

**PARTICIPANT INFORMED CONSENT FORM (PICF)**  
(English)

Protocol / Study number: \_\_\_\_\_

Participant identification number for this trial: \_\_\_\_\_

Title of project: **“Impact of socioeconomic variables and nutritional status at diagnosis on the clinical outcomes of cancer in children and adolescents.”**

The contents of the information sheet dated \_\_\_\_\_ that was provided have been read carefully by me / explained in detail to me, in a language that I comprehend, and I have fully understood the contents. I confirm that I have had the opportunity to ask questions.

The nature and purpose of the study and its potential risks / benefits and expected duration of the study, and other relevant details of the study have been explained to me in detail. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal right being affected.

I understand that the information collected about me from my participation in this research and sections of any of my medical notes may be looked at by responsible individuals from AIIMS. I give permission for these individuals to have access to my records.

I agree to take part in the above study.

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(Signatures / Left Thumb Impression of the participant)

Date:  
Place:

(When the patient is a minor /or unable to affix signature due to physical or mental disability)

Signature of parent/guardian: \_\_\_\_\_

Complete postal address: \_\_\_\_\_

This is to certify that the above consent has been obtained in my presence.

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Signatures of the Principal Investigator

Date:  
Place:

**PARTICIPANT INFORMATION SHEET (PATIENT/GUARDIAN OF PATIENT)**

You are invited to take part in this research study. Before agreeing to participate in the study, it is important that you read and understand this sheet. It describes the aim and method of the research, expected duration of participation, possible risk if associate with the study along with the possible benefits that you might gain from taking part in the study. It also mentions your right to withdraw from the study at any time. If you participate, you will receive a copy of this form to keep for your record.

**i) Title of the Study/Project**

Impact of socio-economic variables and Nutritional status at diagnosis on the clinical outcome of children and adolescents with cancer.

**ii) Aims and methods of the research.**

In this study aim is to assess nutritional status, dietary pattern, socio-economic status and micronutrient and vitamin status of children with cancer at diagnosis. Analyze the correlation of the nutritional status with demographic, socio-economic, dietary and clinical variables and see relationship with various clinical outcomes.

**iii) Expected duration of the subject participation.**

Maximum 45 minutes

**iv) The benefits to be expected from the research to the subject or to others.**

It will be helpful to assess the nutritional status of pediatric cancer patients at diagnosis and contributing factors which affect the clinical outcome are detected and this may be used in improvement of the overall survival in future.

**v) Any risk to the subject associated with the study.**

No risk involved

**vi) Maintenance of confidentiality of records.**

Records will be kept confidential as per rules.

**vii) Provision of free treatment for research related injury.**

There is no chance of injury to the patients in this study.

**viii) Compensation of subjects for disability or death resulting from such injury.**

Not applicable

**ix) Freedom of individual to participate and to withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.**

All patients will be given full freedom to participate or not in the research work. They can withdraw any time if they wish to do so.

- x) Amount of blood sample in quantity, in Tea Spoon Full, to be taken should be mentioned.**

NA

- xi) Costs and source of investigations, disposables, implants and drugs/contrast media must be mentioned.**

NA

- xii) Telephone number/contact number of Investigator**

For any questions about this study or your rights, please contact

Richa Srivastava

- xiii) In case of drug trials: Not applicable**

**General and Socioeconomic Data****General data**

- 1 Name (patient) : \_\_\_\_\_
- 2 Guardian name : \_\_\_\_\_  
 Relationship: \_\_\_\_\_  
     Mother  
     Father  
     Other
- 3 Age :
- 4 Sex (Male=1, Female=2) :
- 5 IR.C.H No. : \_\_\_\_\_
- 6 Date of birth (DD/MM/YY) :
- 7 Date of registration (DD/MM/YY) :
- 8 Date of interview (DD/MM/YY) :
- 9 Address : \_\_\_\_\_  
 \_\_\_\_\_
- 10 Contact no. : \_\_\_\_\_
- 11 Subject is studying :  \_\_\_\_\_  
 (Yes =1, No=2, NA=3)  
 If yes specify class

**Demographics data**

- 12 Type of community where the child's family lived. :   
 (Urban=1, Rural=2)

<b>13</b>	Child's family belongs to which state? (Delhi=1, Haryana=2, Uttarpradesh=3, Bihar=4, Uttaranchal=5,Rajasthan=6,Madha- pradesh=7,others=8)	:	<input type="checkbox"/>				
<b>14</b>	Distance of your resident from the hospital?	:	_____				
<b>15</b>	Education status of mother and father of the child. (Illiterate=1, Primary=2, High School=3, Intermediate=4, Graduate=5, Post Graduate & above=6, Others=7)	:	<table border="0"> <tr> <td><b>Mother</b></td> <td><b>Father</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	<b>Mother</b>	<b>Father</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Mother</b>	<b>Father</b>						
<input type="checkbox"/>	<input type="checkbox"/>						
<b>16</b>	Family type (Nuclear= 1, Joint=2)	:	<input type="checkbox"/>				
<b>17</b>	Family size (total no. of family members)	:	<table border="0"> <tr> <td><b>Children</b></td> <td><b>Adult</b></td> </tr> <tr> <td><input type="checkbox"/><input type="checkbox"/></td> <td><input type="checkbox"/><input type="checkbox"/></td> </tr> </table>	<b>Children</b>	<b>Adult</b>	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>
<b>Children</b>	<b>Adult</b>						
<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>						
<b><u>Socio-economic data</u></b>							
<b>18</b>	Religion (Hindu=1, Muslim=2, Christian=3, Jain=4, Sikh=5, Other=6)	:	<input type="checkbox"/>				
<b>19</b>	Presently child's parents are working? (Yes=1, No=2, NA=3)	:	<table border="0"> <tr> <td><b>Mother</b></td> <td><b>Father</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	<b>Mother</b>	<b>Father</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Mother</b>	<b>Father</b>						
<input type="checkbox"/>	<input type="checkbox"/>						
<b>20</b>	Occupation of parents (Agriculture and Allied=1, Business=2, Service=3, Labour class=4, Retired=5, Others=6, Housewife=7)	:	<table border="0"> <tr> <td><b>Mother</b></td> <td><b>Father</b></td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	<b>Mother</b>	<b>Father</b>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Mother</b>	<b>Father</b>						
<input type="checkbox"/>	<input type="checkbox"/>						
<b>21.</b>	Family monthly income		<input type="text"/>				

## Section I

**Disease history and vaccination history related data**

	Diagnosis	:	_____
<b>2</b>	Cancer type	:	_____
<b>3</b>	Cancer site	:	_____
<b>4</b>	Family history of cancer (Yes=1, No=2, NK=3, NA=4)	:	_____
<b>5</b>	Solid tumours (Malignant=1, Non-malignant=2)	:	<input type="checkbox"/>
<b>6</b>	Duration of illness	:	<input type="checkbox"/> <input type="checkbox"/>
<b>7</b>	Wt. Loss during last 3 months in percentage (%).	:	<input type="checkbox"/> <input type="checkbox"/>
<b>8</b>	Vaccinations give to the child? (Yes=1, No=2, Inadequate=3, NK=4)	:	<input type="checkbox"/>
		:	<input type="checkbox"/>
		:	<input type="checkbox"/>

**Dietary pattern, health and hygiene related data**

1	Has food intake declined over the past few days due to loss of appetite? (Yes=1, No=2, NA=3)	:	<input type="checkbox"/>
2	Has food intake declined over the past few days due to digestive problem? (Yes=1, No=2, NA=3)	:	<input type="checkbox"/>
3	How many major meals does the child eat daily? (1meal=1, 2meal=2, 3meal=3)	:	<input type="checkbox"/>
4	How many minor meals does the child eat daily? (1meal=1, 2meal=2, 3meal=3)	:	<input type="checkbox"/>
5	Child is (Vegetarian=1, Ova-vegetarian=2, Non-vegetarian=3)	:	<input type="checkbox"/>
6	Baseline knowledge of personal hygiene	<b>Score [Yes =1, No= 0]</b>	
1.	Are you bathe regularly and washing your body often?		<input type="checkbox"/>
2.	Are you brushing your teeth, flossing and rinsing every day?		<input type="checkbox"/>
3.	Are you washing your hands before eating meals and after using toilet?		<input type="checkbox"/>
4.	Are you cleaning and trimming your fingers nails and toenails weekly.		<input type="checkbox"/>
5.	Are you cleaned and dry your ears every?		<input type="checkbox"/>
6.	Are you keeping your hairs clean with shampoo and oil?		<input type="checkbox"/>
7.	Are you washing your feet when you take bath or shower.		<input type="checkbox"/>
8.	Are you Changing used clothes for clean ones every day?		<input type="checkbox"/>
<b>Score-</b>	<b>Total</b>		<input style="width: 150px; height: 20px;" type="text"/>

**Food Frequency Questionnaire**

<b><i>Foods</i></b>	<b><i>Amt. g/ml</i></b>	<b><i>Daily</i></b>	<b><i>3-4/wk.</i></b>	<b><i>1-2/wk.</i></b>	<b><i>2-3/mth.</i></b>	<b><i>1/mth.</i></b>	<b><i>Rarely</i></b>	<b><i>Never</i></b>
<b>Cereals:</b>								
Wheat								
Rice								
Sooji								
Bread								
Others								
<b>Pulses</b>								
<b>Green L. Vegt.</b>								
<b>Other Vegt.</b>								
<b>Root Vegt.</b>								
<b>Fruit</b>								
<b>Fruit Juices</b>								
<b>Milk</b>								
<b>Curd/ Paneer</b>								
<b>Eggs</b>								
<b>Chicken/ Meat/fish</b>								
<b>Oil/ Ghee/ Butter</b>								
<b>Sugar</b>								
<b>Sweets</b>								
<b>Chips/ Kurkure</b>								
<b>Cold Drinks</b>								
<b>Biscuits</b>								
<b>Cake/ Pastery</b>								
<b>Ice Cream</b>								
<b>Noodles/ Maggi</b>								
<b>Pizza / Burger</b>								
<b>Fried Snacks</b>								
<b>Choclote/toffies</b>								



<b>Food Faddism Questionnaire</b>	
(Yes=1, No=2, Don't know=3)	
1. Can eating healthy foods make your child live longer?	<input type="checkbox"/>
2. Is diet high in fat related to high blood cholesterol?	<input type="checkbox"/>
3. Is diet low in iron related to anemia?	<input type="checkbox"/>
4. Which type of cooking fat has more cholesterol? (Ghee=1, Refined oil=2, Don't know= 3)	<input type="checkbox"/>
5. Which food item is high in protein? (Egg=1, Apple=2, Don't know= 3)	<input type="checkbox"/>
6. Healthy foods sold in market are higher in nutritional value than regular homemade food.	<input type="checkbox"/>
7. In order to be healthy, your child should eat some food that he/she never had before.	<input type="checkbox"/>
8. Fruit juices give more energy than milk.	<input type="checkbox"/>
9. Fruits are better source of energy than cereals. (Specify name)	<input type="checkbox"/>
<b>Restriction related questions</b>	
1. If your child is suffering from cancer, then you should give him low salt non spicy food.	<input type="checkbox"/>
2. You restrict to your child for eating pickles.	<input type="checkbox"/>
3. You restrict to your child for eating fermented food items (example-curd). (if yes specify)	<input type="checkbox"/>
4. You restrict to your child for eating egg. (if yes specify)	<input type="checkbox"/>
5. You restrict to your child for eating meat/chicken/fish. (if yes specify)	<input type="checkbox"/>
6. You restrict to your child for eating milk and milk products. (if yes specify)	<input type="checkbox"/>

7. You restrict to your child for eating whole cereals and pulses.  
(if yes specify)
8. You restrict to your child for eating specific vegetables.
9. You restrict to your child for eating specific fruit.
10. You restrict to your child for eating nuts.
11. You restrict to your child for eating fat and oils.
12. You restrict to your child for eating sugar and jiggery.

## Recipe standardization for conversion to raw food equivalent

Name of the recipe	Serving size	Ingredient	Amount of raw ingredients(gm)
<b>Cereal group</b>			
Wheat Chapati	1	Wheat Flour	50
Paratha	1	Wheat Flour	60
		Oil	10
Puri	1	Wheat Flour	40
		Oil	20
Wheat daliya	1 Katori	Wheat porridge	50
		vegetables	50
		Oil	10
Khichari	1 Plate	Rice	40
		Dal	35
Boiled Rice	1 plate	Rice	40
Poha/chidwa	1 plate	Rice flakes	40
		Oil	10
		vegetables	30
Suji Utpam	1	Suji	50
		Oil	10
Bread Toast	1	Refined wheat flour	40
		Oil/butter	10
<b>Legumes and pulses</b>			
Moong dal	1 Katori	Moong dal	35
		oil	5
Malka masoor dal	1 katori	Malka masoor dal	35
		oil	5
Arhar dal	1 katori	Malka masoor dal	35
		oil	5
Chana dal	1 katori	Chana dal	35
		oil	5
Mix dal	1 katori	Urad dal	10
		Chana dal	10
		Lobia	10
		oil	5
Rajma	1 katori	Rajma	30
		oil	10
		Tomato+ onion	20
Chowle	1 katori	Chowle	30
		oil	10

		Tomato+ onion	20
Black Chana	1 Katori	Chana	30
		Oil	10
		Tomato+ onion	20
Kadi	1 katori	Besan	10
		Buttermilk (ml)	200
		Spinach/daniya/onion	15
		Oil	5
<b>Vegetables and curries</b>			
Potato and Tomato sabji	1 katori	Potatoes	80
		Tomatoes	10
		Oil	5
Potato cauliflower sabji	1 katori	Potato	50
		Cauliflower	30
		Oil	5
Potato peas sabji	1 katori	Potato	50
		Peas	30
		Oil	5
Brinjal Potato sabji	1 katori	Brinjal	30
		Potato	20
		Oil	5
Lady finger sabji	1 katori	Lady finger	80
		Oil	5
Pumpkin	1 katori	Pumpkin	70
		Oil	5
Bottle gourd sabji	1 katori	Bottle gourd	80
		Oil	5
Carrot peas sabji	1 katori	Carrot	50
		Peas	30
Cabbage potato and peas sabji	1 katori	Cabbage	30
		Potato	20
		Peas	20
		Oil	5
Palak paneer sabji		Spinach	80
		Paneer	20
		Oil	5
Methi aloo saag		Fenugreek leaves	80
		Potato	20
		Oil	5
Beans aloo sabji		Beans	50
		Potato	30
Matar Paneer sabji		Peas	20
		Paneer	30
		Onion	10

		Tomato	10
		Oil	5
<b>Milk and milk products</b>			
Rice Kheer	1 katori	Milk	200 ml
		Rice	10
		Sugar	20
Suji Kheer	1 Katori	Milk	200 ml
		Suji	10
		Sugar	20
Custard	1 katori	Milk	200 ml
		Corn starch	10
		Sugar	20
Gajar ka halwa	1 katori	Milk	200 ml
		Carrot	100
		Sugar	20
Milk fruit shakes	1 glass	Milk	200 ml
		Fruit	80
		Sugar	20