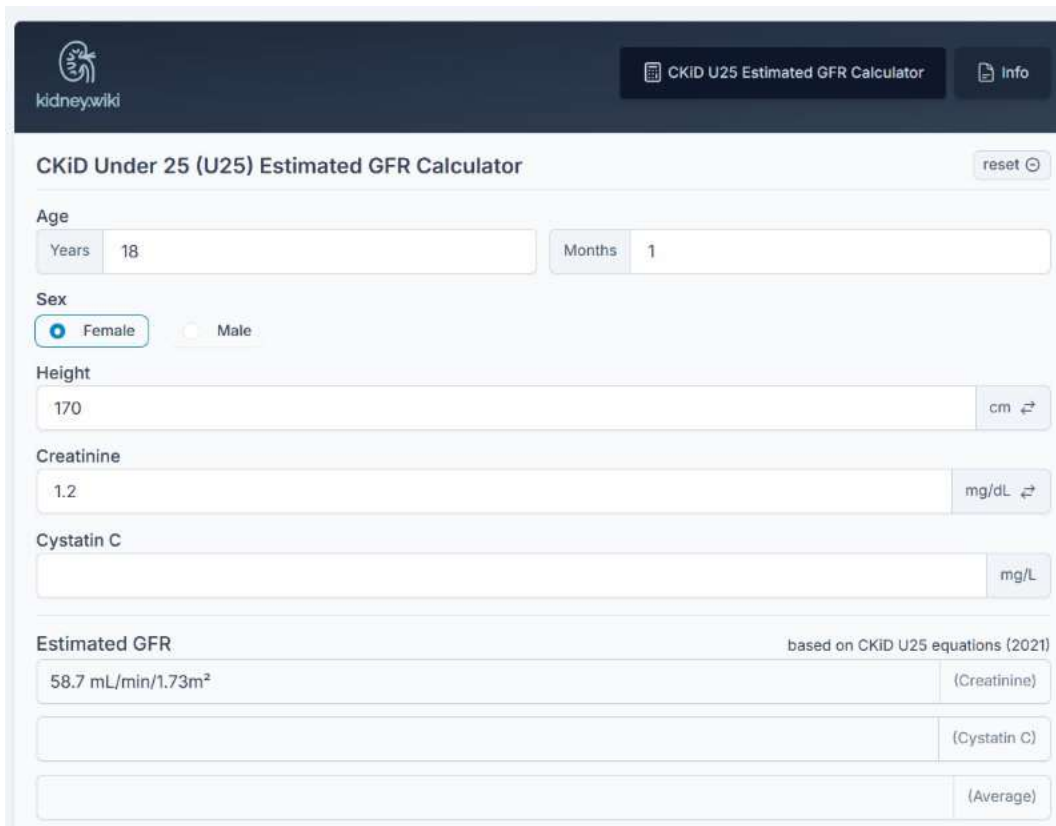
U25eGFR calculator is also accessible from the CKiD website's Investigator Resources webpage.

Go to <https://statepi.jhsph.edu/ckid/investigator-resources/>

Click on "Learn More about Calculators"

Then under CKiD Under 25 (U25) GFR estimating equations click on "Go to Calculator on kidney.wiki"

Below is an example of an 18 year old female who is 170 cm in height with creatinine measurement of 1.2.



The image shows a screenshot of the CKiD U25 Estimated GFR Calculator interface with the following input values: Age (Years: 18, Months: 1), Sex (Female), Height (170 cm), Creatinine (1.2 mg/dL), and Cystatin C (empty). The Estimated GFR result is displayed as 58.7 mL/min/1.73m² based on CKiD U25 equations (2021).