Attachment 1.
(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 1.6.96

Principal Investigator Dr. N.H. Alam
Trainee Investigator (if any) _____
Application No. 96-011
Supporting Agency (if Non-ICDDR,B) _____
Title of Study Evaluation of the ... comminuted chicken diet in the treatment of persistent diarrhoea in children

Project status:
( ) New Study
( ) Continuation with change
( ) No change (do not fill out rest of form)

Circle the appropriate answer to each of the following (If Not Applicable write NA).

1. Source of Population:
   (a) Ill subjects (Yes) No
   (b) Non-ill subjects Yes, No
   (c) Minors or persons under guardianship (Yes) No
2. Does the study involve:
   (a) Physical risks to the subjects Yes (No)
   (b) Social Risks Yes (No)
   (c) Psychological risks to subjects Yes (No)
   (d) Discomfort to subjects (Yes) No
   (e) Invasion of privacy Yes (No)
   (f) Disclosure of information damaging to subject or others Yes (No)
3. Does the study involve:
   (a) Use of records, (hospital, medical, death, birth or other) (Yes) No
   (b) Use of fetal tissue or abortus Yes (No)
   (c) Use of organs or body fluids (Yes) No
4. Are subjects clearly informed about:
   (a) Nature and purposes of study (Yes) No
   (b) Procedures to be followed including alternatives used Yes (No)
   (c) Physical risks Yes (No) NA
   (d) Sensitive questions Yes (No) NA
   (e) Benefits to be derived (Yes) No
   (f) Right to refuse to participate or to withdraw from study (Yes) No
   (g) Confidential handling of data (Yes) No
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes (No) NA
5. Will signed consent form be required:
   (a) From subjects Yes (No)
   (b) From parent or guardian (if subjects are minors) (Yes) No
6. Will precautions be taken to protect anonymity of subjects Yes No
7. Check documents being submitted herewith to Committee:
   ___ Umbrella proposal - Initially submit an overview (all other requirements will be submitted with individual studies).
   ✓ Protocol (Required)
   ✓ Abstract Summary (Required)
   ✓ Statement given or read to subjects on nature of study, risks, types of questions to be asked, and right to refuse to participate or withdraw (Required)
   ___ Informed consent form for subjects
   ✓ Informed consent form for parent or guardian
   ✓ Procedure for maintaining confidentiality
   ___ Questionnaire or interview schedule *

* If the final instrument is not completed prior to review, the following information should be included in the abstract summary:
1. A description of the areas to be covered in the questionnaire or interview which could be considered either sensitive or which would constitute an invasion of privacy.
2. Examples of the type of specific questions to be asked in the sensitive areas.
3. An indication as to when the questionnaire will be presented to the Cttee. for review.

We agree to obtain approval of the Ethical Review Committee for any changes involving the rights and welfare of subjects before making such change.

Principal Investigator

Trainee

SECTION I: RESEARCH PROTOCOL

Title: Evaluation of the effect of a soluble fiber (Sun Fiber) supplemented comminuted chicken diet in the treatment of persistent diarrhoea in children

Principal Investigator: Dr N.H. Alam

Co-principal Investigator: Dr R. Meier

Co-investigators: Drs G. Fuchs, S.A. Sarker, P.K. Bardhan, N. Dewan, H. Schneider, K. Gyr

Duration of the project: 2 years from the date of commencement

Funding source: SANDOZ Nutrition, Bern, Switzerland

Total Project Cost: US $ 82,611

Name of the Division: Clinical Sciences Division

Signature of the Division Director : _____

Date : 15/5/96

Abstract Summary:

Dietary fiber is generally considered as a major regulator of bowel function. In the recent years, considerable interest has been generated in soluble dietary fibers as a subject of research and its therapeutic application. Partially hydrolyzed guar gum (Sun Fiber), a easily fermentable fiber and soluble in nature if added to food will undergo fermentation liberating short chain fatty acids (SCFAs) which will cause improvement of small intestinal and colonic function including intestinal absorption of nutrients and colonic absorption of salt and water and thus reduce the course of diarrhoeal illness. In a double-blind controlled clinical trial this protocol proposes to study the effects of a soluble fiber (Sun Fiber) supplemented comminuted chicken diet (minced chicken meat, glucose and oil mixture) in the treatment of persistent diarrhoea in children. 90 male patients aged 5-18 months will be randomized to receive either comminuted chicken based diet or comminuted chicken based diet supplemented with Sun Fiber. Other supportive therapy such as rehydration therapy and vitamin and mineral will be given to both the groups. A standard hospital management will be provided. After completion of the study the clinical responses such as stool output, duration of diarrhoea, success of therapy and weight change will be compared between the two groups. If this agent is found to be effective, then it might be recommended to use this agent in the dietary therapy of persistent diarrhoea.

SECTION II: RESEARCH PLAN

INTRODUCTION

Objective: **To evaluate the effect of a soluble fiber supplemented comminuted chicken diet in the treatment of persistent diarrhoea in children.**

Background:

In the recent years it has been recognised that the consumption of dietary fiber is one of the hallmarks of a healthy life style. Currently the beneficial effects of the water-soluble fiber has generated much interest as a subject of clinical research. Dietary fiber is generally considered as a major regulator of bowel function. Following the 'fiber hypothesis' put up by Denis Burkitt and Hugh Trowell (1-4), several basic laboratory and clinical studies have been carried out. The term 'dietary fiber' has been defined as the plant polysaccharides and lignin which are resistant to hydrolysis by human digestive enzymes (5, 6). The classification of Fiber has been done on the basis of the chemical structure (7-10). Fiber can be divided into non-polysaccharide and non-starch polysaccharide. The only non-polysaccharide fiber is lignin, a polymer of phenolic alcohol that is insoluble in water. The non-starch polysaccharides can be divided into cellulose and non-cellulose fiber. Cellulose consists of unbranched D-glucose chains in 1, 4-beta linkage and is water insoluble. Non-cellulose polysaccharides include hemicelluloses, mucillages, gums and pectins. Non-cellulose polysaccharides consist of various beta linkages of wide variety of hexose and pentose sugars. The polysaccharide chains are heteroglycans (chains with more than one type of monosaccharide). The hemicellulosic materials are polymers of xylose, mannose, and glucose with side chains of galactose and arabinose. The pectic substances are polymers of galacturonic acids. The gums and mucillages are likewise branched carbohydrate polymers (e.g. guar gum, which is a linear mannan with galactose side chains). Non-cellulose polysaccharides vary in degree of water solubility (7, 9, 10). Fiber is mainly fermented in the human colon by the colonic microflora. Many of the effects of fiber on stool output arise from this fermentation. The main products of fiber fermentation are short-chain fatty acids (SCFAs) including acetate, propionate, and butyrate. SCFAs are the major anions in the colon. Bacteria utilize SCFAs and proliferate, absorbing water from the colonic mucosa in the course of their metabolism, thus decreasing the free water content in the lumen (11). The SCFAs not utilized by the bacteria are largely absorbed by the colon (12). Their transepithelial transport is associated with stimulation of sodium transport from the colon in several species including man (13-15). This effect may be particularly important in infectious diarrhoeal diseases where fasting and purging may deplete the colon of SCFAs (16). So, luminal SCFAs levels in the colon may be a factor determining the clinical course of infectious diarrhoeal diseases. SCFAs have been shown to be clinically important in at least one diarrhoeal disease - transmissible gastroenteritis of swine (17). Animals infected with the virus develop an acute enteritis with marked fluid loss from the small intestine. Young animals develop severe diarrhoea as their colonic mucosa is incapable of absorbing fluid, whereas older infected animals increase their colonic absorption six-fold over control. This compensatory response prevents severe diarrhoea and is related to the development of colonic fermentation with the production of SCFAs (17). Cholera is a disease in man affecting the small intestine where fluid and electrolyte secretion is increased and absorption decreased leading to profuse watery diarrhoea. As the human colon has the capacity to absorb water and electrolyte (18), some

compensation is expected reducing the diarrhoeal loss. However, Speelman et al. (19) in a perfusion study showed impaired absorption of fluid and electrolyte through the colonic mucosa in acute cholera patients which may be explained partly due to lack of SCFAs in the colon. This speculation has been confirmed recently in one study (20).

The mechanism of SCFAs enhanced colonic absorption of water and electrolytes might be exploited in the treatment of infectious diarrhoeal diseases. Oral rehydration therapy has dramatically changed the management of acute diarrhoeal disease. Yet, oral rehydration therapy is in the process of being improved. Cereal based oral rehydration solutions (ORS) have been shown to reduce the stool volume by about 30% to 40% thereby yielding an improved ORS formulation (21, 22). A part of the effect on stool volume reduction might be attributed to SCFAs produced by unabsorbed carbohydrate including dietary fiber in the colon. Diversion colitis is an inflammatory process affecting the bypassed colon and rectum following surgical diversion of faecal stream (23). The inflammation disappears after surgical reanastomosis, and topical steroids are usually ineffective (24). Rectal instillation of SCFAs has resulted in the disappearance of symptoms and of endoscopic changes over a period of 4-6 weeks: remission has been maintained for over a year by regular rectal SCFAs treatment (25). So, these findings suggest that SCFAs may play a role in mucosal healing in colitis.

SCFAs, the fermentative product of dietary fiber are used by colonic epithelial cells as a source of energy for their various metabolic activities (26, 27). Human colonocytes use butyrate in preference to glucose, glutamine, or ketone bodies as fuel source (26). Thus in contrast to small intestinal cells. colonic epithelial cells derive the major part of their energy supply from the lumen rather than from the blood. Depriving luminal nutrition of the mucosa induces fluid secretion (28). The lack of luminal SCFAs in the colon may be involved in special diarrhoeal states such as diversion colitis and antibiotic associated diarrhoea etc. Diarrhoea is not uncommon after abdominal operations, particularly after closure of a temporary colostomy (29). Although there is no proof, this postoperative diarrhoea might be attributed to lack of SCFAs in the colon and may perhaps be reversed by the intake of fermentable fiber (29, 30). Lengthy preoperative bowel preparations by antibiotic and lavage and diminished oral nutrition probably might cause the development of postoperative diarrhoea (30). Lack of luminal SCFAs can similarly explain the diarrhoea often seen in the terminal stages of malnutrition and starvation. In these situations, intestinal infections might not always be implicated and it seems likely that diarrhoea is a manifestation of organ-specific malnutrition of the colon (31). Diarrhoea is also often associated with the use of broad spectrum antibiotics. Colonisation by toxin producing clostridium difficele accounts for only a third of these cases (32). The use of oral antibiotics suppress the formations of SCFAs from fermentable carbohydrate (33), a feature which might also be responsible for diarrhoea.

Persistent diarrhoea is a major clinical problem encountered by the physicians of the third world countries. Overall, studies in several developing countries have shown that 3-20% of acute diarrhoeal episodes in children under 5 years of age become persistent (34). A wide spectrum of functional disturbances occurring in persistent diarrhoea has been noted, and it appears that the pathogenesis of this syndrome is multifactorial. Suggested mechanism in the pathogenesis of persistent diarrhoea are: (a) persistance of pathogens, (b) continued mucosal injury, (c) delayed repair, and (d) bacterial overgrowth However, it seems that whatever is the primary insult to the intestinal tract, small intestinal mucosal injury highlights the pathophysiology (35). Depending upon the severity of the mucosal

damage, changes occur in the digestive, secretory, absorptive, and reabsorptive capacities of macro- and micro-nutrients. Two of the most important absorptive problems are carbohydrate and fat malabsorption. Considering these functional disturbances of small intestine, modified diets have been used for the management of persistent diarrhoea in ICDDR,B and other centres. Recent controlled study (36) has shown 65% success with a comminuted chicken based diet (Minced chicken, glucose and soy oil/coconut oil mixture)(unpublished data).

Colonic function in persistent diarrhoea has not been studied yet. The colon also plays an important part for conserving water and electrolyte (37). Water movements across the colonic epithelium are not by active transport but passive in response to solute absorption. SCFAs are the predominant anions in the colonic lumen and are a major contributor to solute transport (38). SCFAs are microbial breakdown products of dietary fibers and are rapidly and almost quantitatively absorbed. Due to indiscriminate use of broad spectrum antimicrobials in persistent diarrhoea and modified diet without polysaccharide/dietary fiber, the colonic concentration of SCFAs may be impaired which might induce colonic dysfunction interfering colonic water and electrolyte absorption (33). A soluble and easily fermantable fiber, if added to the diet in the treatment of persistent diarrhoea, might help in (a) improving the colonic function, (b) binding the secondary bile acids and bacterial toxins etc. Although, there are numbers of evidence suggesting antidiarrhoeal effect of fermentable fibers, their therapeutic effect in diarrhoeal diseases is yet to be confirmed.

Guar gum as a soluble fiber

Guar gum is a dietary fiber obtained from the endosperm of the seeds of the Indian cluster bean (Cyanopsis tetragonolobus) of the family Leguminosae. The guar plant is a pod bearing, nitrogen fixing legume. It has been grown for centuries in India and Pakistan, where it is one of the principal crops and used as food for both humans and animals. Now it has been grown in America for use in different industries (food, cosmetics, paper industries etc.) (39).

Chemically, guar gum is a non-starch polysaccharide, a galactomannan, which on contact with water forms a highly viscous gel. In the colon guar gum is fermented to form SCFAs. Initially, guar gum was used in food processing as thickener and emulsion stabilizer on the basis of its gelling property (39). Our present interest about guar gum is its therapeutic use as a dietary fiber.

Sun Fiber (partially hydrolysed guar gum)

As guar gum forms gel with water and is rather viscous, its suitability for use in therapeutic purposes (e.g. liquid enteral nutrition) is not well accepted. Sun Fiber, a soluble fiber is a guar gum that has been partially hydrolysed in vitro by the enzyme, endo-B-mannase. It is expected that Sun Fiber will be readily fermented by colonic microflora with the production of the same products of fermentation as guar gum. The partially hydrolysis of the guar gum (as in Sun Fiber), significantly reduces the viscosity of the fiber solution. It is expected that it will not cause delay in gastric emptying and also not interfere with normal absorption of macronutrients (carbohydrate, protein, and fat). In one study (40), it has been shown that addition of Sun Fiber to a liquid formula diet significantly delayed the colonic transit time without affecting the oro-caecal transit time. The results of another study (41) recently conducted in Liestal, Switzerland showed that the Sun Fiber does not affect the normal

absorption of glucose, amino acid and fat (Dissertation for MD, University of Basel).

We hypothesize that addition of easily fermentable soluble fiber (partially hydrolysed guar gum) might help in improving small intestinal and the colonic function, accelerating the water and solutes absorption and thus reducing the diarrhoeal loss.

Materials and method

Patients selection criteria:

Age : 5 - 18 months
Sex : only male children
Duration of diarrhoea: > 2 weeks but < 6 weeks
Diarrhoea with acute onset

Exclusion criteria:

1. Stool volume of less than 40 g/kg body weight during the first 24 hours of admission (baseline observation period).

2. Presence of complications such as high fever (>38°C), severe infections (pneumonia, septicaemia, meningitis etc), electrolyte imbalance, altered mentation, and presence of organisms such as cholera or shigella in stool requiring antimicrobial treatment).
3. Clinically apparent severe degree of malnutrition (marasmas or kwashiorkor). Informed consent will be obtained from parents/legal guardian before inclusion into the study.

Study design: The study will be double-blind, controlled and randomized.

Randomization

A randomization list will be prepared by using random number table (permuted block) taking block length of 2, 4 and 6. The randomization list will contain a serial number and a code for one of the diets as diet-A or diet-B. The two diets look identical. The diets will be prepared and supplied according to the serial number and diet code by one of the dieticians not involved in this study.

Sample size calculation:

Based on a recently completed study in ICDDR,B with comminuted chicken diet, we expect that 90% of the patients receiving comminuted chicken diet supplemented with a easily fermentable soluble fiber will recover within 7 days as against 65% in controls receiving comminuted chicken diet. Taking a significance level of 0.05 and 80% power to detect a difference of this magnitude or more between the groups 40 patients are needed in each group. Assuming a drop out rate of 10% the sample size of total 90 patients will be required.

Patient management and treatment schedule:

Detailed clinical history will be obtained and a thorough physical examination will be performed including anthropometric measurements (recumbent length, body weight, mid-arm circumference, and triceps skinfolds thickness). Vital signs will be recorded every 8 hours. Routine clinical care will be provided, and regular assessment of patients' condition will be monitored and recorded.

The patients will be maintained in fluid balance using intravenous fluids/ORS as needed by the clinical state and purging rate throughout the entire study period. During the first 24 hours (baseline observation period), baseline data on stool output, vomitus, food intake, and requirement of I.V. fluids will be obtained, and stool output rate will be calculated. The diet during this period will be milk-suji (cow's milk and rice powder mixture containing 68 kcal/100 ml), the usual hospital diet. Breast feeding will be continued and its intake will be measured.

The eligible patients will be randomly assigned to one of the two dietary groups. In the next 24 hours, the patient will receive the study diet (pre-balance period). The oral intake of food will be offered to achieve at least 110 kcal/kg/day for nonbreastfed and 80 kcal/kg/day for partially breastfed baby. All feed will be given 2 hourly.

Investigations (Routinely performed for persistent diarrhoea patients at ICDDR,B

The following investigation will be done after admission of the patient in the study ward:

1. Blood for CBC, electrolytes, albumin, serum total solids. (3 ml of venous blood will be needed for these tests.
2. Stool for M/E, Sudan III, helminths, and parasites by formal ether concentration, and cryptosporidium.
3. Stool for pH and reducing substances, electrolytes and osmolality.
4. Stool for C/S - campy., cholera, shigella, salmonella and ELISA for Rotavirus. *E. coli* colonies will be saved and tested for ETEC, EPEC and EAEC
5. Urine M/E, C/S (if required).

Balance study

Patient selection: The first 20 patients from each treatment group will be selected for the balance study.

Procedure: The study diet will be continued, as started on 2nd day. At the 48th hour of admission, the first marker as charcoal tablet will be given. A 2nd charcoal marker will be given after 72 h at the same time of first marker. Time of appearance of first marker in stool will be taken as 0 h. Collection of stool and urine will be started with the appearance of the first marker until 2nd marker comes out. 5 ml of acetic acid will be given in the collecting buckets. 72 h dietary intake will be measured and recorded. All vomitus will be collected in the same way. These samples will be kept at -20°C. Aliquotes of stool samples from homogenized 72 h collection will be taken and analysed for fat (42),

nitrogen (43), and carbohydrates by subtracting those from total energy. Total energy content will be determined by calorimetry (44). Dietary and breast milk contents for fat, carbohydrate and nitrogen will also be analysed. Total urinary N_2 excretion/day will be determined.

$$\text{Absorption coefficient} = \frac{\text{Intake - Loss}}{\text{Intake}} * 100$$

Composition of diets/l

	Diet A	Diet B
Ground chicken meat	150.0 g	150.0 g
Glucose	20.0 g	20.0 g
Soyabean oil	35.0 g	35.0 g
Nacl	1.0 g	1.0 g
Calcium lactate	0.5 g	0.5 g
Mgcl2	0.2 g	0.2 g
Sun Fiber (partially Hydrolysed guar gum	20.0 g	-
Water up to	1.0l	1.0 l
Energy kcal/100 ml	50.0	50.0

As elemental diets have been shown to cause micro-nutrient deficiency in patients suffering from prolonged sickness, a commercially prepared vitamin -mineral mixture will be given to all patients daily for two weeks. After recovery from diarrhoea, a transitional diet, rice suji (usual ICDDR,B hospital practice) will be tried, and if tolerated, the patients will be sent home on this diet.

Management of patients who fail on study diets:

Management of those patients who fail to respond will be tried by more dietary manipulation through elimination of different dietary components and maintaining parenteral hydration and nutrient support.

Transfer from study:

Any child developing sepsis, convulsion, enterocolitis, pneumonia, or any other serious condition will be immediately transferred to the intensive care unit, and will be excluded from the study. Data obtained from these patients will also be included for analysis.

Follow-up: To monitor the patients prognosis and also to ensure proper dietary management, a weekly follow-up for first 2 weeks and then bi-weekly for another 6 weeks will be made. The patients' parents will be asked to come to the hospital for the follow-up check-ups. Six weeks after discharge, trial with cow's milk test feed will be given during follow-up visit and then the patients will be observed for 6 hours. If tolerated, then transition to normal milk-based diet will be advised, otherwise milk-free diet will be continued.

Data analysis:

The data generated from the study will be entered in a microcomputer using the statpack gold package programme and will be analysed by using SPSS. Continuous variables will be compared between the groups using t-test or non-pagmetric tests according to the distribution of data. Dichitomous variables will be compared by x^2 test.

Organisation of the trial:

The study will be conducted in the metabolic ward of ICDDR,B. Patients attending in the treatment centre of ICDDR,B will be evaluated for recruitment for study.

Study Schedule:

The study will be started soon after the approval of RRC, ERC and approval of budget. The initial one and half years will be utilised for patient recruitment and data collection and data analysis and reporting of the findings will be done during the last 6 months of the study period.

Methods:

Stool will be collected in a polythene bag fitted in a plastic container placed beneath the cholera cot with a hole connected with the bucket. Collected stool weight will be measured every 6 hours using a sartorius weighing scale.

Urine volume will be collected separately by using pediatric urine collector (PUC) bags. Body weight will be measured at admission, at randomisation and 6 hours until diarrhoea ceased and then every 24 hours until discharge using a sartorius weighing scale with a precision of 1g.

Definition:

1. Diarrhoea - passage of 4 or more liquid motions within 24 hours.
2. Persistent diarrhoea - diarrhoea persisting for more than 2 weeks following an episode of acute diarrhoea.
3. Cessation of diarrhoea - passage of soft stool or formed stool, and no liquid stool in 48 hours.
4. Duration of diarrhoea: the period from the time of randomisation to the last abnormal stool.
5. Success of therapy: patients in whom diarrhoea was stopped in day 7 combined with body weight greater than admission weight or two consecutive days of weight gain >20g/day.

Response variables

1. Duration of diarrhoea.
2. Stool output (g/kg/24 hrs) over the study period.
3. Coefficient of absorption of fat, protein and carbohydrate.
4. Weight change (gain or loss) by day 7.
5. Amount of I.V. needed (a proxy indicator of diarrhoeal severity).
6. Proportion of success in each dietary group.

Safety issues of the product:

Sun fiber is a product of partially hydrolyzed guar gum. Guar seed has been used as food for both human and animals for centuries in this subcontinent. Human volunteer studies (40, 41) have shown that it does not interfere with absorption of glucose, aminoacids and fat. It has also no hepatic, renal and haemotologic toxic effect.

In our present study entitled "Effect of a soluble fiber (Sun Fiber- partially hydrolyzed guar gum) supplemented Oral Rehydration Solution in the treatment of acute non-cholera diarrhoea in children" we did not observe any untoward side effects related to this agent, although this study is yet to be finished. Sun Fiber has been used as food additive to enteral nutrition products. However, no side effects have been reported so far.

References

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BUDGET PROPOSAL

Title: Evaluation of the effect of a soluble fiber (Sun Fiber) ... PD in children
Project duration: 2 years from starting
Principal Investigator: Dr. N.H. Alam

Line Items	% effort	Amount in US $ 1st year	2nd year	Total
PERSONNEL COST				
Dr. N.H. Alam (#1698-0), PI	15	2,493	2,742	5,235
Dr. S.A. Sarker (#1447-5), Co-Invest.	5	806	887	1,693
Dr. P.K. Bardhan (#1429-0), Co-Invest.	5	860	946	1,806
Dr. N. Dewan (#3449-6), Co-Invest.	5	587	645	1,232
Res. Physician	100	2,400	2,400	4,800
Sr Health Asstt.	100	4,536	4,990	9,526
Health Worker (4)	100 x 4	2,000	2,000	4,000
Secretarial support	15	938	1,032	1,970
Sub-total:		14,620	15,642	30,262
TRAVEL cost of dissemination of study findings		0	3,000	3,000
SUPPLIES & MATERIALS				
-Drugs		200	200	400
-Hospital/lab supplies		200	100	300
-Stationeries		500	300	800
-Nonstock supplies		500	500	1,000
Sub-total:		1,400	1,100	2,500
OTHER CONTRACTUALS				
-Postage, Fax, DHL, etc.		500	500	1,000
-Printing & publication		0	300	300
-Patient food & diet		500	500	1,000
-Service charge		500	500	1,000
Sub-total:		1,500	1,800	3,300
INTERDEPARTMENTAL SERVICES				
-Transport		300	200	500
-Medical illustration		100	100	200
-Xerox, library service		300	200	500
-Lab. & Pathological test		6,000	4,000	10,000
-Patient hospitalization		8,000	4,600	12,600
-Staff clinic charges		300	200	500
Sub-total:		15,000	9,300	24,300
CAPITAL EXPENDITURE				
-PC with printer and accessories and Deep Freezer		5,000	0	5,000
TOTAL DIRECT COST:		37,520	30,842	68,362
Indirect Cost (31%)		11,631	9,561	21,192
TOTAL PROJECT COST:		49,151	40,403	89,554

18/6/96

Consent Form

"Evaluation of the effect of a soluble fiber (Sun Fiber) supplemented comminuted chicken based diet in the treatment of persistent diarrhoea".

Your child is suffering from persistent diarrhoea. Major treatment of this disease is dietary management in addition to rehydration therapy. ICDDR,B is carrying out a study to evaluate the efficacy of a soluble fiber (Sun Fiber) supplemented comminuted chicken based diet in the treatment of persistent diarrhoea. This study will not cause any risk to the patients health. On the other hand, the study material might help in early recovery of your child. If you agree to enrol your child in this study, the following tests will be carried out, which are routine examination of this disease at ICDDR,B.

(1) 3 ml of venous blood (from any suitable vein in hands) will be taken for different tests (i.e. CBC, electrolytes) on admission.

(2) Stool samples will be taken for routine, culture, electrolytes, and osmolarity tests.

(3) Urine samples for routine examination.

(4) Stool, urine and vomit samples will be saved at -20°C and subsequently will be used for balance study.

In addition to rehydration therapy, your child will get either comminuted chicken diet supplemented with a soluble fiber or comminuted chicken diet alone. Breast feeding will be allowed ad libitum.

If at anytime you wish to withdraw your child from the study you are free to do so without any obligation. Even then your child will get the standard treatment in this hospital. If the above conditions are acceptable to you, please sign or give your thumb impression.

_____ _____

Signature of the Investigator

Signature/Thumb/Impression
of the parent/guardian

Date:_____

Witness:_____

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র
মহাখালী, ঢাকা-১২১৭
সম্মতি পত্র

দীর্ঘস্থায়ী ডায়রিয়ার চিকিৎসায় সানফাইবার মিশ্রিত মুরগীর স্যুপের কার্যকারীতা পরীক্ষা

আপনার শিশু দীর্ঘস্থায়ী ডায়রিয়া রোগে ভুগছে। এই রোগের প্রধান চিকিৎসা শরীরের লবণ এবং পানির ঘাটতি পূরণ এবং শিশুর খাবার পরিবর্তন করা। মুরগীর স্যুপ এই রোগের চিকিৎসার ব্যাপারে মোটামুটি কার্যকর। কিন্তু এই খাবারের কার্যকারীতা আরও উন্নত করার জন্যে মুরগীর স্যুপের সাথে সানফাইবার মিশিয়ে আই.সি.ডি.ডি.আর,বি একটি গবেষণা চালিয়ে যাচ্ছে। এই পরীক্ষা শিশুর জন্যে সম্পূর্ণ নিরাপদ। অপরদিকে এই গবেষণায় ব্যবহৃত সান ফাইবার শিশুর ডাইরিয়া তাড়াতাড়ি ভাল করতে সাহায্য করতে পারে। আপনি যদি আপনার শিশুকে এই গবেষণায় অংশগ্রহণ করাতে চান তাহলে আমরা নিম্নলিখিত পরীক্ষাগুলো যাহা এই রোগে সাধারণতঃ করা হয়।

১। শিশুর হাতের শিরা হতে ৩ মিঃলি রক্ত বিভিন্ন পরীক্ষার জন্য নেয়া হবে।
২। পায়খানা পরীক্ষা করা হবে।
৩। প্রস্রাব পরীক্ষা করা হবে।
৪। পায়খানা, প্রস্রাব এবং বমির কিছু নমুনা-২০° সেঃ তাপমাত্রার সংরক্ষণ করা হবে যা পরবর্তীতে ব্যালান্স স্ট্যাডির জন্য ব্যবহৃত হবে।

শিশুর লবণ পানির ঘাটতি পূরণ করা ছাড়াও শিশুকে যে কোন একটি খাবার (মুরগীর স্যুপ অথবা সানফাইবার মিশ্রিত মুরগীর স্যুপ) দেয়া হবে। মা শিশুকে প্রয়োজনমত বুকের দুধ খাওয়াতে পারবেন। যদি কোন সময় আপনি আপনার শিশুকে গবেষণা থেকে প্রত্যাহার করে নিতে চাইলে আপনি তা করতে পারবেন। এর পরও আপনার শিশুকে এই হাসপাতালে প্রচলিত চিকিৎসা সুবিধাদি দেয়া হবে।

উপরোক্ত শর্তগুলোতে আপনি যদি রাজী থাকেন তাহলে নীচে আপনার স্বাক্ষর/ বৃদ্ধাঙ্গুলির ছাপ দিন।

.....	.....	.....
সই	সই	সই/টিপসই
গবেষণাকারী	স্বাক্ষী	রোগীর অভিভাবক
তাং.....	তাং.....	তাং .....