

**Title: Atorvastatin therapy in the  
treatment of dyslipidemia in children  
with steroid sensitive nephrotic  
syndrome**

**Date : 27<sup>th</sup> January 2024**

**NCT number : ID not yet assigned**

**APPENDIX-I**  
**DATA COLLECTION SHEET**

**Title: Atorvastatin therapy in the treatment of  
dyslipidemia in children with steroid sensitive  
nephrotic syndrome**

Serial No:

Hospital Reg.No:

Hospital Name:

**Researcher:**

Dr Saieef Zaman

MD (Pediatric Nephrology) Phase B

Department Of Pediatric Nephrology

National Institute of Kidney disease & Urology

Phone: 01766400573

Date of admission/outdoor visit .....

Date of enrollment: .....

Address: .....

Telephone/Mobile No.....

**Socio demographic data:**

1. Name:
2. Age :
3. Sex : 1=Male, 2=Female
4. Father's name:
5. Mother's name:
6. Legal guardian's name:
7. Residence:  
1=Rural, 2= Urban
8. Religion:  
1= Islam, 2= Hindu, 3= Christian, 4= Others
9. Fathers occupation:  
1= Farmer, 2= Business, 3= Service, 4= Day laborer, 5= others
10. Mothers occupation:  
1= Housewife, 2= Business, 3= Service, 4= Day laborer, 5= others
11. Socioeconomic status (monthly income in taka):  
1=Low ( $\leq$  11,210 Tk), 2=Lower middle (11211-44204 Tk),  
3=Upper Middle (44205- 1,68050 Tk), 4= High ( $>$ 1,68,051Tk)
12. Level of education (Father):  
1=Primary, 2=High school, 3= College & University, 4= No education
- 13) Level of education (Mother):  
1=Primary, 2=High school, 3= College & University, 4= No education

14) Immunization: Immunized as per EPI Schedule (1) Not immunized (2)

☐

15) Duration of nephrotic syndrome:

16) Clinical diagnosis:

1= infrequent relapse, 2= frequent relapse 3=steroid dependent

17) Treatment with corticosteroid/other immunosuppressant:

1=corticosteroid,2=mycophenolatemofetil,3=tacrolimus 4=Cyclosporin,  
5=others

☐☐

18) History of Cardiovascular disease in family:

19) Date of starting treatment:

Dietary Advice:

Diet Advice + Atorvastatin therapy:

20) Demographic variable of patient:

Baseline and clinical characteristics
Gender: Male/ Female :
Age :
Rural/Urban:

**21) Clinical variable:**

Date		(Baseline)
Weight		
Height		
BMI		
Temperature		
Pulse		
Blood Pressure		
Respiratory rate and chest findings		
Heat coagulation test (HCT)		
Edema		
Ascites		
Others (muscle/joint pain, indigestion/diarrhea etc.)		

## 22) Laboratory variable:

Date			(Baseline)
CBC	Hb% ESR TLC N L M E Platelet		
CRP			
S. creatinine			
<b>Urine R/M/E</b> Albumin RBC Pus cell			
Urine Culture			
Chest X ray			
Spot Urinary PCR			
S. Albumin			
S. Fasting Lipid Profile	Total cholesterol TG LDL HDL		
SGPT			
S.CPK			
RBS			

Dr Saieef Zaman  
MD (Pediatric Nephrology) Phase B  
Dept. Of Pediatric Nephrology  
National Institute of Kidney disease & Urology  
Phone : 01766400573

## Follow Up Sheet

### A. Clinical F/UP

Clinical variable	1 month	3 month	6 month
Weight			
Height			
BMI			
Temperature			
Pulse			
Blood Pressure			
Respiratory rate and chest findings			
HCT			
Edema			
Ascites			
Others,(Muscle/joint pain. Indigestion/diarrhea etc.)			
Date & signature			

Dr Saieef Zaman  
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Phone: 01766400573

## B. Laboratory F/UP

Laboratory variable			1 month		3 month		6 month	
CBC								
Hb%								
ESR								
TLC								
N								
L								
M								
E								
Platelet								
CRP								
S. Creatinine								
<b>Urine R/M/E</b>								
Albumin								
RBC								
Pus cell								
Urine culture								
Chest X ray								
Spot Urinary PCR								
S. Albumin								
S.Fasting	T.Cholesterol	TG						
Lipid Profile	LDL	HDL						
SGPT.								
S CPK								
RBS								
Date & Signature								

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Phone: 01766400573

**AewnZ mꠤ꠆wZcÎ/ ( Local Language Bangla) Consent form  
Atorvastatin therapy in the treatment of dyslipidemia in children with  
steroid sensitive nephrotic syndrome**

**Phone: 01766400573**

**M†el†Ki cwiwPwZt**

**f~wgKv:**

**D†İk" jÿ" :**

**M̧elbvi SzwK:**

**Ṃelbvi Ask MÖÖṇbi myweavw`:**

**weKí:**

vii

## LiP:

GB M<sub>1</sub>elbvq Ask M<sub>1</sub>Ön<sub>1</sub>bi Rb<sub>1</sub> Avcbvi evowZ †Kvb LiP †bB|

## †MvcbxqZv:

M<sub>1</sub>elbv PjvKvjxb I cieZx©†Z mgq Z<sub>1</sub> K<sub>1</sub>Vvi fv†e †Mvcb Kiv n†e| Avcbvi ev”Pvi Rb<sub>1</sub> GK  
M<sub>1</sub>elbv PjvKvjxb I cieZx©†Z mgq Z<sub>1</sub> K<sub>1</sub>Vvi fv†e †Mvcb Kiv n†e| Avcbvi ev”Pvi Rb<sub>1</sub>  
GKwU AvBwW †`lqv n†e| Avcbvi AvBwW b<sup>α</sup>i m<sup>α</sup>wjZ me ai†bi KvMR c<sub>1</sub> Avcbvi bvg,  
wVKvbv ewm†q Awd†mi dvBwjs †Kwe†b†U Zvjve× \_vK†e| e<sup>3</sup>w<sup>3</sup>MZ welqvw` Z<sub>1</sub>  
we†kø†b, cÖwZ†e`b •Zix cÖKvkbvi Kv†R e<sup>envi</sup> Kiv n†e Ges M<sub>1</sub>elbvi cixÿK e<sup>3</sup>ZxZ Kv†iv  
Kv†Q cÖKvk Kiv n†e bv| d†j Avcbvi Z<sub>1</sub> †KD Rvb†Z cvi†e bv|

## †<sup>^</sup>”Qv g~jK Ask M<sub>1</sub>Önb:

GB M<sub>1</sub>elbvq Avcbvi ev”PviAsk M<sub>1</sub>Önb m<sup>α</sup>ú~Y© †<sup>^</sup>”Qvg~jK| Avcwb M<sub>1</sub>elbvq Ask  
M<sub>1</sub>Ön<sub>1</sub>b A<sup>^</sup>xK...wZ Rvbv†Z cv†ib A<sub>1</sub>ev M<sub>1</sub>elbv PjvKvjxb †h †Kvb mgq M<sub>1</sub>elbv †\_†K  
Avcbvi ev”Pv†K cÖZ<sup>envi</sup> K†i wb†Z cv†ib| Zv†Z Avcbvi wPwKrmvi ZviZg<sup>3</sup> n†ebv| GB  
di†g<sup>^</sup>vÿi Ki†j Avcbvi ev”Pvi AvBbMZ †Kvb AwaKvi Le© n†e bv|

## mgqt

GB M<sub>1</sub>elbvq Avcbvi 6 □□□ □□□ □□□□ □□□ □□□□□ □□□□□□□□ □□, □□□ 1,3 □□  
□□□ □□ □□□□ □□□□ □□□□

## cÖkævejxt

hw<sup>3</sup> Avcbvi †Kvb cÖkæ \_v†K Z†e `qv K†i wRÁvmv Ki†eb| Avwg Avcbvi D<sub>1</sub>Ëi cÖ`vb Kivi  
h<sub>1</sub>vmva<sup>3</sup> †Pón Ki†ev| hw<sup>3</sup> fwel<sup>3</sup>†Z Avcbvi †Kvb □□□□□□□ D†`«K nq Zvn†j M<sub>1</sub>elYviZ  
□□□ □□□□ □□□□□, □□□□ □□□□□ wefvM, □□□□□- 628, □□□□□□□□ □□□□□□□□□□ □□  
□□□□□ □□□□□□□ □□□□ □□□□□□□ □†hvMv†hvM Ki†Z cvi†eb □ Avgvi †gvevBj bv<sup>α</sup>vi  
nj 01766400573□

## m<sup>α</sup>§wZ<sup>^</sup>xKv†ivw<sup>3</sup>t

Avwg M<sub>1</sub>elYvq wb†qvwrZ wPwKrm†Ki mv†\_ (whwb Avgvi ev”Pvi kvixwiK cixÿv Ki†eb)  
GB M<sub>1</sub>elYv wb†q Av†jvPbvq mš`wó cÖKvk KiwQ| Avwg GUv ey†SwQ †h, M<sub>1</sub>elYvq Ask  
M<sub>1</sub>ÖnY †<sup>^</sup>”Qv g~jK Ges Avwg †h †Kvb mgq †Kvb eva<sup>3</sup>evaKZv QvovB M<sub>1</sub>elYv †\_†K  
Avgvi ev”Pv†K weiZ ivL†Z cvwi| Avwg Dc†iv<sup>3</sup> welq,†jv c†owQ / Avgvi m<sup>α</sup>§†L cwVZ  
n†q†Q Ges †<sup>^</sup>”Qvq M<sub>1</sub>elYvq Ask M<sub>1</sub>ÖnY Ki†Z m<sup>α</sup>§wZÁvcb KiwQ|

M<sub>1</sub>el†Ki<sup>^</sup>vÿi t

ZvwiLt

bvgt

Ask M<sub>1</sub>ÖnbKvixi<sup>^</sup>vÿit

ZvwiLt

bvgt

Awffve†Ki<sup>^</sup>vÿi/e,,×v<sup>1/2</sup>ywji Qvet

ZvwiLt

bvgt



□□□□□□  
ZvwiLt

□□□□□□□□

bvgt

## APPENDIX-III

### **AewnZ mᳵᳶwZcÎ/Assent Form (Local language Bangla)** **Atorvastatin therapy in the treatment of dyslipidemia in children with** **steroid sensitive nephrotic syndrome**

**Investigator: Dr. Saieef Zaman**

**Phone: 01766400573**

GB mᳵᳶwZcÎ DᳶÎk" nj AvcbvᳶK cÖᳶqvRbxq Z\_ cÖ`vbKiv, ᳶh Z\_,ᳶjv AvcbvᳶK  
wm×všÎ wbᳶZ mvnvh" Kiᳶe, Avcwb GB MᳶelYvq AskM<sup>a</sup>nb Kiᳶeb wKbv?

#### **MᳶelᳶKi cwiwPwZt**

Avwg Wvt mvCd Rvgvb, b`vkbvj Bbw÷wUDUAe wKWwb wWwRᳶRR GÛ BDᳶivjwRᳶZ  
wkî wKWbx wefvᳶMi Gg.wW ᳶiwmᳶWwÝ, ᳶdBR-we Gi wPwKrmK wnᳶmᳶe Kg©iZ  
AvwQ| Avwg wkî ᳶbᳶd«vwUK wmbᳶW«vg ᳶivᳶMi KviᳶY iᳶᳶ ᳶKvᳶjᳶ÷ᳶji cwigvY ᳶewk  
\_vKᳶj, Zvi wPwKrmvi Dci MᳶelYv KiwQ| Avwg AvcbvᳶK GB mᳶúᳶK© c«ᳶqvRbxq Z\_`  
c«`vb Kᳶi GB MᳶelYvq AskM«nᳶbi Avn&evb KiwQ|

#### **f~wgKv:**

ᳶbᳶd«vwUK wmbᳶW<sup>a</sup>vg wKWbxi GKwU wbivgq ᳶhvM" ᳶivM|GB ᳶivᳶMi GKwU Ab`Zg  
RwUjZv nᳶ"Q GB ᳶivMx ,ᳶjviiᳶᳶᳶ mvaviYZ ᳶKvᳶjᳶij (Pwe©i) cwigvY ᳶekx \_vᳶK| GB  
ᳶKvᳶjᳶij Gi evowZ cwigvY `xN©w`b aᳶi \_vKᳶj GBme ᳶivMxi kixᳶi wewfbœ aiᳶbi  
RwUjZv ᳶhgb: iᳶbvjx miæ ev eÛ nᳶq hvq, iᳶ PjvPᳶj evav m,wó nq Ges cieZ©xᳶZ ü`ᳶivᳶMi  
SzuwK e,,w× Kᳶi| `xN©w`b kixᳶi ᳶKvᳶjᳶij (Pwe©i) cwigvY ᳶekx \_vᳶKᳶj `xN© ᳶgqv`x  
wKWbx ᳶivᳶMi SzuwK e,,w× Kᳶi|

#### **DᳶÎk" jÿ :**

GB MᳶelYvi DᳶÎk" nᳶ"Q, ᳶbᳶd«vwUK wmbᳶW<sup>a</sup>vg Gi Rb" Avcbvi kixᳶi ᳶh ᳶKvᳶjᳶij  
(Pwe©i) Gi gvÎv e,,w× ᳶcᳶqᳶQ wKbv, ᳶmUv wK `xN©w`b AvᳶQ wKbv Ges ᳶmUvi  
wPwKrmv Kiv| Ges Zvi Rb" Avgiv wKQz cixÿv Kiel ᳶmwU AviI ᳶKvb RwUjZv %oZwi  
KᳶiᳶQ wKbv Zv RvbᳶZ cviᳶev| MᳶelbvU wkî ᳶbᳶd<sup>a</sup>vjwR wefvᳶMi Dᳶ`vᳶM  
cwiPvwjZ|□□□□ hw` GB Mᳶelbvq AskMÖnb KivᳶZ mᳶᳶZ \_vᳶKb Zvnᳶj Avwg Avcbvi  
ᳶivMmᳶúᳶÛ wKQz Z\_` wbe|

#### **Mᳶelbvi SzwK:**

GB Mᳶelbvq Ask MÖnᳶb ev`Pvᳶ`i SzwKi mᳶᳶvebv bvB|

## M†elbvi Ask MÖÖn†bi myweavw`:

GB M†elbvq Ask MÖnb Ki†j Avcbvi wPwKrmv †ÿ†Î jvfevb n†Z cvi†e| wKWbxi GB `xN© †gqv`x Amy†Li Kvi†Y Avcbvi kix†i †Kv†j†ij Gi cwigvY gvÎvwZwi³ e,,w× †c†q†Q wKbv,Zv `xN©`qx Av†Q wKbv Ges †mUvi wPwKrmv cv†eb| Ges GB mgm`vi Kvi†b Ab`vb` †h mgm`v,†jv n†Z cv†i †mUvi mα†Ü Avcbw AeMZ n†eb| Avi cÖv\_wgK ch©v†q GwU Rvbv mαe n†j Avcbvi Rb` cieZ©x†Z wK e`e`v wb†Z n†e Zv Avcbv†K Rvwb†q w`e|

## weKí:

GB M†elbvq Ask MÖnb Kiv wKsev bv Kiv†Z Avcbvi †b†d«vwUK wmb†W³vg Gi wPwKrmvi †Kvb ZviZg` n†e bv| Ask MÖnb Kivi ci †h †Kvb mgq Avcbx M†elbv †\_†K mwi†q wb†Z cvi†eb|

## LiP:

GB M†elbvq Ask MÖn†bi Rb` Avcbvi evowZ †Kvb LiP †bB|

## †MvcbxqZv:

M†elbv PjvKvjxb I cieZx©†Z mgq Z\_` K†Vvi fv†e †Mvcb Kiv n†e| Avcbvi Rb` GK M†elbv PjvKvjxb I cieZx©†Z mgq Z\_` K†Vvi fv†e †Mvcb Kiv n†e| Avcbvi Rb` GKwU AvBwW †`Iqv n†e| Avcbvi AvBwW bα^i mα^wjZ me ai†bi KvMR cÎ Avcbvi bvg, wVKvbv ewm†q Awd†mi dvBwjs †Kwe†b†U Zvjve× \_vK†e| e`w³MZ welqvw` Z\_` we†kø†b, cÖwZ†e`b •Zix cÖKvkbvi Kv†R e`envi Kiv n†e Ges M†elbvi cixyK e`ZxZ Kv†iv Kv†Q cÖKvk Kiv n†e bv| d†j Avcbvi Z\_` †KD Rvb†Z cvi†e bv|

## †`^”Qv g~jK Ask MÖnb:

GB M†elbvq Avcbvi Ask MÖnb mαú~Y© †`^”Qvg~jK| Avcbw M†elbvq Ask MÖn†b A`^xK...wZ Rvbv†Z cv†ib A\_ev M†elbv PjvKvjxb †h †Kvb mgq M†elbv †\_†K □□□□ cÖZ`vnvi K†i wb†Z cv†ib| Zv†Z Avcbvi wPwKrmvi ZviZg` n†ebv| GB di†g `^vyi Ki†j Avcbvi AvBbMZ †Kvb AwaKvi Le© n†e bv|

## mgqt

GB M†elbvq Avcbvi 6 □□□ □□□ □□□□ □□□ □ □□□□□□□□□ □□, □□□ 1,3 □□ □□□ □□□□ □□□□ □□□□

## cÖkævejxt

hw` Avcbvi †Kvb cÖkæ \_v†K Z†e `qv K†i wRÁvmv Ki†eb| Avwg Avcbvi DËi cÖ`vb Kivi h\_vmva` †Pón Ki†ev| hw` fwel`†Z Avcbvi †Kvb □□□□□□□ D†`«K nq Zvn†j M†elYviZ □□□ □□□□ □□□□, □□□□ □□□□ wefvM, □□□□- 628, □□□□□□□ □□□□□□□□□ □□□□ □□□□□□ □□□□ □□□□□□ □†hvMv†hvM Ki†Z cvi†eb □Avgvi †gvevBj bvα^vi nj 01766400573□

## mαšwZ `^xKv†ivw³t

Avwg M†elYvq wb†qvwrZ wPwKrm†Ki mv†\_ (whwb Avgvi kvixwiK cixyv Ki†eb) GB M†elYv wb†q Av†jvPbvq mš`wó cÖKvk KiwQ| Avwg GUv ey†SwQ †h, M†elYvq Ask MÖnY †`^”Qv g~jK Ges Avwg †h †Kvb mgq †Kvb eva`evaKZv QvovB M†elYv †\_†K weiZ ivL†Z cvwi| Avwg Dc†iv³ welq,†jv c†owQ / Avgvi mαš†L cwVZ n†q†Q Ges †`^”Qvg M†elYvq Ask MÖnY Ki†Z mαšwZAvcb KiwQ|

M†el†Ki ^vÿi t

ZvwiLt

bvgt

Ask MÖnbKvixi ^vÿit

ZvwiLt

bvgt

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ZvwiLt

bvgt

## APPENDIX-IV

### INFORMED CONSENT FORM IN ENGLISH

**TITLE: Atorvastatin therapy in the treatment of dyslipidemia in children with steroid sensitive nephrotic syndrome**

**Investigator: Dr Saieef Zaman**

**Phone no: 01766400573**

**ID no. of the participant:** The aim of this consent form is to give you the information that will help you to make decision whether you will participate in research.

#### **About the Researcher:**

I am Dr. Saieef Zaman, working as a doctor of MD phase B resident in the department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology. I am researching on topics related to the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome. I will provide you necessary information and invite you to participate in this study. The purpose of this consent form is to give you relevant information which will help you whether you will participate in this research or not.

#### **Introduction:**

Nephrotic syndrome is a curable disease Hypercholesterolemia is one of the complications of this disease. For this reason, these children are more susceptible to developing atherosclerosis. Atherosclerosis is one of the major risks for developing

cardiovascular diseases. Also, these patients may develop glomerulosclerosis ultimately ending in CKD.

**Purpose of the study:**

Aim of the study is to measure the serum Fasting lipid profile in different types of Steroid Sensitive Nephrotic Syndrome in Children and manage it either by dietary intervention or by dietary intervention and atorvastatin to find out which is better. This study will be held in the Pediatric Nephrology/Nephrology Department. If you give your consent to participate in this study, then I will take some information about your child.

**Risk of the study:**

There is low risk to participate in this study.

**Advantages in participating in this study:**

Your child will benefit if they participate in this study. We will be able to know whether your child is developing increased amounts of lipid in the blood as it is a common side effect of the disease and appropriately manage it so no further complications arise from this condition. You can withdraw your child at any time from this study.

**Alternative:**

The normal treatment of your child shall proceed as per general treatment procedure of the hospital, even if your children do not participate in the research.

**Compensation for the study:** There is no excess cost in participating in this study.

**Confidentiality:**

In the duration of the study, your information will not be disclosed. We will give an ID to your child. Your file containing all information will be secured. Except the researcher and people related to research, this information will not be disclosed to others.

**Rights as participants:**

You can actively participate in this study. You can withdraw your child at any time. If you participate in this study, this will be fruitful for your child. No rights will be hampered to participate in this study.

**Time Period:**

The research will take 6 months of your time. Your child will be followed up at 1, 3 month & 6 month after participation.

**Questions or problem:**

You can ask me any question any time during this study. I will try my best to give an answer. In future, if any questions arise, please contact me by asking for Dr Saieef Zaman in Room no 628, Department of Pediatric Nephrology, National Institute of Kidney Disease & Urology. My phone no is 01766400573.

**Informed consent:**

I have been informed regarding this study. I understand that I can actively participate in this study and can withdraw my child at any time. All the above things are explained in front of me. I give my consent to participate in this study.

<b>Signature of investigator:</b>	<b>Date:</b>	<b>Name:</b>
<b>Signature of guardian:</b>	<b>Date:</b>	<b>Name:</b>
<b>Signature (Participant):</b>	<b>Date:</b>	<b>Name:</b>
<b>Signature (Witness to consent):</b>	<b>Date:</b>	<b>Name:</b>

**APPENDIX-V**

**INFORMED ASSENT FORM IN ENGLISH**

**TITLE: Atorvastatin therapy in the treatment of dyslipidemia in children with steroid sensitive nephrotic syndrome**

**Investigator: Dr Saieef Zaman**

**Phone no: 01766400573**

**ID no. of the participant:**

The aim of this assent form is to give you the information that will help you to make decision whether you will participate in research.

**About the Researcher:**

I am Dr.Saieef Zaman, working as a doctor of MD phase B resident in the department of Pediatric Nephrology, National Institute of Kidney Diseases and Urology. I am researching on topics related to the treatment of dyslipidemia in children with Steroid Sensitive Nephrotic Syndrome. I will provide you necessary information and invite you to participate in this study. The purpose of this assent form is to give you relevant information which will help you whether you will participate in this research or not.

**Introduction:**

Nephrotic syndrome is a curable disease Dyslipidaemia is one of the complications of this disease. For this reason, these children are more susceptible to developing atherosclerosis. Atherosclerosis is one of the major risks for developing cardiovascular diseases. Also, these patients may develop glomerulosclerosis ultimately ending in CKD.

**Purpose of the study:**

Aim of the study is to measure the serum Fasting lipid profile in different types of Steroid Sensitive Nephrotic Syndrome in Children and manage it either by dietary intervention or by dietary intervention and atorvastatin to find out which is better. This study will be held in the Pediatric Nephrology. If you give your consent to participate in this study, then I will take some information about you.

**Risk of the study:**

There is low risk to participate in this study.

**Advantages in participating in this study:**

You will benefit if you participate in this study. We will be able to know whether you are developing increased amounts of lipid in the blood as it is a common side effect of the disease and appropriately manage it so no further complications arise from this condition. You can withdraw yourself at any time from this study.

**Alternative:**

The normal treatment of yourself shall proceed as per general treatment procedure of the hospital, even if you do not participate in the research.

**Compensation for the study:** There is no excess cost in participating in this study.

**Confidentiality:**

In the duration of the study, your information will not be disclosed. We will give an ID to you. Your file containing all information will be secured. Except the researcher and people related to research, this information will not be disclosed to others.

**Rights as participants:**

You can actively participate in this study. You can withdraw yourself at any time. . If you participate in this study, this will be fruitful for you. No rights will be hampered to participate in this study.

**Time Period:**

The research will take 6 months of your time. Your will be followed up at 1,3 month & 6 month after participation.

**Questions or problem:**

You can ask me any question any time during this study. I will try my best to give an answer. In future, if any questions arise, please contact me by asking for Dr Saieef Zaman in Room no 628, Dept of Pediatric Nephrology, National Institute of Kidney Disease & Urology. My phone no is 01766400573.

**Informed consent:**

I have been informed regarding this study. I understand that I can actively participate in this study and can withdraw myself at any time. All the above things are explained in front of me. I give my consent to participate in this study.

**Signature of investigator:**

**Date:**

**Name:**

**Signature (Participant):**

**Date:**

**Name:**