tachment 1. Date 27.4.1981.

ETHICAL REVIEW COMMITTEE, ICDDR,B.

incipal Investigator DR. A.R. SAMADI Trainee Investigator (if any) DR. MASUD AHMED 26

plication No. 81-20 Supporting Agency (if Non-ICDDR,B) Nil

tle of Study STUDY OF STANDARD ORS Project status:
TREATMENT OF DEHYDRATION OF INFANTS (✓) New Study
ESS THAN SIX MONTHS OF AGE. ( ) Continuation with change
( ) No change (do not fill out rest of form)

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

Source of Population:
(a) Ill subjects (Yes) No
(b) Non-ill subjects Yes (No)
(c) Minors or persons under guardianship (Yes) No

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)

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

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
(d) Sensitive questions Yes (No)
(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

5. Will signed consent form be required:
(a) From subjects Yes No NA
(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)
NA Informed consent form for subjects
✓ Informed consent form for parent or guardian
✓ Procedure for maintaining confidentiality
NA 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.

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

Hamadi
Principal Investigator

Trainee

→ Research Review Committee

SECTION I - RESEARCH PROTOCOL

1. Title: Study of Standard ORS in Treatment of Dehydration of Infants Less Than Six Months of Age

2. Principal Investigator: Dr. Aziz R. Samadi

3. Starting Date: Immediately after approval of the project

4. Completion Date: 7 months after starting date

5. Total Direct Cost: US $ 15,520

6. Scientific Program Head:

This Protocol has been approved by the Pathogensis and Therapy Working Group

Signature of Scientific Program Head: W.B.

Date: 20/4/81

7. Abstract Summary:

A research project is proposed to document the safety of standard ORS for rehydration in infants of less than six months including neonates in both breast-fed and bottle-fed children. This age group is selected for the reason that however, these children are treated with ORS, no clinical and biochemical response of these children have been studied so far. Hence, WHO Scientific Group on Diarrhoeal Diseases Research recommends priority for research in this area. The clinical and biochemical response of these children to ORS will be evaluated by

clinical and electrolyte balance studies. The results of this study will explain the scientific basis for the safety of standard ORS in treatment of young children including neonates. This study will lead to world-wide acceptability of ORS as a single rehydration solution for all age groups.

8. Reviews:

a. Research Review Committee: _____

b. Ethical Review Committee: _____

c. Director: _____

d. BMRC: _____

e. Controller/Administrator: _____

SECTION II - RESEARCH PLAN

A. INTRODUCTION

1. Objectives: The objectives of this study are: (a) to examine and explain the scientific basis for the safety of WHO standard ORS for treatment of dehydration in infatns less than six months. (b) to study the comparative clinical and biochemical response to standard ORS in exclusive breast-fed and bottle-fed infants of under six months of age.

2. Background: The concept of oral rehydration solution containing salt and sugar is not new. However, its scientific basis was not known until the 1960s, when in vitro and in vivo studies demonstrated that glucose could mediate sodium transport across the small intestinal mucosa (1). In 1964, Phillips (2) showed that glucose absorption, glucose-mediated sodium, chloride and water absorption remained largely intact in cholera patients.

Oral rehydration based on the knowledge that glucose enhances sodium and water absorption was first used in 1968 in adults (3) and later in older children with cholera (4). Further studies included infants over three months of age with non-cholera diarrhoea (5,6,7,8,9). A number of studies have recently confirmed the safe use of oral rehydration therapy in treatment of infantile non-cholera diarrhoea (1). A recent study demonstrated that 39 out of 40 neonates were treated successfully with standard ORS (10).

Standard ORS is advised by WHO for treatment of dehydration due to diarrhoea in all age groups including young infants due to its efficacy, simplicity, uniformity and cost effectiveness (1). However, there is concern from some pediatricians (11,12) in giving to young infants standard WHO ORS (Na 90 mmol/L Cl 80 mmol/L, HCO_3 30 mmol/L, K 20 mmol/L, glucose 111 mmol/l). They believe this may lead to sodium retention and hypernatremia due to a) low concentration of sodium in infantile non-cholera diarrhoea (1,2) and, b) renal immaturity of these young infants (13). Pizaro (10) in 1979 demonstrated that even neonates can be rehydrated successfully with standard ORS and plain water at the ratio of 2:1.

Although breast-fed infants are advised to be rehydrated with standard ORS (14), no comparative study has been done so far to document the safety of standard ORS in both exclusive breast-fed and bottle-fed infants of under six months age. The early supplementation of ORS with breast milk which contains only 7 mmol of sodium per liter (15) and half strength milk which has 22 mmol of Na per liter will protect these children against hypernatremia on one hand and enhance their nutritional status on the other hand.

Due to lack of information on certain areas of diarrhoeal diseases, the WHO Regional Scientific Working Group on Diarrhoeal Diseases held a meeting on 2-3 March 1981 in New Delhi to identify the

priority areas for research in relation to diarrhoeal diseases. One of the priority areas for research is the comparative study of the effect of oral fluid therapy in breast-fed and bottle-fed children of young infants including clinical and biochemical response to treatment.

In order to document the safety of ORS, it is suggested to test the hypothesis that ORS does not cause hypernatremia in any child under six months whether breast-fed or bottle-fed. Also in order to test the above hypothesis, clinical and balanced electrolyte studies will be carried out.

3. Rationale:

The safety of standard ORS in breast-fed infants and bottle-fed infants of under six months of age has not been documented yet. It is worthwhile to study and document the safety of ORS in these children. This study will eliminate the concerns from some pediatricians and will assure the safety of standard ORS in exclusively breast-fed and bottle-fed young infants.

The clinical and biochemical response to ORS also has not been yet studied in breast-fed and bottle-fed infants of less than six months. This study will provide information on clinical and biochemical responses of these two groups of children through standard ORS. Comprehensive electrolyte balance study and will explain the scientific basis for the safety

of standard ORS.

B. SPECIFIC AIMS:

1. To document the safety of standard ORS in both breast-fed and bottle-fed infants of under six months of age.

2. To document the safety of standard ORS in neonates.

3. To find out the differences, if any, in clinical and biochemical response in both breast-fed and bottle-fed infants.

C. METHODS OF PROCEDURES:

1. Subjects: Approximately 50 male infants (25 exclusively breast-fed and 25 bottle-fed) of less than six months age and of less than 5.0 Kg weight on admission, suffering from acute diarrhoea (less than 5 days duration) with mild and moderate dehydration, who have not received any fluid therapy prior to admission and belonging to similar socio-economic status will form the subject of this study. The socio-economical standard of these patients will be determined by the following indices: (1) The means of transport to the hospital (by foot within a distance of 1 km and by rickshaw from a distance over 1 km). (2) Educational level of

mothers, (none or less than 6 grade) (3) The fathers' income (less than Tk.750 per month). The children in each group will be sub-grouped into 0-1 and 1-6 months.

2. Samples' Selection: The patients who fulfill the above criteria will be selected for the study. Every two patients, the first breast-fed and bottle-fed infants will be taken for the study. The selection of the patients on the basis of above mentioned criteria will be continued until 50 patients 25 breast-fed and 25 bottle-fed are completed. It is planned to include 10 neonates in each group.

3. Clinical Procedure: On admission medical history will be obtained, physical examination including weight and length measurement will be performed. The dehydration state of the children will be assessed by the WHO method (14). The following specimens will be taken on admissions: Stool for microscopic examination and pH and culture including ELISA test for rotavirus, finger blood for sp. gravity, serum sodium and potassium, complete blood count, urine analysis, (8 hourly urine will be collected by urine bag for determination of sodium excretion). The amount of stool and vomitus will be measured every 24 hours. The schedule for clinical evaluation and further investigation is as follows:

	Admission	4th Hr.	8th Hr.	24th Hr.	48 Hr.
Clinical evaluation	+	+	+	+	+
Specific Gravity	+	+	+	+	+
Hct	+	+	-	+	+
Weight	+	+	+	+	+
Na & K	+	+	+	+	+
24 Hr. Urine for Na	-	-	-	+	+
WBC & Diff.	-	+	-	+	-
Stool culture & Microscopy & pH	any time passed stool				
Intake (ORS + Milk)	every 3 hours				
Output (Stool,vomiting, urine)	-	+	+	+	+
Stool sodium	-	-	-	+	+
Stool potassium	-	-	-	+	-
Breast Milk sodium	-	-	-	+	-
Milk Na & K (B.M. + formula)	-	-	-	+	-

Patients will be under constant observation in the study ward. Special

attention will be given for appearance of any complication, which will be treated accordingly.

4. Treatment: The treatment is based on WHO recommendations (14).

Timing	Amount of Fluid
First 4-6 hours (ORS):	200-400 ml (50-100 ml kg)
Maintenance (ORS):	The stool & vomiting losses will be compensated by ORS. Each case will be evaluated and adjustments will be made.
Feeding	Breast milk* will be started at 3 hours after admission and will be continued every 3 hours.

*The breast milk will be expressed by hand or extractor 1 ml sample of each breast-milk before feeding the baby will be collected for Na + K determination.

In bottle-fed group ½ strength formula** will be started at 3 hours and will be continued every 3 hours.

**Half strength formula will be performed for 24 hours and a sample of that will be examined for Na + K content.

5. Definitions:

(1) Acute Diarrhoea: Acute diarrhoea is defined as the passing of liquid watery stools. These liquid stools are usually passed more than 3 times per day.

(2) Successful Rehydration: Successful rehydration is defined as absence of clinical signs of dehydration and return of sp. gravity within normal range within 8 hours regardless of frequency of stool.

(3) Treatment Failure: Treatment can fail because a) patient is still dehydrated after 8 hours of treatment b) patient again becomes dehydrated after rehydration c) rise of sp. gravity >1030 d) patient develops electrolyte abnormality ($K < 2.0$ or >6.0, $Na \leq 125$, > 150 mEq/L).

6. Analysis of Data: After completion of study the data will be analysed as follows:

TABLE 1

Comparison of pre-admission duration of diarrhoea in breast-fed and bottle-fed neonates and infant groups

GROUPS	Mean pre-admission duration of diarrhoea	
	Mean	St. deviation
Breast-fed neonate		
Bottle-fed neonate		
Breast-fed infant		
Bottle-fed infant		

Statistical difference:

TABLE 2

Nutritional status of breast-fed and bottle-fed neonates and infants on discharge assessed by weight and length ratio

Nutritional Status	NEONATES		INFANTS	
	Breast-fed No. (%)	Bottle-fed No. (%)	Breast-fed No. (%)	Bottle-fed No. (%)
Normal				
Malnourished				

Statistical difference:

TABLE 3

Completion of rehydration in breast-fed and bottle-fed neonates by different indices.

HOURS	BREAST-FED		BOTTLE-FED	
	Clinical assessment No (%)	Sp. Gravity No. (%)	Clinical assessment no (%)	Sp.Gravity no. (%)
Hour 0				
Hour 4				
Hour 8				
Hour 24				

Statistical difference:

TABLE 4

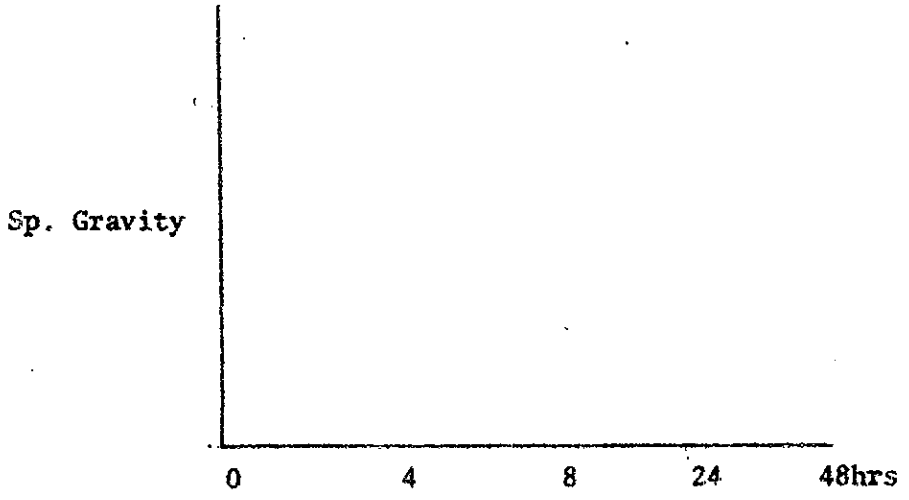
Completion of rehydration in breast-fed and bottle-fed infants by different indices.

HOURS	BREAST-FED		BOTTLE-FED	
	Clinical assessment No (%)	Sp. Gravity No. (%)	Clinical assessment No (%)	Sp. Gravity No. (%)
Hour 0				
Hour 4				
Hour 8				
Hour 24				

Statistical difference:

FIGURE I

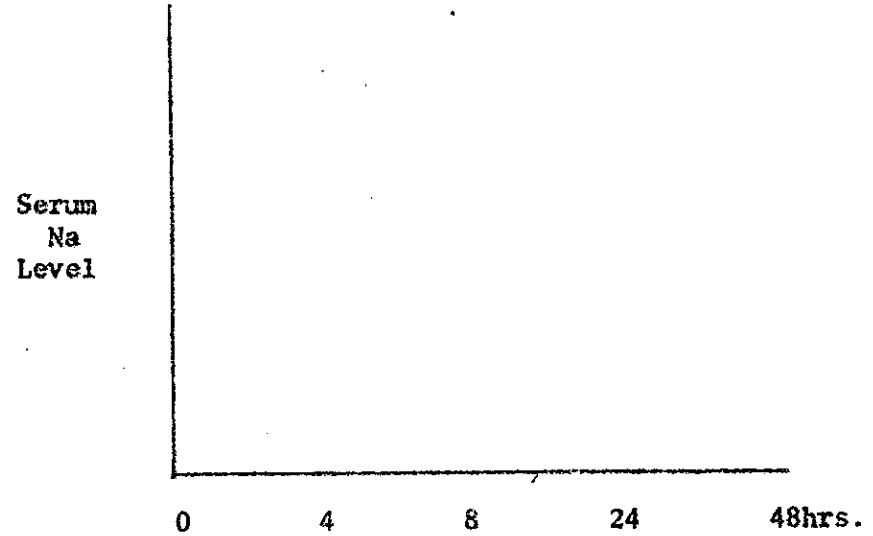
Comparison of mean (± SE) specific gravity curves between breast-fed and bottle-fed neonates and infants.



Statistical difference:

FIGURE II

Comparison of mean (±SE) serum sodium curves in neonates and infants in breast-fed and bottle-fed groups



Statistical difference:

TABLE 5

Twenty-four hour Sodium and K intake and output in breast-fed bottle-fed neonates and infants

GROUPS	Mean±SD Intake			Mean±SD Output		
	ORS	B.M.	Formula	Stool	Vomit	Urine
Breast-fed Neonates						
Bottle-fed Neonates						
Breast-fed Infants						
Bottle-fed Infants						

Statistical difference:

TABLE 6

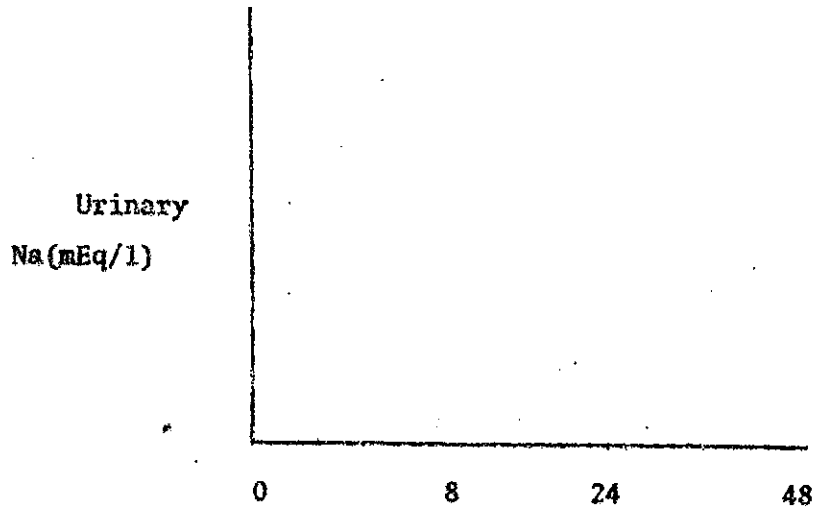
Comparison of weight gain on discharge in breast-fed and bottle-fed neonates and infants

GROUPS	Weight gain in Gms/Kg. of Body weight	
	Breast-fed Mean±SD	Bottle-fed Mean±SD
Neonates		
Infants		

Statistical difference:

FIGURE 3

Comparison of urinary excretion of sodium in breast-fed and bottle-fed neonates and infants for 48 hours.



Statistical difference:

TABLE 7

24-hour Fluid Intake in breast-fed and bottle-fed neonates and infants.

GROUPS	24 hours Fluid Intake (ORS+Milk)ml/kg of body weight	
	Breast-fed	Bottle-fed
Neonates		
Infants		

Statistical difference:

TABLE 8

ORS Na Fluid output during first 24-hour in breast-fed and bottle-fed neonates and infants.

GROUPS	ORS Na intake(mEq/Kg)		Na Output (mEq/Kg)	
	Breast-fed	Bottle-fed	Breast-fed	Bottle-fed
Neonates				
Infants				

Statistical difference:

D. SIGNIFICANCE:

The results of this study will fill the gap in our knowledge in relation to safety of standard ORS in exclusively breast-fed and bottle-fed infants This information is necessary for worldwide recommendation of standard ORS for the treatment of diarrhoeal diseases of young infants.

E. FACILITIES REQUIRED:

1. Office space: Already provided
2. Laboratory space : Already provided
3. Hospital Resources : 80 patients X 3-day/pt.
4. Animal Resources: Infant mice for ST Testing.
5. Logistic support: Nil

6. Equipment : Nil

7. Other requirements: Nil

F. COLLABORATIVE ARRANGEMENTS: Nil

SECTION III - BUDGET

A. DETAILED BUDGET

1. PERSONNEL SERVICES

Name	Position	Efforts %	Annual Salary	Project Requirements Taka	Dollar
Dr. A.R. Samadi	Prin. Investigator	15%			4600
Dr. R. Islam	Co. Investigator	10%		2,600	
Dr. P.K. Bardhan	Co. Investigator	20%		4,000	
Dr. Masud Ahmad	Co. Investigator	25%		4,500	
Mr. M.A. Wahed	Co. Investigator	10%		3,000	
3 Sr. Staff Nurse		25%		6,900	
1 Study clerk		25%		1,980	
Bacteriology Technician		20%		2,000	
Biochemistry Technician		30%		3,500	
Clin. Path. Tech		25%		2,500	
			Subtotal:	40,940	$ 4600

2. SUPPLIES AND MATERIALS:

Stool culture, examination	1,500	
Stool microscopic exam.	400	
Hct and Sp. Gravity	600	
Sodium and Potassium	2,400	
ST Tests	1,500	
LT Tests	1,500	
ELISA Tests	1,200	
Glass Ware, plastic		150
ORS	1,600	

3. EQUIPMENTS: Nil

		Project Requirements Taka	Dollar
4.	HOSPITALIZATION:		
	50 Patients X 3	22,500	
5.	OUTPATIENT: Nil		
6.	TRANSPORT: Nil		
7.	TRAVEL (International):		$3000
8.	TRANSPORT OF THINGS: Nil		
9.	RENT: Nil		
10.	PRINTING FORMS:	1.000	
	PUBLICATION	3,000	
11.	CONTACTUAL SERVICE: Nil		
12.	CONSTRUCTION: Nil		
	Subtotal: Taka	47,200	$4150

B. BUDGET SUMMARY

	Taka	Dollar
1. Personnel		7,330
2. Supplies		1,646
3. Equipment		-
4. Hospitalization		1,500
5. Outpatients		-
6. CRL Transport		-
7. Travel (International)		3,000
8. Tranport of Things		-
9. Rent/Communication		-
10. PrintingReproduction		630
11. Contractual		-
12. Construction		-
		US$ 14,106
	Plus 10%	1,414
	Grand Total	US$ 15,520

ABSTRACT SUMMARY

1. A research project is proposed to document the safety of standard ORS for rehydration in infants of less than six months including neonates in both breast-fed and bottle-fed children. This age group is selected for the reason that however, these children are treated with ORS, no clinical and biochemical response of these children have been studied so far. Hence, WHO scientific group on Diarrhoeal Diseases Research recommends priority for research in this area.

2. The clinical and biochemical response of these children to ORS will be evaluated by clinical and electrolyte balance studies.

   These patients on admission will have a medical history, physical examination, finger blood and will be rehydrated with ORS. Breast milk or ½ strength formula will be given three hours after beginning of ORS.

3. The risks may be those associated with finger blood. Small amount of blood will be collected by capillary tube which does not cause any stress in the patient. Any possible infection due to prick is eliminated since the blood will be collected by experienced trained technician. The other risk which may be thought is probable development of hypernatremia with ORS. Though young infants under six months of age including neonates are being treated with standard ORS, close supervision will be made by physicians to detect

any development of hypernatremia and immediate treatment will be provided.

4. The research records are kept in a locked filing cabinet in the investigators office. Samples and records will be identified by code number and the link between patient and code number will be kept in a separate locked file.

5. A signed informed consent will be obtained from the patients.

6. No interview.

7. The individual patients will benefit from the treatment of their illnesses. The society will benefit if the research project document scientifically the treatment of dehydration of young infants by standard ORS. This benefit will include worldwide acceptablility of standard ORS for treatment of dehydration in all age groups.

8. The research will use medical records of the patients, blood, stool and urine.

REFERENCES

1. World Health Organization 1980. Oral Rehydration Therapy-Rectal Advances. KIP/05.

2. Phillips A.R. 1964. Fed. Proc. 32: 705.

3. Nalin D.R., Cash R.A., Islam R. et al. 1968. Oral maintenance therapy for cholera in adults. Lancet, 2: 370-373.

4. Hirschhorn N., Cash R.A., Woodward W.E. et al. 1972. Oral fluid therapy of Apache children with infectious diarrhoea. Lancet, 2: 15-18.

5. Chatterjee A., Mahalanbis D., Jalan K.N. et al 1978. Oral rehydration in infantile diarrhoea. Arch Dis Child, 53: 284-289.

6. Nalin D.R., deCespede C., Mata E. et al 1978. Comparison of sucrose with glucose in oral therapy of infant diarrhoea. Lancet 2: 277-279.

7. Sack D.A., Chowdhury A.M.A.K., Eusof A. et al 1978. Oral rehydration in rotavirus diarrhoea: A double blind comparison of sucrose with glucose electrolytes solutions. Lancet, 2: 280-283.

8. Pizaro D., Posada G., Mohs E., et al 1979. Evaluation of oral therapy for infant diarrhoea in an emergency room setting: the acute episode as an opportinity for instructing mothers in home treatment. Bulletin of the World Health Organization 57(6):983-986.

9. Nalin D.R., Levine M.M., Mata L. et al 1979. Oral rehydration and maintenance of children with rotavirus and bacterial diarrhoea. Bull. Wld. Hlth. Org. 57: 453-459.

10. Pizaro D., Posada G., Mata L. et al 1979. Lancet, 2: 1209-1210.

11. Finberg L. 1970. Treatment of the critically ill child with dehydration secondary to diarrhoea 1970. Pediatrics, 45: 1029-1036.

12. Finberg L. 1980. The role of oral electrolyte glucose solutions in hydrations for children international and domestic aspects. The Journal of Pediatrics, 96: 51-54.

13. Harrison H.E. and Finberg L. 1964. Hypernatremic dehydration 1964. Pediatr. Clin. North.Am. 11: 955-961.

14. World Health Organization 1980. A manual for the treatment of acute diarrhoea. WHO/CDD/SER/80.2.

15. Nelsons Text book of Pediatrics 1979. Hlth Ed., Philadelphia, W.B. Saunders Co: 198.

16. World Health Organization 1981. Identified research requirements in the control of diarrhoeal diseases (CDD). Meeting of the Regional Scientific Working Group on Diarrhoeal Diseases, New Delhi, 2-3 March.

17. World Health Organization 1980. Guideline for trainers of community health workers on the treatment and prevention of acute diarrhoea. WHO/CDD/SER/80.1.

CONSENT FORM

(STATEMENT READ AND EXPLAINED VERY CLEARLY TO THE SUBJECT WHEN CONSENT IS OBTAINED)

ICDDR,B has been carrying out research on the use of Oral Rehydration Therapy as the most economic, simple and effective treatment of diarrhoea. At present we are testing the safety of Standard ORS for rehydration in infants under six months in a comparative study of exclusively breast-fed and bottle-fed children. We would request you to participate in the study.

If you decide to participate in this study;

1. Your child will be given best possible care for diarrhoea.

2. Your child will be required to stay in the hospital with the mother until diarrhoea stops for at least 2-3 days, may be more.

3. During stay in the hospital, we would like to test finger pick blood 5 times (1-2 drops each time), to determine the state of health of your baby.

   These are all routine tests.

4. If Oral Solution, fails to correct dehydration or cause any other discomfort, immediately the child will be taken off the study and treated with proper intravenous fluid.

5. 1 c.c. sample of breast milk or artificial milk will be required for test before each feeding.

6. Even if you decide not to participate in the study, your baby will receive all be treatment available in this hospital.

7. You are at liberty to withdraw your child from the study at any time without any obligation without jeopardizing your child's medical care and treatment.

Understanding and realizing fully, if you are voluntarily willing to participate in the study, please sign your name or your left thumb impression below.

_____
Signature of Investigator

Date:_____

Signature:_____
or left thumb impression of the patient's legal guardian.

Date:_____

ICDDR,B Admission No._____

সম্মতি পত্র

(সম্মতি প্রদানের পূর্বে রুগীর অভিভাবকে নিম্নোক্ত বিষয় বিশদ ভাবে বুঝিয়ে দেয়া হল)

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র খাবার সেলাইন দিয়ে কি ভাবে অতি কম খরচে অথচ সকল ভাবে উদরাময় রোগের চিকিৎসা করা যায় তা নিয়ে গবেষণা চালিয়ে যাচ্ছে। বর্তমানে আমরা ছয়মাসের নিচের শিশুদের উদরাময় রোগের চিকিৎসায় প্রচলিত খাবার সেলাইনের উপযুক্ততা পরীক্ষা করতে যাচ্ছি। শুধু মাত্র মায়ের দুধের উপর নির্ভরশীল ও বোতলের দুধেরই উপর নির্ভরশীল উভয় গ্রুপের উপর তুলনামূলক পরীক্ষা চালান হবে।

আমাদের এই গবেষণায় আপনি সহায়ক হলে নিম্নোক্ত ব্যবস্থাদি গ্রহণ করা হবে -

১। আপনার শিশুর উদরাময় রোগের চিকিৎসার সুব্যবস্থা থাকিবে।

২। শিশুর পায়খানা ঠিক না হওয়া পর্যন্ত ২/৩ দিন বা প্রয়োজনে তার বেশী সময় শিশুকে সহ হাসপাতালে থাকতে হবে।

৩। হাসপাতালে চিকিৎসাধীন থাকা কালীন শিশুর পরীক্ষার অবস্থা জানার জন্য আংগুল থেকে দুই ফোঁটা করে রক্ত ৫ বার পরীক্ষার প্রয়োজন হবে।

৪। এই খাবার সেলাইন দিয়ে আপনার শিশুর চিকিৎসা সম্ভব না হলে বা কোন প্রকার জটিলতা ও অসুবিধা দেখা দিলে শিরার মাধ্যমে উপযুক্ত সেলাইন দিয়ে চিকিৎসা করা হবে।

৫। বাড়ীতে যাওয়ার পূর্ব মুহূর্তে মায়ের দুধ বা বোতলের দুধ ১ সি সি পরিমাণ পরীক্ষার জন্য নিতে হবে।

৬। আমাদের এই গবেষণায় অংশগ্রহণে কোন প্রকার আপত্তি থাকলে অন্যান্যের মত আপনার শিশুরও উপযুক্ত চিকিৎসার ব্যবস্থা থাকবে।

অঃপৃঃদ্রঃ

৭। ইহা ছাড়াও গবেষণা চলাকালীন যে কোন সময়ে আপনি ইচ্ছা করলে গবেষণা থেকে প্রত্যাহার করতে পারবেন। ইহাতে আপনার শিশুর স্বাভাবিক চিকিৎসায় কোন প্রকার ত্রুটি হবে না।

উপরোক্ত বিষয়টি ভালভাবে বুঝে আপনি চুক্তিনামা ও বিনা দ্বিধায় আমাদের এই গবেষণায় অংশ গ্রহণে রাজী থাকলে নিচে স্বাক্ষর বা বাম হাতের বৃদ্ধাংগুলীর ছাপ দিন।

গবেষকের স্বাক্ষর

তারিখ----------

অভিভাবকের স্বাক্ষর বা বাম হাতের বৃদ্ধাংগুলীর ছাপ

তারিখ----------

আই, পি, ডি, ডি, আর-বি, তৃতীয় মং------