Attachment 1.
(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 6/2/92
10/3/92

Principal Investigator Dr A.K. Mitra & Dr. H. Ashraf

Trainee Investigator (if any) _____

Application No. 92-004

Supporting Agency (if Non-ICDDR,B) _____

Title of Study "Algorithm for the management of persistent diarrhoea in hospitalized children in Bangladesh"

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)
   (d) Sensitive questions (Yes)
   (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)
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

A-032066

SECTION I - RESEARCH PROTOCOL

1. TITLE:	ALGORITHM FOR THE MANAGEMENT OF PERSISTENT DIARRHOEA IN HOSPITALIZED CHILDREN IN BANGLADESH
2. PRINCIPAL INVESTIGATORS :	Dr Amal K Mitra and Dr Hasan Ashraf
CO-INVESTIGATORS:	To be named
PROJECT CO-ORDINATOR:	Dr D Mahalanabis
3. STARTING DATE:	March 1, 1992
4. COMPLETION DATE:	February 28, 1993
5. TOTAL DIRECT COST:	US $ 45,000
POSSIBLE SOURCE OF FUNDING:	WHO
6. SCIENTIFIC DIVISION:	This protocol has been approved by the Clinical Science Division

Dmahalanabis

Signature of the Associate Director,
Clinical Sciences Division

Date: 1/2/92

7. ABSTRACT SUMMARY:

Management of persistent diarrhoea still poses a formidable challenge to the physicians. Though there is yet no established treatment for this disease, sufficient knowledge exists to permit a consensus on the treatment of persistent diarrhoea. In a recent meeting at Mombassa and in a subsequent workshop at New Delhi, a consensus algorithm was evolved for the management of persistent diarrhoea. This algorithm would identify the initial risk factors (clinical and laboratory) and intercurrent factors (clinical and laboratory) associated with treatment failures and to evaluate these alone or in combinations as predictors of treatment failures. This will also help to identify factors (clinical and laboratory) associated with early discharge from the hospital and to evaluate these alone or in combinations as predictors of early discharge. We hypothesize that the rate of failure in patients treated according to this algorithm would be less than 20%. It would permit us to evaluate certain prognostic factors which will predict a poor outcome on this treatment algorithm. The study will continue for one year. Diet will be offered after initial hydration. Patients with systemic complications will be initially managed and diet will be offered if stabilize within 24 hours. Breast feeding will be allowed ad libitum. Study diet will be given at the rate of 150 kcal/kg/24 hours in 6 divided feeds. A multivitamin mineral mixture in three times of RDA will be offered daily. The patients will get other usual hospital managements.

Discharge from the hospital will be considered for patients with cessation of diarrhoea with a gain in weight of more than 20g/day for 2 consecutive days, and weight/length > 70% NCHS standards. After discharge, patients will be followed up after two weeks for a weight record and change of diet.

8. REVIEWS:

a) Chairman, Research Review Committee:_____

b) Chairman, Ethical Review Committee:_____

c) Director, ICDDR,B:_____

SECTION II - RESEARCH PLAN

INTRODUCTION:

This study is a part of the standard core proposal for a multicentre study for the evaluation of an algorithm for the management of persistent diarrhoea in a hospital setting organized by WHO/ADDR. The other countries involved in this multicentre study are India, Pakistan, Mexico, Peru and Viet Nam.

Background:

Persistent diarrhoea is defined as an episode which starts acutely, but continues more than 14 days(1). Recently persistent diarrhoea in children is identified by the World Health Organization as a major public health problem in developing countries and a research topic of high priority(1). Nutritional consequences of diarrhoea are often adverse(2-4); there remains a substantial risk of death when diarrhoea lasts longer than usual(5). In a study in northern India more than 50% of diarrhoeal deaths in children under 5 in a rural community were associated with persistent diarrhoea(5).

Dietary management is an important component of case management strategy of persistent diarrhoea in infants and young children. Considerable amount of research has gone into designing diets which provide adequate energy and nutrients and at the same time do not aggravate the clinical course of persistent diarrhoea. In infants and young children, a diet based on chicken meat, vegetable oil and glucose has been shown to be beneficial(6,7). Recently a less expensive diet, improvised from localy available ingredients such as rice powder, egg white, glucose, vegetable oil and salt has been found to be highly absorption efficient and effective in infants and young children with persistent diarrhoea(8). It has been also postulated that a mixture of a cereal plus milk could be the basis of first line dietary treatment in infants and young children with persistent diarrhoea, and has been in use at the Clinical Research Centre of ICDDR,B.

Although different studies have shown the efficacy of several diets, there is yet no established treatment of patients with persistent diarrhoea. In a recent meeting at Mombassa and in a subsequent WHO/ADDR workshop at New Delhi, a consensus algorithm was evolved for the management of persistent diarrhoea. This treatment algorithm would identify a) patients who need hospitalization for their persistent diarrhoea syndrome, b) an initial energy dense mixture of milk or yoghurt, cereal, and oil, c) infection and weight decline associated with persistent diarrhoea, d) appropriate treatment of dysentery, and e) a modified diet with a reduced starch load for a subgroup failing on the initial diet. About

25-30% of patients fail to improve on the dietary treatment currently in use in our centre and most other countries(8,9). The figure seems to be even higher (40-50%) in the health facilities where there is no standard treatment policy for the patients with persistent diarrhoea.

HYPOTHESIS:

More than 80% of children with persistent diarrhoea admitted to hospital can be successfully treated using the initial step of the management protocol. Clinical and laboratory characteristics documented on admission can discriminate children who are at high risk of subsequently becoming treatment failures. Intercurrent factors (clinical and laboratory) can discriminate children who are at high risk of becoming treatment failures. Clinical and laboratory characteristics documented on admission can discriminate children who will be discharged early and who might have been treated successfully at home.

SPECIFIC OBJECTIVES:

Research questions

a. To estimate the rate of treatment failures in children with persistent diarrhoea selected to hospital care according to the algorithm criteria and treated according to it.

b. To identify initial factors (clinical and laboratory) associated with treatment failures and to evaluate these alone or in combinations as predictors of treatment failures.

c. To identify intercurrent factors (clinical and laboratory) associated with treatment failures and to evaluate these alone or in combinations as predictors of treatment failures.

d. To identify factors (clinical and laboratory) associated with early discharge from the hospital and to evaluate these alone or in combinations as predictors of early discharge.

Response variables

Treatment failures are defined as patients who, in the absence of infection or complications, have any of the following:

a. appearance or reappearance of signs of dehydration anytime after the initial stabilization period;

b. increase of stool volume to more than 200 g/kg/d during any 24 hour period after being started on the treatment algorithm.

c. stool volume >60g/kg/d on day 7 of the treatment protocol;

d. weight at the end of day 7 on the treatment algorithm less than the rehydration weight at admission; in the absence of weight gain on any of two days of days 5,6 and 7 and provided there is a dietary intake greater than 100 Cal/kg/d on three consecutive days (days 5,6 and 7).

STUDY DESIGN:

Inclusion/Exclusion criteria

All patients 4-35 months of age with diarrhoea (>3 liquid stools/24 h) for 14 days or more will be registered. In order to recruit enough patients in a year, females will have to be admitted in the study in the proportion of 1 female for 3 male patients (in practice, all consecutive males and every third female will be recruited).

a. Inclusion criteria

Weight for height <80% of NCHS standards or weight for age <75% of NCHS standards; or associated systemic infections requiring hospitalization, such as pneumonia, urinary tract infection; or some or severe dehydration.

b. Exclusion criteria

Patients with the following features will not be included in the study;

- exclusively breastfed infants <6 months of age,
- presence of oedema,
- chronic underlying illness (tuberculosis, chronic renal failure, severe congenital disease, AIDS, abdominal conditions that would preculude feeding),
- severe congenital malformation (as this could affect the tolerance of the diet),
- severe condition requiring hospitalization in Intensive Care Unit,
- lack of parental consent.

Patients fulfilling at least one of the above described inclusion criteria, without any of the exclusion criteria will be admitted in the study.

Sample size estimate

We estimate that 80% of the patients with persistent diarrhoea admitted in the study will be cured at day 7 after admission. Therefore, in order to show that the success rate of the treatment is 80% with a 5% significance level and a 90% power of detecting a difference between the success rate of 5 percentage points or more in either direction:

test success rate	80%
anticipated success rate	75-85%
level of significance	5%
power of the test	90%

For a two-sided test:

$$n = \frac{\left[Z_{1-\alpha}\sqrt{P_0(1-P_0)} + Z_{1-\beta}\sqrt{P_a(1-P_a)} \right]^2}{(P_a - P_0)^2}$$

For (1-Po)=0.2 and (Pa-Po)=0.05, it will be necessary to include 718 children in the study. This calculation was taken from "Sample size determination in health studies: a practical manual", WHO Press, 1991, Geneva. This will therefore require that about 120 children be included per treatment centre, as the study will be conducted simultaneously in 6 research centres.

Enrollment of subjects

Ethical review and informed consent

a. Ethical review

The written approval of the institutional review panels is attached.

b. Informed consent

A written consent (see attached copy) will be taken from the patient's parent or legal guardian after giving him/her full information about the study. The investigator giving the information will be clearly identified.

Baseline examination

A detailed baseline examination including both clinical and laboratory parameters will be performed on all patients admitted in the study in order to:

- determine the patient's eligibility for inclusion in the study, and

- collect relevant data prior to beginning the study that will allow description of the study population to compare the patients selected in the different centres where the study will be conducted.

The baseline examination will include:

- identification of the patient (name, age, date of birth, socio-economic status of the parents, state of literacy of the guardians).

- a description of the symptoms prior to admission and their duration including stool frequency, consistency, duration of diarrhoea, vomiting, fever

- a description of the feeding status prior to admission and also after the onset of illness, as these may differ,

- details of any treatment given for this illness prior to admission in the study,

- results of the physical examination, including the state of dehydration and nutrition determined according to standard criteria (weight for height and weight for age according to NCHS standards), and a screening for abnormal signs pertaining to any system.

- results of any microscopic, microbiological and biochemical exmainations performed on admission:

  Blood: serum electrolytes, creatinine, blood sugar by dextrostix, hemogramme, total serum proteins and serum specific gravity (to be repeated on day 8 for a third of the treatment successes and in case of treatment failure). Blood cultures will be performed when indicated by clinical judgement and in all cases of third degree malnutrition.

  Urine: microscopy, sugar by dipstick and specific gravity. Cultures will be performed when indicated by clinical judgement.

  Stool: microscopic examination for pus cells, red blood cells and parasites. Concentration methods will also be used to isolate *Entamoeba histolytica* and *Giardia lamblia*.

- in PBS 7.4 for rotavirus, using Dakopatts ELISA KITS;

- pH and reducing substances using clinitest, on admission and repeated daily;

- for fat globules by Sudan staining.

- for culture of *Salmonella, Shigella, V. cholerae, Campylobacter jejuni* by standard methods according to the WHO manual (34).

- the following assays will also be performed: five morphologically similar colonies of *E. coli* will be picked and stocked in nutrient agar as stab cultures and tested for labile toxin (LT) and the stable toxin (ST) by DNA probes. Hep2 cell assay will be used for the identification of adherent *E. coli* (35). Adherent *E. coli* EAEC-L and EAgg EC will also be sought in colony hybridization assays using EAF and aggregative DNA probes; in neutral formal for the isolation of *Cryptosporidium;*

In addition, other tests such as chest x-rays will be done as clinically indicated.

The form on which the results of this baseline history and examination will be recorded have been developed by CDD and ADDR (copy attached).

Standard case management

a. Rehydration period/Stabilization period:

Children who are dehydrated on admission will be rehydrated according to WHO guidelines using standard glucose ORS over 4-6 hours. Intravenous rehydration will be used to correct severe dehydration, or in children whose hydration status cannot be maintained adequately orally and when there is ileus. If children are not fully rehydrated after the first 4-6 hours, the fluid deficit will be recalculated and the calculated amount of standard ORS will be given over the next 4-6 hours. When dehydration has been corrected, the children will enter the study protocol and this time will be considered 0 hour.

Children who have no clinical evidence of dehydration will be able to start the study without delay.

It is recognized that some children may be too ill to be able to start the study protocol straight after admission. This will essentially include patients with sepsis. These

children will be managed as their condition dictates for a period of upto 24 hours, the stabilization period. After that period, if their condition is considered to be sufficiently stable to allow them to enter the study then they will start on the study protocol (time-0 hour). If the patient remains unwell and is judged unable to take food during the stabilization period, he will be excluded from further participation in the study and treated in the Intensive Care Unit. The feeding regimen for children during the stabilization period will depend on the child's condition; the study diet may be used.

b. Replacement of fluid losses:

Standard glucose ORS will be offered on a volume to weight basis to replace the ongoing stool losses. Water will be allowed *ad libitum* and the amounts consumed will be recorded.

c. Feeding:

Patients will be divided into two groups depending on their pre-admission feeding status:

- *partially breastfed children* (children receiving more than 2 breastfeeds/day and also getting other milk or some semisolids). Breastfeeding will be allowed *ad libitum* and the child will be weighted before and after each breastfeeding; diet A (see annex 1) will be offered at the rate of 150 Cal/kg/d in 6 divided feeds (plus one feed for malnourished patient); each feed being offered after the child has taken a breastfeed.

- *non breastfed children* (children receiving less than 2 breastfeeds/day or no breastfeeds with additional semisolids with or without milk). Diet A will be offered at the rate of 150 Cal/kg/24h in 6 divided feeds (plus one feed for malnourished patient); the diets will be prepared in the metabolic ward kitchen, under the supervision of the dietician of the study. The diet will be increased beyond 150Cal/kg/day if the following criteria are met: the child is consuming all the diet offered and is not gaining weight adequately for age and nutritional status.

A multivitamin and mineral mixture, 1-1.5 tablets of Centrum and 1-2 tablets of Caltrate supplied by *Lederle Laboratory*, providing amounts of vitamins and minerals equivalent to 3 RDAs for children 1-3 years of age will be administered daily to all patients. The composition of this multivitamin and mineral mixture is described in annex 2.

d. Infection on admission or occuring during the study:

Systemic infection will be suspected if these clinical signs are present: general appearance of unwellbeing with one or more of symptoms: temperature unstability, hypotension, hypoglycemia, persistent acidosis in spite of adequate hydration and treated accordingly. Otitis media, pneumonia, UTI and other probable bacterial infections will be treated with antibiotics (Ampicillin, Amoxicillin, Cloxacillin) as indicated without interrupting the management protocol. Children having gross blood in the stool or stool culture positive for *Shigella* will be treated according to the WHO guidelines for the management of shigellosis, using the first and second line antibiotics recommended are nalidixic acid and pivmecillinam respectively.

Treatment failures

a. Definition:

The treatment failures on initial dietary and other treatment will be defined as patients who in the absence of infeciton or complication have any of the following:

- appearance or reappearance of signs of dehydration anytime after the initial stabilization period;
- increase of stool volume to more than 200g/kg/d during any 24 hour period or to more than 2000ml in any 24 hour period; for female, more than 10 watery stools per day in any 24 hour period;
- stool volume greater than 60g/kg/d on day 7 of the treatment protocol; for female, more than 6 watery stools per day on day 7;
- weight at the end of day 7 on the treatment algorithm less than the rehydration weight at admission in the absence of weight gain on any of the two days 5,6 and 7 and provided there is a dietary intake superior to 100Cal/kg/d on three consecutive days (days 5,6 and 7). Patients whose caloric intake has been less than 100Cal/kg/d for three consecutive days will be fed with nasogastric tube for 3 days at the rate of 125 Cal/kg/d (consistency of the diet will have to be modified slightly for NG feeding; increased volumes will therefore be offered to maintain equivalent calorie intake). At the end of this three day period, they will be reassessed for criteria for treatment failure.

TREATMENT FAILURE WILL INDICATE THE NEED FOR DIETARY CHANGE.

b. Management of treatment failures:

Fluid therapy: the same protocol as described before will be followed;

Feeding: patients will be offered a lactose-free diets (diet B) whose composition is described in annex 3. These diets will be offered at the rate of 150Cal/kg/d. Breastfed children will be allowed breastfeeding *ad libitum*. The multivitamin and mineral mixture will be administered to all patients until release from the study.

c. Treatment failures on the lactose free diet (diet B):

The same failure criteria as described above will be used. However, management of the patients considered treatment failures on the lactose-free diet will differ from centre to centre. These patients will then receive diet B in which glucose is the only carbohydrate source.

Discharge and follow-up after discharge

The end of diarrhoea will be defined as the beginning of 48 hours with less than or equal to 2 liquid stools per day. Patients will be discharged after cessation of diarrhoea if their weight gain is superior to 20g/d for two consecutive days and their weight for height greater than 70% of NCHS standards. Patients discharged from the hospital will be asked to come back for a follow-up visit two weeks after discharge.

Organization of the study

Description of facilities

The study will be conducted at the Clinical Research Centre (CRC) of the ICDDR,B, Dhaka. About 60,000 patients attend annually the CRC of whom 300 have persistent diarrhoea. Children fulfilling the eligibility criteria and attending between 8 a.m. and 12 noon on week days will be considered for admission in the study. Not more than 3-4 patients will be recruited each week to enable research staff to carry out all specific activities.

Methods

- Nude weight will be taken at admission, after rehydration and every 24 hours, on a beam scale with a sensitivity of 10g.

- Stool will be weighted by using pre-weighted diapers; stool consistency will be noted.

- Vomitus frequency will be recorded

- Urine will only be collected in male patients using urine bags.

- Intake of intravenous fluids, ORS, plain water, drugs and feeds will be monitored continuously and recorded after compilation at 4 hours, 8 hours, 24 hours and every 24 hours thereafter.

Volumes and frequency of output (stool, urine, vomitus) as well as volumes and frequency of input (ORS, water, feeding) will be recorded continuously with summaries recorded at the change of each nursing shift. For the data summary for the multicentre study, data recording would ideally be done at admission, 0 time, 4 hours after admission, 8 hours after admission and every 24 hour period after time 0.

Data collection

Standardized data recording forms have been specially developed by WHO and ADDR for this study. A sample of this form is attached in annex 4.

Data analysis

Analysis of the combined data sets will be performed by the Secretariat of WHO/CDD and ADDR. Data will be entered on coded forms and then keypunched into a prepared data base. Data will be double entered. Programmes will be built in to detectvalues outside expected ranges and consistency checks will be designed. The following major outcome variable will be measured:

Percent of treatment failures for each category of patients admitted in the study (malnourished, dehydrated, with systemic infection, ...).

In addition the following variables will be measured so that our experience with the algorithm can be described in greater detail and related to characteristics of the patients on admission:

- weight gain,

- stool output,

- duration of diarrhoea,

- mean calorie intake

Descriptive statistics, means, medians, and frequency distributions will be calculated for each variable. These variables will then be compared between centres using Chi squared or Fisher Exact Statistics as appropriate.

The following parameters will be examined for their relative risk in the treatment failure group versus the successes and 2 by 2 tables will be constructed to calculate specificity, sensitivity and positive predictive value of individual and combination of characteristics:

- age,
- nutritional status,
- feeding history,
- fever on admission,
- purging rate on admission,
- number of stool per day before admission,
- anorexia after admission,
- presence of reducing substances in the stool, etc.

Definitions:

1. Diarrhoea: 3 or more watery or liquid stools in 24 h;
2. Persistent diarrhoea: the diarrhoea which starts acutely, but continues longer than 14 days; an interval of >48 h will be considered as separate episode;
3. Cessation of diarrhoea: 48 hour period with less than 3 liquid stools per 24 hour;
4. Stool output: the weight of stool in g/kg of initial hydration body weight expressed per 24 h, and for the entire duration of diarrhoea;
5. Weight gain (or loss): the increase (or loss) in weight at day 7 on diet A compared with initial hydration weight;
6. ORS and plain water: the volume of ORS or plain water taken in ml/kg of hydration body weight expressed per 24 h, and for the entire duration of diarrhoea;

7. Dysentery: acute diarrhoea with visible blood in the stool, often with abdominal pain and fever;

8. Food intake: the total amount of food offered minus the amount leftover, expressed in g/kg of hydration body weight per 24 h, and for the entire duration of diarrhoea;

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Annex 1

COMPOSITION OF DIET- A

	Amt(g)	Ene(Cal)	Pro(g)	CHO(g)	Fat(g)
Rice	9.00	32.40	0.55	7.11	0.07
Milk Powder	5.20	25.48	1.38	1.95	1.35
Veg oil	2.00	17.16	0	0	2.00
Sugar	1.00	3.83	0	0.99	0
Water cooked volume upto 100 ml					
Total	100.00	78.87	1.93	10.05	3.42
Total/100g		78.87	1.93	10.05	3.42

AA Score	1.00
Estimated digestibility	0.94
% Protein energy	9.77
% Protein energy (Corrected)	9.19
% Fat energy	39.00
% CHO energy	51.04
Lactose content (g/150 Cal)	3.70

Annex - 2:

COMPOSITION OF THE MULTIVITAMIN AND MINERAL MIXTURE

CENTRUM AND CALTRATE TABLETS
(Lederle Laboratory)

	USRDA (1 YR)	CENTRUM	%RDA	CALTRATE	%RDA
Vit A (ug RE)	400	1500	375		
Vit D (ug)	10	10	100		
Vit E (mg)	5	30	500		
Vit K (ug)	15	25	160		
Vit C (mg)	40	60	150		
Thiamin (mg)	0.7	1.5	214		
Riboflavin (mg)	0.8	1.7	213		
Niacin (mg)	9	20	222		
Vit B6 (mg)	1	2	200		
Folate (ug)	50	400	800		
Vit B_{12} (ug)	0.7	6	857		
Pentoth acid (mg)	3	10	333		
Biotin (ug)	20	30	150		
Ca (mg)	800	162	20	600	95
P (mg)	800	125	16		
Mg (mg)	80	100	125		
Fe (mg)	10	18	160		
Zn (mg)	10	15	150		
Cu (mg)	1	2	200		
I (ug)	70	150	214		
Se (ug)	20	25	125		
Mn (mg)	1.25	2.5	200		
F (mg)	1	0	0		
Co (ug)	50	25	50		
Mo (ug)	37.5	25	57		

Annex 3

COMPOSITION OF DIET - B

	Amt(g)	Ene(Cal)	Pro(g)	CHO(g)	Fat(g)
Rice	6.00	19.50	0.42	4.42	0
Glucose	4.00	15.20	0	4.00	0
Egg White	16.00	8.48	1.76	0.16	0.03
Veg oil	4.00	36.00	0	0	4.00
Water cooked volume upto 100 ml					
Total	100.0	79.18	2.18	8.58	4.03
Total/100g		79.18	2.18	8.58	4.03
AA Score			1.00		
Estimated digestibility			0.96		
% Protein energy			11.01		
% Protein energy (Corrected)			10.57		
% Fat energy			45.83		
% CHO energy			43.32		

SECTION III - BUDGET

Detailed budget

A/C code	Personnel	% time	US $
4600	Trainee Research Fellow (1)	100	1500.0
	Trainee Health Assistant (2)	100	2000.0
	Trainee Dietician (1)	100	1000.0
	Volunteer (3)	100	1200.0
			5,700.0
Laboratory costs:			
4807	Stool M/E (100 x 1.65)		165.0
	TC, DC, HCT (150 x 2.59)		388.5
	Serum sp. gr. & protein (150 x 0.85)		127.5
	Platelet count (100 x 1.25)		125.0
	Urine analysis (150 x 3.00)		450.0
	Stool fat (Sudan III stain) (150 x 0.88)		132.0
	Cryptosporidium in stool (150 x 1.65)		247.5
			1,635.5
4808	Stool culture (V. cholera, Shigella salmonella) (150 x 7.15)		1072.5
	Pick E. coli for ST/LT (150 x 2.75)		412.5
	R/S or stool collection for rotavirus (100 x 1.20)		120.0
	ST/LT toxin assay by ELISA (150 x 4.95)		742.5
	Rotavirus ELISA (100 x 4.58)		458.0
	Detection of EIAC (150 x 6.75)		1012.5
	Detection of EAEC (150 x 6.75)		1012.5
	Campylobacter isolation (150 x 7.32)		1098.0
	Clostridium isolation (150 x 12.56)		1884.0
	Aeromonas & plesiomonas (100 x 3.80)		380.0
	Dark-field screening for vibrios (50 x 1.84)		92.0
	Blood culture (100 x 8.00)		800.0
	Urine culture (60 x 4.58)		274.8
			9,359.3
4809	Stool sugar (150 x 2.00)		300.0
	Stool osmolality (150 x 2.92)		438.0
	Stool pH (150 x 3.58)		537.0
	Stool electrolytes (150 x 5.78)		867.0
	Serum electrolytes (300 x 4.40)		1320.0
	Serum creatinine (60 x 3.85)		231.0
	Blood glucose (50 x 2.42)		121.0
	Stool TLC (100 x 2.2)		220.0
4810	Chest X-ray (60 x 5)		300.0
	Abdominal X-ray (20 x 5.5)		110.0
			4,444.0

4813	Patient hospitalization (30 x 7 x 100)	21,000.0

Supplies & materials:

3715	Urine collection bag (800 x 1)	800.0
	Polythene sheet (800 x 0.5)	400.0
	Diapers, towels	160.0
	Rice powder, eggs, sugar, glucose, oil	800.0
3704	Office supplies	150.0
		2,310.0

Other contractual:

4300	Print and publication	200.0
	Xerox	100.0
	Medical Illustration	150.0
	Post and communication	100.0
		550.0

Summary

Personnel (Contractual)	5,700.0
Laboratory costs	15,440.0
Patient hospitalization	21,000.0
Supplies and materials	2,310.0
Other contractual	650.0
Total	45,000.0

CONSENT FORM

(Statement read and clearly explained to the parents of the patients when consent is obtained.)

Your child is suffering from persistent diarrhoea, management of which still poses a formidable challenge to the physicians. Persistent diarrhoea in children is identified by the World Health Organization as a major public health problem in developing countries and a research topic of high priority. In a recent meeting at Mombassa, and in a subsequent ADDR/WHO Workshop at New Delhi, a consensus algorithm was evolved for the management of persistent diarrhoea. If you allow your child to take part in this study, then your child will get treatment according to the algorithm. Your child has to stay in this hospital for at least 7 days to complete the study. The patient will get a type of diet(Diet A) for the first 7 days and other treatment needed according to the algorithm. After improvement the child will be discharged and followed up after 2 weeks. If there is no improvement after 7 days, the patient will be offered another diet(Diet B).After improvement, he/she will be discharged and will be followed up similarly after 2 weeks. Blood, stool, urine will be collected on admission and after 7 days and sent to the laboratory for proper examination.

Taking part in the study totally depends upon your own decision. You may withdraw your child from the study anytime and proper care will not be altered by that. If you are willing voluntarily to join in this study, then please sign your name or put left thumb impression on this consent form.

Signature of Investigator Signature or L.T.I. of parent

Witness:---------- Date:----------

সম্মতি পত্র

(সম্মতিপত্র নেয়ার প্রাক্কালে এই বিবৃতি পড়ে শোনানো হয়েছে এবং পরিষ্কারভাবে বুঝিয়ে দেয়া হয়েছে।)

আপনার শিশুর দীর্ঘস্থায়ী লেয়ারিয়া রোগে ভুগছে। দীর্ঘস্থায়ী লেয়ারিয়া রোগের চিকিৎসা বেশ জটিল। বিশ্ব স্বাস্থ্য সংস্থার মতে শিশুদের দীর্ঘস্থায়ী লেয়ারিয়া একটি বৃহৎ জনস্বাস্থ্য সমস্যা এবং তাই একটি প্রকাশ গবেষণার বিষয়। প্রথমে মোম্বাসা এবং পরে নয়াদিল্লীতে অনুষ্ঠিত কর্মশালায় গবেষকগণ দীর্ঘস্থায়ী লেয়ারিয়া রোগের চিকিৎসা প্রদ্ধতি সম্বন্ধে একটি সুনির্দিষ্ট নীতিমালায় পৌঁছাতে সক্ষম হন। আপনি যদি আপনার শিশুকে এই গবেষণায় অংশগ্রহণ করাতে চান, তাহলে আপনার শিশুকে একটি সুনির্দিষ্ট প্রদ্ধতিতে চিকিৎসা নিতে হবে। আপনার শিশুকে হাসপাতালে ৭ দিন থাকতে হবে। আপনার শিশুকে প্রথম ৭ দিন এক প্রকারের আবার ও অন্যান্য প্রয়োজনীয় চিকিৎসা নিতে হবে। ভাল হবার পর শিশুকে ছুটি দেয়া হবে এবং ২ সপ্তাহ পর আবার দেখাতে আসতে হবে। প্রথম ৭ দিন চিকিৎসার পর যদি শিশুর উন্নতি না হয় তবে আপনার শিশুকে অন্য এক প্রকার আবার দেয়া হবে। রোগীর উন্নতি হবার পর ছুটি দেয়া হবে এবং একইভাবে সপ্তাহ পর শিশুকে দেখাতে আসতে হবে। ভর্তির সময় ও ৭ দিন পর আপনার শিশুর রক্ত, মল ও মূত্র পরীক্ষা করা হবে।

এই গবেষণায় অংশগ্রহণ করা সম্পূর্ণভাবে আপনার নিজের ইচ্ছার উপর নির্ভর করে। এই গবেষণায় অংশ না নিলেও আপনার শিশু এই হাসপাতালের সকল প্রয়োজনীয় চিকিৎসা পাবে এবং ইচ্ছা হলে যে কোন সময় নাম প্রত্যাহার করতে পারবেন। আপনি উপরে উল্লিখিত শর্তে রাজী থাকলে এবং আপনার শিশুকে এই গবেষণায় অংশগ্রহণ করাতে চান, তাহলে নীচে সই (বা টিপ সই) দিন

গবেষকের স্বাক্ষর

অভিভাবক

তারিখ

সাক্ষী

Annex 4

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

REGISTRATION AND HISTORY

1.1

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Centre Code ☐ Study Code ☐ Patient Number ☐☐☐

Patient's Name _____

Patient's Address _____ ☐☐

_____

Date and time of admission

Date ☐☐ (day) ☐☐ (month) ☐☐ (year)

Time ☐☐ (hour) ☐☐ (min.)

Birthday, Age and Sex

Birthday ☐☐ (day) ☐☐ (month) ☐☐ (year)

Age ☐☐ Sex ☐

Father's occupation _____ ☐ Mother's occupation _____ ☐

Number of siblings ☐☐ Monthly income ☐☐☐☐

Duration of diarrhoea before admission (days) ..... ☐☐☐

Number of stools in 24 hours before admission ..... ☐☐☐

Number of vomitus in 24 hours before admission ..... ☐☐☐

Stool consistency (loose = 1, watery = 2) ..... ☐

Presence of blood in stool (no = 1, yes = 2) ..... ☐

Presence of mucus in stool (no = 1, yes = 2) ..... ☐

Fever before admission (no = 1, yes = 2) ..... ☐

Appetite before admission (unchanged = 1, reduced = 2) ..... ☐

Presence of cough (no = 1, yes = 2) ..... ☐

Weight loss (no = 1, yes = 2) ..... ☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

REGISTRATION AND HISTORY
1.2

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

HISTORY OF PREVIOUS ILLNESS (within 2 months) (no = 1, yes = 2)

Diarrhoea ☐
Dysentery ☐
Acute respiratory infection ☐
Measles ☐
Otitis ☐
Others (specify) _____ ☐

TREATMENT HISTORY FOR THIS EPISODE

Treatment sought prior this consultation (no = 1, yes = 2) ☐
If yes, where _____ ☐

Treatment received since beginning of this episode

1. _____ ☐
2. _____ ☐
3. _____ ☐
4. _____ ☐
5. _____ ☐

What treatment has the child received in the last 48 hours?

1. _____ ☐
2. _____ ☐
3. _____ ☐

FEEDING HISTORY PRIOR TO ILLNESS

Breastfeeding (no = 1, yes = 2) ☐
If yes, how many times per day ☐☐
Formula/animal's milk (no = 1, yes = 2) ☐
Solid/Semi-solid foods (no = 1, yes = 2) ☐
At what age were solid/semi-solid foods first given? (in months) ☐☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

REGISTRATION AND HISTORY
1.3

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Describe briefly the normal diet of the child:

FEEDING HISTORY SINCE BEGINNING OF ILLNESS

Breastfeeding (no = 1, yes = 2) ☐

If yes, how many times per day? ☐

Formula milk (no = 1, yes undiluted = 2, yes diluted = 3) ☐

Animal's milk (no = 1, yes undiluted = 2, yes diluted = 3) ☐

Soya milk (no = 1, yes = 2) ☐

Has the diet been changed since the start of this episode? (no = 1, yes = 2) ☐

If yes, who advised you to make the change? (specify) ☐

And how was the diet modified?

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

PHYSICAL EXAMINATION

2.1

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Nude weight ☐☐ kg ☐☐☐ g

Height or Length ☐☐☐ cm

Heart rate ☐☐☐ beats/mn

Respiration rate ☐☐ Resp/mn

Rectal Temperature ☐☐ °C ☐

ASSESSMENT OF DEHYDRATION

General condition (alert = 1, restless = 2, lethargic = 3) ☐

Eyes (normal = 1, sunken = 2, very sunken = 3) ☐

Tears (present = 1, absent = 2) ☐

Mouth and tongue (moist = 1, dry = 2, very dry = 3) ☐

Thirst (normal = 1, increased = 2, unable to drink = 3) ☐

Skin pinch (normal = 1, slow = 2, very slow = 3) ☐

Degree of dehydration (no dehydration = 1, some = 2, severe = 3) ☐

EXAMINATION OF OTHER SYSTEMS (normal = 1, abnormal = 2)

Skin/Hair ☐ (If abnormal, specify) _____

Head ☐ (If abnormal, specify) _____

Eyes ☐ (If abnormal, specify) _____

Mouth ☐ (If abnormal, specify) _____

Throat ☐ (If abnormal, specify) _____

Ears ☐ (If abnormal, specify) _____

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

PHYSICAL EXAMINATION

2.2

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Respiratory system	☐	(If abnormal, specify) _____
Heart	☐	(If abnormal, specify) _____
Pulses	☐	(If abnormal, specify) _____
Abdominal examination	☐	(If abnormal, specify) _____
Distension	☐	(If abnormal, specify) _____
Bowel sounds	☐	(If abnormal, specify) _____
Ano-rectal	☐	(If abnormal, specify) _____
Perineum	☐	(If abnormal, specify) _____
Genitalia	☐	(If abnormal, specify) _____
Neurological system	☐	(If abnormal, specify) _____
Other abnormality	☐	(If abnormal, specify) _____

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

LABORATORY EXAMINATION
3.1

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

BLOOD

	Na mEq/l	K mEq/l	Total CO2 mmol/l
Admission to study	☐☐☐	☐☐	☐☐
Day 8	☐☐☐	☐☐	☐☐
On failure	☐☐☐	☐☐	☐☐

	Hematocrit %	Spec. Grav	Total prot g/100 ml	Glucose g/100 ml
Admission in study	☐☐	☐☐☐☐☐	☐☐☐	☐☐
Day 8	☐☐	☐☐☐☐☐	☐☐☐	☐☐
On failure	☐☐	☐☐☐☐☐	☐☐☐	☐☐
Blood culture (no = 1, yes = 2)				☐
If yes, results				☐☐

URINE

	Sediment (no = 1, yes = 2)	Dipstick	Spec. Grav.
Admission in study	☐	☐☐	☐☐☐☐☐
Day 8	☐	☐☐	☐☐☐☐☐
On failure	☐	☐☐	☐☐☐☐☐
Urine culture (no = 1, yes = 2)			☐
If yes, results			☐☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

LABORATORY EXAMINATION
3.2

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

STOOL MICROSCOPY

	Blood cells (no = 1, yes = 2)	Pus cells (no = 1, yes = 2)	Sudan III (neg = 1, pos = 2)
Admission in study	☐	☐	☐
Day 8	☐	☐	☐
On failure	☐	☐	☐

	Reducing Substances Before Hydrolysis	Reducing Substances After Hydrolysis	pH
On admission	☐☐☐☐	☐☐☐☐	☐☐
Day 1	☐☐☐☐	☐☐☐☐	☐☐
Day 2	☐☐☐☐	☐☐☐☐	☐☐
Day 3	☐☐☐☐	☐☐☐☐	☐☐
Day 4	☐☐☐☐	☐☐☐☐	☐☐
Day 5	☐☐☐☐	☐☐☐☐	☐☐
Day 6	☐☐☐☐	☐☐☐☐	☐☐
Day 7	☐☐☐☐	☐☐☐☐	☐☐
Day 8	☐☐☐☐	☐☐☐☐	☐☐
Day 9	☐☐☐☐	☐☐☐☐	☐☐
Day 10	☐☐☐☐	☐☐☐☐	☐☐
Day 11	☐☐☐☐	☐☐☐☐	☐☐
Day 12	☐☐☐☐	☐☐☐☐	☐☐
Day 13	☐☐☐☐	☐☐☐☐	☐☐
Day 14	☐☐☐☐	☐☐☐☐	☐☐
Day 15	☐☐☐☐	☐☐☐☐	☐☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

LABORATORY EXAMINATION
3.3

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

STOOL MICROBIOLOGY ON ADMISSION

Entamoeba histolytica (absent = 1, present = 2, not tested = 9) ☐

Giardia lamblia (absent = 1, present = 2, not tested = 3) ☐

Salmonella (absent = 1, present = 2, not tested = 3) ☐

Shigella (absent = 1, dysenteriae = 2, flexneri = 3, sonnei = 4 ☐

boydii = 5, not tested = 9)

Vibrio cholerae (absent = 1, present = 2, not tested = 3) ☐

Campylobacter jejuni (absent = 1, present = 2, not tested = 3) ☐

Rotavirus (absent = 1, present = 2, not tested = 3) ☐

Escherichia coli (absent = 1, present = 2, not tested = 3) ☐

LT ☐

ST ☐

EAEC-L ☐

EAgg EC ☐

Cryptosporidium (absent = 1, present = 2, not tested = 3) ☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

LABORATORY EXAMINATION
3.4

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

STOOL MICROBIOLOGY ON DISCHARGE (1/3) OR IN CASE OF FAILURE

Entamoeba histolytica (absent = 1, present = 2, not tested = 9) ☐

Giardia lamblia (absent = 1, present = 2, not tested = 3) ☐

Salmonella$ (absent = 1, present = 2, not tested = 3) ☐

Shigella (absent = 1, dysenteriae = 2, flexneri = 3, sonnei = 4 ☐

boydii = 5, not tested = 9)

Vibrio cholerae (absent = 1, present = 2, not tested = 3) ☐

Campylobacter jejuni (absent = 1, present = 2, not tested = 3) ☐

Rotavirus (absent = 1, present = 2, not tested = 3) ☐

Escherichia coli (absent = 1, present = 2, not tested = 3) ☐

LT ☐

ST* ☐

EAEC-L ☐

EAgg EC ☐

Cryptosporidium (absent = 1, present = 2, not tested = 3) ☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.1

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Name

Centre Code ☐ Patient Number ☐☐☐ Date of admission ☐☐ ☐☐

	Admission - 0 hour	0 - 4 hours	4 - 8 hours
Temperature:	☐☐ ☐	☐☐ ☐	☐☐ ☐
Weight:	☐☐ ☐☐☐	☐☐ ☐☐☐	☐☐ ☐☐☐
Stool Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Stool Frequency:	☐☐	☐☐	☐☐
Stool Consistency	☐ ☐	☐	☐
Stool Character:	☐	☐	☐
Urine Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Vomitu Frequency:	☐☐	☐☐	☐☐
ORS Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of IV (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of Water (ml):	☐☐☐	☐☐☐	☐☐☐
Type of diet	☐	☐	☐
Diet consumed (g):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Diet consumed (Cal):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Breastfeeding Frequency:	☐☐	☐☐	☐☐
Breastf. volume (ml)	☐☐☐☐	☐☐☐☐	☐☐☐☐
Hydration Status:	☐	☐	☐
Other complaints:	☐	☐	☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.2

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Name

Centre Code | Patient Number | Date of admission

	8 - 24 hours	DAY 2	DAY 3
Temperature:			
Weight:			
Stool Volume (ml):			
Stool Frequency:			
Stool Consistency			
Stool Character:			
Urine Volume (ml):			
Vomitu Frequency:			
ORS Volume (ml):			
Volume of IV (ml):			
Volume of Water (ml):			
Type of diet			
Diet consumed (g):			
Diet consumed (Cal):			
Breastfeeding Frequency:			
Breastf. volume (ml)			
Hydration Status:			
Other complaints:			

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.3

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Name

Centre Code | Patient Number | Date of admission

	DAY 4	DAY 5	DAY 6
Temperature:			
Weight:			
Stool Volume (ml):			
Stool Frequency:			
Stool Consistency			
Stool Character:			
Urine Volume (ml):			
Vomitu Frequency:			
ORS Volume (ml):			
Volume of IV (ml):			
Volume of Water (ml):			
Type of diet			
Diet consumed (g):			
Diet consumed (Cal):			
Breastfeeding Frequency:			
Breastf. volume (ml)			
Hydration Status:			
Other complaints:			

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.4

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Nami

Centre Code ☐ Patient Number ☐☐☐ Date of admission ☐☐ ☐☐

	DAY 7	DAY 8	DAY 9
Temperature:	☐☐ ☐	☐☐ ☐	☐☐ ☐
Weight:	☐☐ ☐☐☐	☐☐ ☐☐☐	☐☐ ☐☐☐
Stool Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Stool Frequency:	☐☐	☐☐	☐☐
Stool Consistency	☐ ☐	☐	☐
Stool Character:	☐	☐	☐
Urine Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Vomit Frequency:	☐☐	☐☐	☐☐
ORS Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of IV (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of Water (ml):	☐☐☐	☐☐☐	☐☐☐
Type of diet	☐	☐	☐
Dt consumed (g):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Dt consumed (Cal):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Breastfeeding Frequency:	☐☐	☐☐	☐☐
Breastf. volume (ml)	☐☐☐☐	☐☐☐☐	☐☐☐☐
Hydration Status:	☐	☐	☐
Other complaints:	☐	☐	☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.5

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Name

Centre Code ☐ Patient Number ☐☐☐ Date of admission ☐☐ ☐☐

	DAY 10	DAY 11	DAY 12
Temperature:	☐☐ ☐	☐☐ ☐	☐☐ ☐
Weight:	☐☐ ☐☐☐	☐☐ ☐☐☐	☐☐ ☐☐☐
Stool Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Stool Frequency:	☐☐	☐☐	☐☐
Stool Consistency	☐ ☐	☐	☐
Stool Character:	☐	☐	☐
Urine Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Vomitu Frequency:	☐☐	☐☐	☐☐
ORS Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of IV (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of Water (ml):	☐☐☐	☐☐☐	☐☐☐☐
Type of diet	☐	☐	☐
Diet consumed (g):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Diet consumed (Cal):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Breastfeeding Frequency:	☐☐	☐☐	☐☐
Breastf. volume (ml)	☐☐☐☐	☐☐☐☐	☐☐☐☐
Hydration Status:	☐	☐	☐
Other complaints:	☐	☐	☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

SUMMARY
4.6

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

Patient's Name

Centre Code ☐ Patient Number ☐☐☐ Date of admission ☐☐ ☐☐

	DAY 13	DAY 14	DAY 15
Temperature:	☐☐ ☐	☐☐ ☐	☐☐ ☐
Weight:	☐☐ ☐☐☐	☐☐ ☐☐☐	☐☐ ☐☐☐
Stool Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Stool Frequency:	☐☐	☐☐	☐☐
Stool Consistency	☐ ☐	☐	☐
Stool Character:	☐	☐	☐
Urine Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Vomitu Frequency:	☐☐	☐☐	☐☐
ORS Volume (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of IV (ml):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Volume of Water (ml):	☐☐☐	☐☐☐	☐☐☐
Type of diet	☐	☐	☐
Diet consumed (g):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Diet consumed (Cal):	☐☐☐☐	☐☐☐☐	☐☐☐☐
Breastfeeding Frequency:	☐☐	☐☐	☐☐
Breastf. volume (ml)	☐☐☐☐	☐☐☐☐	☐☐☐☐
Hydration Status:	☐	☐	☐
Other complaints:	☐	☐	☐

WORLD HEALTH ORGANIZATION

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA

END OF THE STUDY
1.1

APPLIED DIARRHOEAL DISEASE RESEARCH PROJECT

UNSCHEDULED IV (no = 1, yes = 2) ☐

If yes, specify reasons _____

_____

WITHDRAWAL FROM THE STUDY (no = 1, yes = 2) ☐

If yes, specify reasons _____

_____

TREATMENT FAILURE (no = 1, yes = 2) ☐

If yes, specify reasons _____

_____

Date and Time of Withdrawal (if applicable)

day ☐☐ month ☐☐ year ☐☐ hour ☐☐ min. ☐☐

Date and Time of Treatment Failure (if applicable)

day ☐☐ month ☐☐ year ☐☐ hour ☐☐ min. ☐☐

Date and Time of Last Abnormal Stool

day ☐☐ month ☐☐ year ☐☐ hour ☐☐ min. ☐☐

Date and Time of Discharge

day ☐☐ month ☐☐ year ☐☐ hour ☐☐ min. ☐☐

Nude weight on discharge (kg) ☐☐ ☐☐☐

Height (cm) ☐☐☐

MULTICENTRE STUDY ON PERSISTENT DIARRHOEA FOLLOW UP

Patient's Name:_____

Centre code /__/ Patient Number /__/__/__/

Date of Follow up /__/__/__/__/__/__/

Diarrhoea continued at home (no=1, yes=2) /__/

If yes, for how many days _____

Diarrhoea reappeared at home (no=1, yes=2) /__/

If yes, when started _____

Diarrhoea resolved after once started at home (no=1, yes=2) /__/

If yes, when resolved _____

Diet continued at home as advised (no=1, yes=2) /__/

If no, reason for discontinuation _____

_____

Nude Weight (kg) /__/__/. /__/__/__/

Height (cm) /__/__/./__/

Mid upper arm circumference (cm) /__/__/./__/

Advice to follow _____

_____

Date of next visit (if any) /__/__/__/__/__/__/