Attachment 1.
(FACE SHEET)

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Date 1 MARCH 92

Principal Investigator A. DE FRANCISCO

Application No. 92-010

Title of Study Measles Surveillance System antibody decay in infants

Trainee Investigator (if any) _____

Supporting Agency (if Non-ICDDR,B) -

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
   - (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
   - (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.

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

Antonio de Francisco
Principal Investigator

A-031959

Trainee

APPLICATION FOR PROJECT GRANT

1.	Principal Investigator	:	Andrès de Francisco
2.	Co-Investigators	:	L. Unicomb J. Chakraborty R. Begum M. Yunus B. Sack
3.	Title of project	:	Measles Surveillance System antibody decay in infants
4.	Starting date	:	As soon as possible
5.	Date of completion	:	Nine months from the starting date
6.	Funding source	:	ICDDR,B CORE
7.	Total budget requested	:	$ 28,940 (or 37,911 with overheads)
8.	Head of programme	:	

R. Bradley Sack

R. Bradley Sack
Associate Director
Community Health Division

MEASLES SURVEILLANCE SYSTEM
ANTIBODY DECAY IN INFANTS
PROTOCOL PROPOSAL

Principal investigator: Dr. A. DE FRANCISCO

Co-investigators:
Ms. L. UNICOMB
Mr. J. CHAKRABORTY
Dr. R. BEGUM
Dr. M YUNUS
Dr. B. SACK

ABSTRACT

Measles is an important vaccine preventable disease which still kills more than one million children every year worldwide. Measles programmes in Africa are currently facing the problem of a high incidence of measles in infants below nine months of age, the age at which immunisation is recommended with the currently widely used Schwarz vaccine. Recent reports available to date from the Indian sub-continent, mainly originated in Bangladesh, show that measles below nine months of age is a public health problem.

Immunization programmes in Bangladesh have not yet achieved a high enough coverage to reach a level of herd immunity which protects infants below the age recommended for measles vaccination. Alternative vaccines have been proposed in order to protect young infants because it is estimated that a very high coverage and an equally high vaccine efficacy are required to cover this group of young infants with the Schwarz vaccine. There is strong evidence that the currently available measles vaccine would be neutralised by maternal antibodies passed to the infant during gestation if applied below nine months of age. Nevertheless, data seem to indicate that maternal antibodies may decay earlier in Bangladeshi infants than in infants of the developed world. This would allow to apply the Schwarz vaccine earlier in life and it would possibly avoid to change the current vaccine utilised by the EPI Programme in Bangladesh.

In order to evaluate this important question which would have relevant repercussions in the immunisation policies for the country and probably for the Indian sub-continent, a cross-sectional serological survey is proposed at Matlab. Two hundred and eighty infants from different age groups between two and eight months of age residing in the treatment area of Matlab will be recruited. Antibody levels to measles will be ascertained by Plaque Neutralisation techniques and ELISA in paired sera from the infant from the mother. Maternal antibody decay in infants will be analysed in the light of the maternal antibody levels and of their nutritional status.

INTRODUCTION

Measles is a vaccine preventable disease which still continues to be an important cause of morbidity and mortality in children in developing countries. It affects 70 million children every year and is responsible for approximately 1.6 million deaths every year worldwide (1,2). For many years measles has been detected as an important public health problem in Africa (3,4). Case fatality ratios (CFR) have been reported as high as 34% in rural and 21% in urban Africa (5). Reports from that continent have documented the impact of measles immunization on mortality and morbidity (6,7), the delayed effect on mortality (8,9,10) and the particularly impressive mortality reduction when immunising children at a very young age (11).

Although there are effective vaccines available for the last 25 years, failure to vaccinate all children is an important factor by which measles continues to account for such high incidence. The age at vaccination has been detected as a crucial factor for the efficacy of the vaccine. The currently recommended Schwarz vaccine leaves children below nine months of age unprotected, which is the age at which measles immunization is recommended with this vaccine (3). Due to the neutralisation of the live attenuated vaccine by passively acquired maternal antibodies if infants are immunised early in life, it has been recommended not to immunise children below nine months of age in developing countries (12). This group of very young infants may continue to act as a reservoir of wild measles virus even if the coverage of older children is ensured.

Studies from Bangladesh are probably the most outstanding reports available from the Indian sub-continent. These have outlined age distribution and risk factors for measles (13,14) and the effects of measles vaccination on mortality (15,16). Recent reports provided by the Matlab Measles Surveillance System (MSS) from the I.C.D.D.R.,B. have described demographical data of measles morbidity in a community of 100,000 with an approximate measles immunisation coverage of 30 percent. Twenty percent of the cases of measles in this population occurred below nine months of age (17,18).

On a worldwide perspective, Black (19) has described geographical differences in maternal measles titers, on placental transfer efficiency and of passive antibody half-life, stressing that there seems to be a pattern of variation of these parameters in different continents. Several factors may account for this

variation of the levels of passively acquired antibodies in infants. It is thus fair to assume that such factors may be important elements in determining the number of children who become susceptible to measles early in life, before the age of immunization. If factors such as malnutrition or low socio-economical status play an important role, as Black seems to suggest, Bangladeshi mothers would produce less quality or quantity of antibodies than European, North American or even West African mothers. This could be represented in a quicker decay of these transferred antibodies from the infant circulation, leaving infants at a higher risk of acquiring measles early in life. This possibility seems highly plausible in the light of such a high proportion of cases occurring at an early age, when infants are thought to be covered with maternal antibodies.

There are no studies at present addressing specifically the issue of antibody decay in Asia. However, data extracted from a study which evaluated seroconversion of different strains of measles vaccines at 4 to 6 months of age in rural Bangladesh show some data on measles antibody levels before immunization (20). Although the study group was not stratified by nutritional status nor by month of age in infancy, it shows clearly that only between 15 and 16 percent of children still had maternal antibodies present at 5 and 6 months of age before immunization as detected by Haemagglutination inhibition. Only 3 percent of this sample of infants had antibodies detected at seven months of age. Even though this is a small sample and was not intended to show antibody decay, it still may reflect a pattern of early loss of antibodies in Bangladeshi infants.

Even though neutralisation by serum probably does not represent the sole method of inactivation of measles virus in vivo, results of this study could be comparable to serological studies carried out in other continents. This would be the first attempt to describe the antibody decay in children in the Indian sub-continent.

Recent analysis of data from an epidemic of measles detected through the Measles Surveillance System in Matlab shows that the highest proportion of measles vaccine failures may be due to vaccination at the wrong age (18). Only one fifth of the 22 percent of immunised children in a cohort from two representative villages had received vaccination between 9 and 11 months of age and showed a vaccine efficacy of 79 percent at that age. None of six infants immunised at between five and eight months of age got measles and the attack rate of 113 non-immunised infants of the same age groups followed for the same period of time was 12.4 percent.

This data seem to indicate that measles immunisation with Schwarz vaccine below nine months of age may have some protective effect and this could be due to a lack of neutralisation of the vaccine by maternal antibodies.

In order to evaluate the pattern of maternal antibody decay in infants of this community and to ascertain if the currently available Schwarz vaccine could be administered effectively below the nine months of age, a survey is indicated. A cross sectional study of infants residing in the Matlab MCH-FP treatment area below the age at immunisation is proposed in order to describe the age at which infants loose maternal antibodies against measles. Because there is a low prevalence of measles in the community, antibodies measured may be acquired passively rather than actively. This group will be stratified by age and nutritional status. Correlation with antibody levels of a group of their mothers will be done.

MATERIALS AND METHODS

Study Population

The present study will be carried out in the Matlab MCH-FP area in children who are currently receiving treatment benefits from the MCH-FP Programme and under the Demographical Surveillance System. Primary health care services, including immunisation and nutritional surveillance and rehabilitation are provided by Project Community Health Workers. Immunisation coverage against measles is reported as 96 percent of children between 9 and 23 months of age. All cases of morbidity in these children are reported by the Community Health Workers who perform bi-monthly visits to all households.

Patients are admitted free of charge to the Hospital if they are referred from the field. They are admitted to the Diarrhoea Treatment Centre (DTC) or to the Mother and Child Health Clinic (MCH). Malnourished patients are admitted in the Nutritional Rehabilitation Unit (NRU) if they are not infectious. Mothers attend the out-patient departments seeking health services provided by the DTC or the MCH Clinics, including family planning services. Child care services are given to healthy children in the community in contacts with the sub-centres. Staff at the Maternity Care Unit performs deliveries in mothers with obstetrical complications detected in the field and referred.

Criteria for selection

Any infant between two and eight months of age residing in the MCH-FP treatment area of Matlab will be eligible providing the infant or the mother does not fulfil criteria for exclusion. Infants who attend a sub-centre clinics either for healthy controls or accompanying their mothers for family planning services are eligible providing they are not acutely ill. Neonates delivered at the Centre will also be included in the study. Mild and moderate malnourished infants or mothers will also be included (see procedure).

Criteria for exclusion

Any infant who has had measles immunization recorded will not be eligible. Mothers who have currently measles or a post-measles complication will be excluded. Children with a current episode of measles will be excluded. Very severe malnourished infants will also be excluded.

Procedure

Four eligible infants and mothers will be selected from the census and RKS lists for each one of the 80 CHWs. All children will be visited by project workers and ascertained on their fulfilment of the selection criteria. They will be asked to participate by visiting the sub-centre. Mothers or infants attending the out-patient department will also be eligible and recruited by the staff at the sub-centre. Signed informed consent will be obtained from the mother or the guardian. Mothers delivering at the Obstetric Unit of the Hospital will also be recruited.

A pre-numbered admission form (see annex) will be applied immediately after admission in the study evaluating the infant's selection criteria. Every child and mother will be identified by the paired serial number of the questionnaire (mothers with 'M' and children with 'C' followed by the serial number). Their identification numbers registered in the Demographical Surveillance System (DSS) will also be recorded.

Infants will be weighted with a Secca beam scale at the sub-centre by paramedics and their length will be measured. Data on these measurements will be written on the admission form. A calculation of the NCHS standard will be carried out. Infants

below the 60 percent level will be excluded. Infants between 60 and 80 percent will contribute to the malnourished group, and those above the 80 percentile will contribute to the well xnourished group. An investigator will be recording every week how many patients of each month age group have been collected in order not to collect more than the required sample (see below). The principal investigator will keep track of all data collected.

Blood samples from infants and the mothers will be then collected through venopuncture performed on recruitment at the sub-centre or at the out-patient department at the Matlab Hospital. Neonates delivered at the Hospital will be recruited by the collection of cord and maternal peripheral blood at the moment of delivery. An attempt to collect three millilitres of blood will be made in all cases. Maternal blood will be extracted through venopuncture at the same time than those of their infants. In cases of delivery, cord blood will be taken before the placenta has been extracted. There is no need to take a sample from the newborn. Only one sample per person is required.

All samples will be numbered accordingly to the admission pre-numbered form and sent to the laboratory at the Matlab Health and Research Centre immediately for processing and freezing for further analysis.

Sample size calculation

The study requires to evaluate the antibody levels of infants at different ages in order to produce a graph showing the point at which the level of antibody declines. Data from Bangladesh show that approximately 15 percent (48/310) of infants at 5-6 months have maternal antibodies in their circulation (calculated from ref. 20). In order to be able to detect a 10 percent drop of infants with antibodies in this age group, we would require 44 infants at the ages of 5-6 months. To evaluate the pattern at different months of age below nine months of age, the required sample size will be around 280 infants, or approximately 40 children per month of age between 2 and 8 months. Half of them will be malnourished and half will not. Baseline antibody at birth will be determined in a subsample of 40 newborns.

Duration of the study

Moderately malnourished patients can be recruited from the Day Care centres at each sub-centre and from the Nutrition

Rehabilitation Unit at the Matlab Health and Research Centre. During 1990, 267 patients were seen in the Nutrition Rehabilitation Unit, most of whom were infants (21). This would represent the possibility of recruiting 58 patients per month. Staff at the maternity ward carried out about 13 deliveries every month during last year.

Screening the data base files with the information of infants in the four treatment blocks of the MCH-FP area and training of the CHWs will be carried out in two weeks. In a further two months the CHWs are expected to have contacted each of the infants and mothers. The enrolment of patients could be completed in about four months. In order to achieve a careful selection screening and for logistical issues, an enrolment period of seven months would be acceptable.

The ELISA tests will be done in one session only when all the samples have been collected. The PRN tests will be done when sufficient samples have arrived to the Laboratory in Dhaka to do them in separate batches as it is current practice with other protocols. Data processing, analysis and reporting will take approximately two months.

It is envisaged that this study will be completed in approximately nine months from the starting date.

Laboratory procedures

Blood samples (3 ml) will be obtained from mothers and from infants by venopuncture or collected directly from the cord at delivery. The samples will be numbered with the unique number given in the admission pre-numbered questionnaire in pairs (mother and infant) and taken immediately to the laboratory to be centrifuged by a project technician. It is expected that approximately 1.5 ml of sera will be obtained after centrifugation. All specimens will be frozen at -20 degrees Centigrade and stored.

All blood samples will be tested for neutralising antibodies and for IgG and IgM antibodies using plaque reduction neutralisation assay and ELISA respectively. HAI requires monkey red blood cells and will not be immediately performed, but the possibility of keeping sera for further testing with this technique will be evaluated. Plaque reduction neutralisation test (PRN) will be performed accordingly to WHO specifications using VERO cells (22). ELISA, which has been referred to as being

relatively insensitive in this context (23), will be done to evaluate passively or actively acquired antibody. ELISA detection of measles specific IgG and IgM class antibodies will be performed following the method described by Sabin for IgG class antibodies (24) and the capture enzyme immunoassay method described by Coulson for rotavirus for the detection of IgM class antibodies (25), using the same measles antigen preparation for both tests. WHO standard measles serum will be included in both the PRN and ELISA tests and the methods will comply with WHO standards.

The antibody determination will be done at the I.C.D.D.R.B. laboratory once all the samples are collected. Both techniques are available at present at the Centre.

ANALYSIS

It is envisaged that this study will produce several data sets. Data will be coded from the questionnaires of admission into coding sheets and entered in the computer using a DBASE IV package. Analysis of the data will be done with DBASE IV, EPI-INFO and SPSS by the principal investigator.

The final expected outcome is a series of values representing antibody levels and activity from paired sera from mothers and their children. This information will be analysed taking into account nutritional status of both the mothers and their children. Antibody results should indicate the most likely age at which infants are exposed to the lowest antibody activity to neutralise the measles virus. The results of the ELISA technique should indicate at which age does the maternal immunity wane and the infant's own immunity raises.

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PAIR NUMBER: C [~~~~~~~~]
M [~~~~~~~~]

ANTIBODY DECAY IN INFANTS

MATLAB - MEASLES SURVEILLANCE SYSTEM

QUESTIONNAIRE

CHILD'S NAME :__:__:__:__:__:__:__:__:__:__:
CCID :__:__:__:__:__:__:__:__:__:__:
CRID :__:__:__:__:__:__:__:__:__:__:
AGE IN MONTHS :__:__:
SEX :__:

1-IMMUNISATION STATUS : 1= vaccinated
0= not vaccinated
9= unknown :__:

2- IF VACCINATED, ENTER THE DATE: :__:__:__:__:__:__:
3- HEALTH CARD SEEN? Y / N :__:

4- MEASLES 1= yes, previously
2= yes, currently
0= no, never
9= don't know :__:

5- AT ADMISSION: 1= Detected by RKs
2= Outpatient Sub-Centre
3= Delivery in Matlab

WEIGHT (kg) :__:__: * :__:__:__:
LENGTH (cm) :__:__: * :__:__:
MUAC (mm) :__:__:__:

NCHS PERCENTAGE :__:__:

MOTHER'S NAME :__:__:__:__:__:__:__:__:__:__:
MCID :__:__:__:__:__:__:__:__:__:__:
MRID :__:__:__:__:__:__:__:__:__:__:
AGE IN YEARS :__:__:

WEIGHT (kg) :__:__: * :__:__:__:
LENGTH (cm) :__:__: * :__:__:
MUAC (mm) :__:__:__:

ANTIBODY DECAY IN INFANTS

MATLAB - MEASLES SURVEILLANCE SYSTEM

B U D G E T

3100 LOCAL SALARIES DESIGNATION	LEVEL	POSI-TIONS	MAN-MONTH	RATE/MONTH	AMOUNT
Manager HS	NOB	1	9	*	*
Medical Officer	NOA	1	6	630	3,780
Technician Lab Dh.	GS5	1	6	320	1,920
SHA	GS4	1	9	280	2,520
Research Assistant	GS4	1	9	280	2,520
Technician Lab Mat.	GS3	1	1	200	200
CHW		4	9	70	2,520
				subtotal	**13,460**
INTERNATIONAL SALARIES					
MCH-FP Physician	P5	1	9	*	*
CONSULTANTS					
Epidemiologist	P5	1	1	3,300	3,300
				subtotal	**3,300**
INTERNATIONAL TRAVEL					
Consultant (Lon-Dha-Lon)		1		2,500	2,500
				subtotal	**2,500**
SUPPLIES AND DRUGS					
Drugs					500
Hospital Supplies					200
Stationary					100
Food for infants and relatives					1,000
Laboratory Supplies					
		Each	#		
ELISA tests (IgG and IgM)		3.00			2,880
Plaque Neutralisation		5.00			2,400
				subtotal	**7,080**

Budget calculated to include mothers and infants to be retested as well as plastic supplies.

INTERDEPARTMENTAL SERVICES

Transport Dhaka	100
Transport Matlab	2000
Water transport Matlab	500
subtotal	2600
TOTAL COST	28,940
OVERHEADS (31%)	8,971
TOTAL PROJECT COST	**37,911**

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH-BANGLADESH
MATLAB MATERNAL AND CHILD HEALTH-FAMILY PLANNING PROGRAMME

MEASLES ANTIBODY DECAY IN INFANTS
ABSTRACT SUMMARY FOR ETHICAL CONSIDERATION

1- The subject population required to participate in the protocol are infants between 2 and 8 months of age living in the MCH-FP treatment area of Matlab and their mothers. Baseline levels will be determined at birth of a subgroup of newborns. The rationale is to ascertain infants' antibody status against measles before immunisation in the light of maternal antibody levels and to attempt to explain why we are seeing so many cases of measles below the age of immunisation. This may result in shifting the age of immunisation against measles to an earlier age in infancy.

2- The potential risk involved is on drawing blood through venopuncture. However, the Community Health Workers will visit all infants and mothers after the bleeding and very severe malnourished infnats or infants with measles will be excluded.

3- The bleeding will be carried out only once in each child and mother pair by trained staff at a health facility level.

4- Laboratory analysis of the antibody levels will be done blindly.

5- (a) Signed consent will be sought in all the cases.
(b) Not applicable. Immunisation will be done as per current routine.
(c) Immediate complications will be dealt with at the health facility during the procedure. Community Health Workers are examining infants and mothers twice a month and any complications will be dealt accordingly either by them or by referring infants or mothers to the sub-centre or to the Matlab Hospital.

6- Interviews, as well as the bleeding, will be done at the sub-centres or at the Matlab Hospital. Transport will be provided. The process should not last more than ten minutes excluding transportation.

7- Young infants cannot be offered measles vaccination before nine months of age because maternal antibodies neutralise the vaccine. However, children detected in this protocol to have low maternal antibody levels will be immunised through the MCH-FP Programme at an early age. For the society in general, we should be able to show the pattern of protection deterioration in infants with increasing age and propose immunisation strategies for Bangladesh more efficient than the ones we are currently practising.

8- Immunisation records.

ANDRES DE FRANCISCO, PI.

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH-BANGLADESH
MATLAB MATERNAL AND CHILD HEALTH-FAMILY PLANNING PROGRAMME

MEASLES ANTIBODY DECAY IN INFANTS

CONSENT FORM TO USE IN THE COMMUNITY OR SUB-CENTRE

The Maternal and Child Health Programme of the I.C.D.D.R.,B. is providing health services for mothers and children in this area for a long time. One of the services given is the prevention of childhood diseases through vaccination. Your child is receiving vaccines against six diseases in the first year of life. One of these vaccine is to stop the children from getting measles and it is given at nine months of age.

The mother gives protection to the child when it is in the womb and children are born protected until they are nine months of age. We are concerned that some children are attacked by measles even before this age. We are not sure why this is happening. We want to know in order to change the age at vaccination, if this is required.

You can help us to find out the reason on why some very young children have measles. To do this we have to study a number of healthy children before they receive the measles vaccination. We are asking you to participate in this study. For this, we need to take one sample of blood of your child and one of the mother. We want to see if the child is protected and if the mother is also protected.

If you agree to join the study, we will take you and your child to the sub-centre and take the sample of blood of the mother and of the child. This will pose no risk to you or to your baby. However, we will visit your child the following day to ensure that there is no problem. If there was any problem with your child, we will treat him or her accordingly. You can refuse to participate still we will continue our service as we are doing now.

If you agree with this, please sign or place your thumbprint on this space:

We thank you for your collaboration with this study.

CONSENT OBTAINED BY: _____

DATE: :__:__: :__:__: :__:__:

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র, বাংলাদেশ
মতলব মাতৃমংগল শিশুকল্যাণ ও পরিবার পরিকল্পণা কার্য্যক্রম

শিশুর হাম প্রতিরোধ ক্ষমতা সমীক্ষা প্রকল্প

সম্মতি পত্র

আন্তর্জাতিক উদরাময় গবেষণা কেন্দ্র, বাংলাদেশ, মতলব মাতৃমংগল শিশুকল্যাণ ও পরিবার পরিকল্পণা প্রকল্প আপনাদের এলাকায় দীর্ঘদিন যাবৎ শিশু ও মায়েদের স্বাস্থ্য সেবা দিয়া আসিতেছে । ঐ সকল সেবাদানের মধ্যে টিকার মাধ্যমে রোগ প্রতিরোধ করাও একটি কার্য্যক্রম । এই কার্য্যক্রমের আওতায় আপনার শিশু জন্মের প্রথম বৎসরের মধ্যে ছয়টি রোগের প্রতিষেধক টিকা গ্রহন করার কথা । ঐগুলির মধ্যে একটি হলো নয় মাস বয়সে হামের টিকা ।

মায়ের গর্ভে শিশু মায়ের নিকট হইতে রোগ প্রতিরোধ ক্ষমতা পায় এবং শিশুর নয় মাস বয়স পর্যন্ত এই প্রতিরোধ ক্ষমতা থাকে । কিন্তু কোন কোন শিশু নয় মাস বয়স পূর্ণ হওয়ার আগেও হামে আক্রান্ত হইতে দেখা যায় । কেন শিশুদের নয় মাস বয়সের পূর্বে হাম রোগ হয় তাহার কারন সম্ভন্ধে এখনও কেহ নিশ্চিত নয় । আমরা জানিতে চাই ঠিক কত মাস বয়সে শিশুকে হামের টিকা দেওয়া প্রয়োজন ।

কেন শিশুদের নয় মাস বয়সের পূর্বে হাম হয় এই তথ্য অনুসন্ধানে আপনি আমাদেরকে সাহায্য করিতে পারেন । ইহার কারন অনুসন্ধান করিতে হইলে কিছু সংখ্যক সদ্যাস্থ্যবান শিশুর প্রয়োজন হইবে যাহাদের এখনও টিকা নেওয়া হয় নাই । ইহার জন্য আপনার শিশু ও আপনার নিকট হইতে পরীক্ষার জন্য রক্তের নমুনার প্রয়োজন যাহা দ্বারা আমরা শিশু ও মা এর রোগ প্রতিরোধ ক্ষমতা কতটুকু আছে তাহা নির্ণয় করিতে পারিব । এই গবেষণা কার্য্যক্রমে আমরা আপনার ও আপনার শিশুর অংশ গ্রহনের জন্য আপনার অনুমতি চাহিতেছি ।

আপনার যদি ইহাতে সম্মতি থাকে তবে আপনি ও আপনার শিশুকে আমরা রক্তের নমুনা সংগ্রহের জন্য ক্লিনিকে নিয়া যাইব । ইহাতে কোন প্রকার ঝুঁকির আশংকা নাই এবং তাহা নিশ্চিত করার জন্য আমার রক্তের নমুনা সংগ্রহের পর দিন আপনার বাড়ীতে আপনাদের কোন অসুবিধা হইল কিনা তাহার খোঁজ খবর নিব । যদি কোন কারনে আপনি বা আপনার শিশুর কোন অসুবিধা হয় তবে আমরা তাহার যথাযত ব্যবস্থা করিব । আপনি ইচ্ছা করিলে এই গবেষণায় অংশ গ্রহন নাও করিতে পারেন । আপনি ইহাতে অংশ গ্রহন না করিলেও আপনার নিয়মিত সদ্যাস্থ্য সেবা এখন যেভাবে পাইতেছেন তাহা অব্যাহত থাকিবে ।

যদি আপনি এই বিষয়ে সম্মত হন তবে অনুগ্রহ করে নিম্নের নির্ধারিত স্থানে সই/টিপ দিন ।

সই/টিপ :_____ তারিখ :_____

আপনার এই গবেষণায় সহযোগিতার জন্য আপনাকে ধন্যবাদ ।

সম্মতি পত্র গ্রহনকারী :_____

তারিখ:_____

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH-BANGLADESH
MATLAB MATERNAL AND CHILD HEALTH-FAMILY PLANNING PROGRAMME

MEASLES ANTIBODY DECAY IN INFANTS

FORM FOR ADMISSION TO THE STUDY

NAME OF THE CHILD _____

CID :__:__:__:__:__:__:__:__:__:__:

RID :__:__:__:__:__:__:__:__:__:__:

NAME OF THE MOTHER _____

MCID :__:__:__:__:__:__:__:__:__:__:

MRID :__:__:__:__:__:__:__:__:__:__:

PLACE OF ADMISSION 1- REFERRAL FROM THE COMMUNITY :__:
2- SUB-CENTRE 3- DELIVERY

DATE OF ADMISSION (DD/MM/YY) :__:__:__:__:__:__:

WEIGHT OF THE CHILD (in Kg) :__:__: . :__:__:

LENGTH (in cm) :__:__:__:

SAMPLE NUMBER :__:__:__: