

200

Date 27.10.86

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator Andrew Hall

Trainee Investigator (if any)

Application No. 86-035

Supporting Agency (if Non-ICDDR,B)

Title of Study Ascaris and worm people

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 No
(b) Non-ill subjects No
(c) Minors or persons under guardian's care 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
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.

Principal Investigator

Trainee

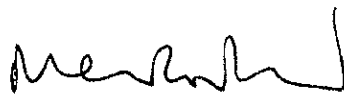
SECTION 1 - RESEARCH PROPOSAL

86-035  
28/10/86

REF  
QX 277  
H174a  
1986

1. TITLE : Ascaris and wormy people.
2. PRINCIPAL INVESTIGATOR : Andrew Hall  
COINVESTIGATOR : Kazi Selim Anwar
3. STARTING DATE : When the money is available
4. DATE OF COMPLETION : 18 months after start
5. TOTAL COST : \$59 400
6. SCIENTIFIC PROGRAMME HEAD : M G M Rowland

This proposal has been approved by the Community Health Services Division

SIGNATURE OF DIVISION HEAD:  DATE: 26.10.86

7. ABSTRACT

When the prevalence of Ascaris lumbricoides in a community is high, a small proportion of infected people tend to harbour a large proportion of all the worms -- they are "wormy people" (Croll & Ghadirian, 1981). It is not known if wormy people are in some way predisposed to infection or if heavy worm burdens are simply randomly distributed among a population, a result of a chance exposure of a few people to a greater than average number of infective stages. The research proposed here is a prospective study of reinfection after treatment to investigate the hypothesis that wormy people become wormy again: this would indicate a predisposition to infection.

The study will involve up to 2000 people living in a crowded slum, conditions in which the transmission of Ascaris is likely to be high. All people found to be infected with Ascaris on the basis of a quantitative stool examination will be given a single dose of a highly effective anthelmintic and their worm burden will be collected. This will serve to identify wormy people. When all the people have been treated -- a process which should take about 6 months -- another round of diagnosis and treatment will be carried out. This will identify wormy people who have become wormy again. Diagnosis and treatment will be carried out once more, six months later, resulting in three treatments and two periods during which people may become reinfected.

The study will include two other main components. The first is a preliminary examination of factors which might predispose wormy people to becoming infected again. In the second, about 300 children aged between 3 and 9 will be weighed every month and a biweekly health diary will be recorded. Growth and nutritional status will be related to initial worminess, to reinfection with worms, and to the incidence of illnesses such as diarrhoea and respiratory tract infections.

8. REVIEWS

1. Ethical Review Committee.

2. Research Review Committee.

3. Director.

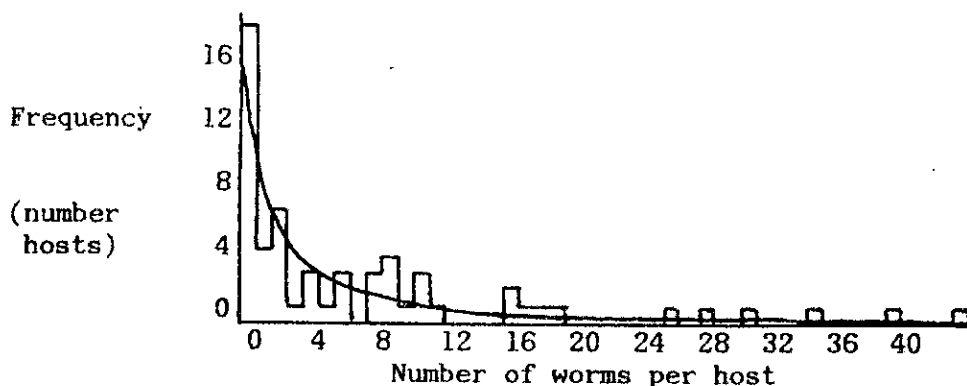
## SECTION II - PLAN OF RESEARCH

### A. INTRODUCTION.

**Worms and disease.** For most species of intestinal worms parasitic in man there is an important distinction between infection and disease (Warren, 1984; Anderson 1985). Because helminths do not generally multiply in number within their hosts a burden of parasites is usually accumulated slowly by a continual exposure to small numbers of infective stages. Light infections tend to be asymptomatic, but as more and more parasites are acquired so disease tends gradually to appear, usually in proportion to the worm burden. This general relationship between an increasing worm burden and disease is variable to some extent and the boundary between infection and disease is indistinct: it depends not only on the number of parasites but also on numerous factors concerned with the physical condition of the host. For example, the disease due to a heavy parasite burden may be exacerbated if the host is already malnourished or concurrently diseased, while moderate worm burdens which are not usually associated with evident disease may become a significant cause of morbidity in an already debilitated host (Hall, 1985). Thus the occurrence of morbidity and the severity of its manifestations depend not only on the general physical well-being of the population of available hosts but also on how parasites are dispersed among those hosts.

**The dispersion of worms.** In the last few years it has become apparent that parasitic worms are not evenly spread in number among infected individuals in a community but are clumped or aggregated in their distribution: up to 70% of all worms in a population of hosts may be found in 20% of those hosts (May, 1985). This pattern is best described by the negative binomial probability distribution which is defined by two parameters, the mean worm burden ( $M$ ) and a measure of dispersion ( $k$ ) which varies inversely with the degree of clumping or aggregation of worms within a community of hosts (Anderson, 1985). Values of  $k$  are typically less than unity when the prevalence of a parasitic worm is high, indicating overdispersion (an example is given in the Figure). The reasons for this aggregation of most of the worms in a few hosts giving rise to "wormy people" are unclear, but genetic, physical, behavioural and environmental factors are probably involved.

**FIGURE.** The frequency distribution of *Ascaris lumbricoides* in 259 Bangladeshi children after anthelmintic treatment. The bars indicate the observed values and the solid line indicates the prediction of the negative binomial probability model in which  $M = 10$  and  $k = 0.44$  (Martin *et al.*, 1983).



The most common worm of man. Ascaris lumbricoides, the large intestinal roundworm, is probably the most common helminth parasite of man in the world today, as well as in Bangladesh: evidence from surveys in Bangladesh indicate that up to 90% of children in some rural areas are infected (Muttalib *et al.*, 1976; Martin *et al.*, 1983). This may be explained by the fact that the transmission of Ascaris in a community is related to the density of people, to insanitary conditions and to a humidity high enough to permit the survival of eggs in the environment (Crompton & Pawlowski, 1985). Bangladesh fulfills all of these criteria more than adequately with an average population density of over 700 people/square km (ESCAP, 1985), no urban or rural sewage system and an average national humidity of 80% (BBS, 1985).

A fertilised female Ascaris living in the human intestine can produce over 200000 eggs a day during a life span of about a year. The eggs pass out with faeces and become infective in moist and shaded conditions in about 14 days at 30 C. Promiscuous defecation and poor personal hygiene encourage faecal-oral transmission: children often pick up eggs from the ground as soon as they start to crawl. The peak prevalence of infection is between the ages of 5 and 15 years and thereafter there is often a small decline in prevalence although it is unclear whether this is due to the development of partial immunity, due to lower rates of infection among adults (Anderson, 1985), or due to a higher death rate among heavily infected people.

The control of Ascaris. For many biological and economic reasons the total eradication of Ascaris is most probably a futile and unreal hope. A recent WHO Conference on the public health significance of ascariasis considered that it would be more sensible and feasible to direct efforts to reduce the intensity of infections and so eradicate morbidity (Crompton *et al.*, 1985). How to do this has been the subject of much debate, and particular attention has been paid to the relative merits of mass treatment compared with selective treatment. (Anderson & May, 1982). Mathematical models indicate that if the aggregation of a species of parasite is fairly high ( $k = 0.5$ ) then to reduce the mean parasite burden by 50% it would be necessary to treat 53% of the population at random; if treatment were given selectively to those with above average worm burdens then only 28% of the population would need to be treated to have the same effect.

The selective treatment of wormy people would not only serve to reduce greatly the average worm burden of a community but it would also eliminate important sources of reinfection for uninfected or lightly infected people, and would reduce the prevalence of morbidity. Giving drugs selectively rather than indiscriminately is also cheaper and more effective as drugs are not wasted on uninfected people.

This approach to controlling ascariasis, the disease caused by Ascaris, seems intuitively to be reasonable. Yet it does not take into account that after treatment people can become infected again immediately: a previous infection does not seem to confer any strong protection against reinfection, and treatment -- however effective, simple and safe -- will only expel the current burden of worms in the intestine. If time and money is expended in identifying wormy people and treating them selectively, does the process have to be repeated every few months in order to identify the new wormy people, or do previously wormy people become wormy again? Is worminess or a predisposition to worminess an enduring condition of some people or is worminess a result of a random exposure of equally susceptible potential hosts

to the infective stages of the parasite?

**The hypothesis to be investigated.** Although it is known that a small proportion of people infected with Ascaris harbour a large proportion of the total worm population, and that they are more likely to be diseased because of their heavy infections, no research appears to have been done on why wormy people are heavily parasitised. Indeed this was a recurring recommendation for research among participants in the recent WHO Conference (Crompton et al., 1985). Therefore the first stage in this research will be a prospective study of reinfection after anthelmintic treatment for Ascaris in order to answer the question: do wormy people tend to become wormy again after treatment? If they do, it would indicate that there is a predisposition to worminess which would warrant further investigation.

**A predisposition to worminess.** Worminess has been defined as having 15 or more worms (Anderson & Medley, 1985) but in the study proposed here the definition of worminess will be based on the distribution of worms between hosts: it will include the most heavily infected 20% of the sample under study who, on previous evidence, should contain about 70% of all worms (May, 1984).

The design of this investigation will allow a preliminary study of physical, environmental and behavioural factors which might have predisposed the initially wormy people to being heavily infected. If after two intervals between deworming a statistically significant number of the initially wormy people became wormy again, then funds would be sought for a more detailed examination of factors which might predispose such people to reinfection in the light of observations already made.

**Growth monitoring.** The investigation will also include serial measurements of the nutritional status and growth of about 300 children aged from 3 to 9. A health diary will also be recorded. This will allow an examination of the association between initial worm burdens and nutritional status, as well as a prospective study of the relationships between reinfection with quantified worm burdens, nutritional status and the incidence and duration of illnesses in wormy compared with lightly infected children.

Although similar studies have been done before in Kenya (Stephenson et al., 1980), in Ethiopia (Freij et al., 1979) and in Bangladesh (Greenberg et al., 1981), they are all susceptible to criticism on the grounds of unquantified worm burdens, light average worm burdens if quantified, small sample sizes or ineffective treatment. The study proposed here would be one of the first to quantify worm burdens accurately for all subjects and to measure in a prospective way the worm load after a period during which reinfection might occur. Other studies have tended to consider children as infected or uninfected, ignoring the fact that there is likely to be a relationship between worm burden and morbidity.

**Drugs.** There are many cheap, highly effective and safe single dose drugs for treating Ascaris including levamisole, piperazine and pyrantel pamoate. The last is the drug of choice of Conn's Current Therapy (1986) and of the AMA Drug Evaluations (1985). Pyrantel is poorly absorbed from the intestine and few side effects have been reported. It acts by paralysing the worms so that they are expelled alive by normal peristalsis. No purgatives are necessary.

This proposed research in perspective. If it was found that wormy people in a community become wormy again after treatment (and conversely that uninfected or lightly infected people stay uninfected or lightly infected), then deworming campaigns could be directed at first identifying wormy people and thereafter concentrate treatment at regular intervals on them, without the need for repeated, time consuming and costly diagnosis.

Treating only the wormy people is a highly efficient way of reducing average worm burdens in a community for the number of people treated, and is the only way to attack morbidity due to Ascaris. In the absence of improvements in sanitation we need to know more about wormy people in order to be able to identify and then protect them from disease, ideally before they are exposed to infection.

## B. AIMS

1. To determine the prevalence and intensity of infections with Ascaris lumbricoides among people living in a crowded slum in urban Bangladesh.
2. To examine prospectively the reinfection of treated people to see if wormy people become wormy again.
3. To begin to try to identify physical, behavioural and environmental factors which might predispose people to becoming wormy.
4. To relate the health and growth of children to the burden of Ascaris before the first anthelmintic treatment, and during subsequent periods when they are exposed to reinfection.

## C. METHODS

Up to 2000 people living in household units in an urban slum of Mirpur, Dhaka will be recruited for this study. Children are likely to comprise over 50% of the sample and are likely to be the most heavily infected. A sample obtained in this way will provide figures for both the age-specific prevalence and age-specific intensity of infection, although it is recognised that it may be harder to study adult males who may leave the household early in the morning to begin work. For this among other reasons, the fieldworkers will begin work soon after dawn.

A fieldworker will visit the household and collect a faecal sample in a plastic cup from every member of the family, excluding people with diarrhoea until they have recovered. The mother will be asked to supervise the collection of faeces from her younger children. The careful and accurate collection of samples will be stressed and supervised as closely as possible.

About 1 g of faeces will be fixed in weighed bottles containing PVA\Schaudinn's fluid. The bottles will be weighed again, then after ether sedimentation of filtered faeces each species of parasite will be identified and the concentration of the eggs of Ascaris, Trichuris trichiura, hookworm and any other helminths will be calculated (Hall, 1981). Intestinal protozoa will also be identified. The processing and examination of faecal samples will be carried out in a temporary clinic which will be set up in Mirpur close

to the study area. This will have at least 4 rooms: one for a laboratory, one for an office, one for a daily clinic and one in which children with heavy worm burdens may receive treatment, accompanied by a relative.

Information will be collected from the head of household or from the wife of the head of household by a questionnaire lasting about 20 minutes (see Appendix A) on the following subjects: age and birth order of children; age, education, occupation and income of parents; number of people in the household; water sources and use; latrines and their use; attendance at MCH-FP clinics; and on recently given treatment for worms.

Because the prevalence of infection with Ascaris is expected to be about 90% at the first treatment, all subjects (except children less than 1 year old unless they are found to be infected) will be given a single dose of pyrantel pamoate (11 mg/kg body weight) and all stools will be collected whether worms are expected or not. This will serve to quantify worm burdens and also indicate the number of infections which have been missed by the single microscopical examination of faeces.

To collect their worms each person will be provided with a lidded plastic bucket of a suitable diameter containing a small volume of an isotonic antiseptic solution into which all faeces will be evacuated. The treatment and collection of stools will be staggered so that no more than 3 people in any one household are collecting their stools and worms at any one time. Treatment will begin with the youngest children first and the mother will be asked to supervise the use of the buckets and to make sure that each child uses the correct bucket and that all stools are passed into the bucket. Each person in the household will be given a bucket of a different colour or marked clearly with an easily identified and remembered picture. It is expected that most worms will be passed on the morning following treatment. All stools and worms will be collected for 48 h after treatment: the buckets will be collected after the first 24 h and replaced with clean ones for the next 24 h.

If there are problems collecting worms from adult males whose employment means they cannot collect their own worms during the day, they will be treated on Thursday morning and asked to collect their stools from Thursday evening onwards including Friday, the traditional day off. Only a 24 h collection may be possible but the peak period of expelling worms should be covered.

A small sum of money (Taka 15) will be given for each satisfactory stool collection. This will serve as a small recompense for the time, effort and inconvenience of collecting a 48 h stool sample, particularly for mothers who will be asked to supervise closely their childrens' defecation. It will act as compensation for the services rendered beyond those that can be reasonably asked for, services which are vital to the practice of the research and services which only result in some inconvenience and extra effort. The investigators consider that this amount of money does not exceed a "reasonable compensation for services rendered" (see Proposed International Guidelines for Biomedical Research Involving Human Subjects, CIOMS, 1982, p 8).

A donation in kind rather than money is not favoured by the investigators for two main reasons. First, if any compensation is given to volunteers then giving in kind is in principal the same as giving money. Thus there is no logical reason not to give money: it is easily obtained, transported and given, it is universally acceptable and can be easily converted to satisfy the



direct and immediate needs of the receiver. This leads to the second point. Giving in kind very often contains a strong element of imposing on people what is good for them, however well meaning the motives, without allowing people to decide for themselves what they want. Also, finding a suitable item to give to people of all ages and both sexes will be very difficult to do and to administer.

The definition of a "satisfactory stool collection" will depend on the a rough agreement between what is collected and the previous microscopical examination of stools. For example, someone whose stool sample showed 5000 epg would be expected to pass more than 3 worms. It is expected that about 90% of people will be infected with Ascaris based on a microscopical examination, and pyrantel should reveal a few light infections not detected by the diagnostic test. Thus it is likely that only about 200 people will not pass worms. If worms are expected but not passed and the infected person denies not having collected all their stools then another dose of pyrantel will be given and all faeces will be collected for a further 48 h. The pyrantel pamoate will be obtained directly from the manufacturers and some samples will be sent for independent analysis to estimate their activity.

The buckets will be collected from each household by daily paid labourers and brought to the clinic which will be set up in Mirpur. A technician will wash each persons worms in saline, divide them into males and females, count them, and then weigh them en masse on a small electronic balance.

All treatment will be supervised by the project physician and particular attention will be paid to children receiving pyrantel who have high Ascaris egg counts. Any young children with possibly heavy worm burdens may be admitted to the Mirpur temporary clinic if their parents wish, so that their treatment can be supervised by the project physician.

After 6 months diagnosis and treatment during which up to 2000 may be enrolled, another faecal sample will be collected from the first subjects examined and the process of diagnosing, treating and collecting Ascaris will be repeated. This will identify those people who have become reinfected during the interim. The process will be repeated after one year so that during the 18 months of the study each person will have had 3 diagnostic tests for worms with appropriate treatment, and with 2 intervals of 6 months between each during which reinfection may occur.

If infections other than Ascaris are identified as well, such as Giardia intestinalis, an appropriate drug will be given a few days after treatment with pyrantel.

The analysis of results will include the following: an examination of the relationship between faecal egg counts, worm burdens and worm biomass; an examination of any association between being heavily or lightly infected before treatment and becoming heavily or lightly infected again; and an examination of any association between being heavily infected before treatment, becoming heavily reinfected, and facts elicited by the questionnaire.

### Growth of wormy children

As children are recruited to take part in the investigation some will be enrolled in a more detailed examination of wormy compared with lightly infected children, in terms of nutritional status, growth and diarrhoeal diseases in particular. With parental consent all children aged between 3 to 9 inclusive will be recruited -- an estimated 400 children. Each will be weighed and measured (height, mid-upper arm circumference) at the time they are given treatment for their Ascaris infections and they will be given a brief medical examination. The mother will be asked questions about the recent health of each child in this age group (see Appendix B). Care will be taken to establish the age of children as accurately as possible using a calendar of events.

Every month during the study each child will be weighed and their arm circumference will be measured. Height will be measured every 3 months. Fieldworkers will visit the household once every two weeks to record the recent and current illnesses of each child, paying particular attention to diarrhoea, dysentery, respiratory tract infections and passing worms (see Appendix C). Mothers will be encouraged to bring children to the project clinic if they are ill, where they will receive free treatment.

In all other respects the children will be treated like the rest of the study subjects: a stool sample will be collected 6 and 12 months after the first deworming, pyrantel will be given and all worms will be collected.

The analysis of this part of the study will examine the association at the first treatment between worminess, initial nutritional anthropometry, the mothers assessment of her child's health and possible indicators of a predisposition to worminess. After both the second and final diagnosis and treatment the analysis will concentrate on those children who become heavily infected during the interim in comparison with children matched for age and sex who have remained uninfected or only lightly infected.

### Predisposition to infection

After the first 12 months of the study, if a significant number of wormy people have become heavily infected again, then proposals will be drawn up for a case control investigation of behavioural, physical and genetic factors which are associated with worminess, particularly in children.

## D. SIGNIFICANCE

If 25% of the population of the world are infected with Ascaris lumbricoides, then over 1,250,000,000 people are infected. If 70% of the population of Bangladesh are infected, then according to current estimates some 70,000,000 people are infected. Thus Ascaris is one of the most common infections in Bangladesh. If 20% of these infected people harbour 70% of all the worms in Bangladesh, then 14,000,000 people are considered to be wormy and may be chronically diseased. Yet because disease is only found in heavily infected people, because when disease occurs its onset is gradual and insidious with no specific symptoms, and because it rarely kills, Ascaris has been neglected as a public health problem in Bangladesh.

If disease due to Ascaris is to be eradicated, leaving only asymptomatic infections with light worm burdens, then wormy people must be identified

and treated. Yet it is not known whether wormy people are somehow predisposed to infection in the first place and are more likely to become reinfected. The best indication of a predisposition to infection is that they become wormy again after treatment. Once worminess has been established as an enduring quality then studies can be undertaken to establish the causes of worminess or identify factors which predispose to reinfection, whether they are genetic, physical, social or behavioural.

#### E. FACILITIES AND SERVICES REQUIRED

None.

#### F. COLLABORATION

Andrew Hall is a Visiting Scientist from the Department of Human Nutrition at the London School of Hygiene and Tropical Medicine. His salary is paid by a grant to the London School by the Overseas Development Administration of the British Government.

Kazi Selim Anwar is a Physician deputed to the ICDDR,B by the Government of Bangladesh. He will extend this period in order to take part in this research.

#### G. REFERENCES

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## ABSTRACT SUMMARY (= Justification of procedures and risks?)

Infections with Ascaris lumbricoides are extremely common in Bangladesh. There is a growing awareness that the distribution of morbidity due to Ascaris is related to the distribution of worms between hosts. This study seeks to examine whether wormy people become wormy again during two 6 month periods after treatment.

There are no risks for the subjects other than those complications which occur occasionally during the treatment of heavy worm burdens. If burdens are heavy then they will be treated under medical supervision. The drug to be used to treat Ascaris acts by paralysing the worms in the intestine which are then expelled with the faeces. Occasionally worms may become tangled in the intestine and cause intestinal blockage. This occurs more commonly in children than in adults. Children whose faecal sample is found to have a very high egg count (over 20 000 epg) will be able to come into the Mirpur temporary clinic for their treatment to be supervised using accepted methods to expel the worms a few at a time. All treatment in the clinic will be supervised by the project physician and the mothers will be able to stay with their children during this time.

The benefits to the subjects will be greater the heavier the worm burden.

A daily clinic will be provided for mothers and their children taking part in the more detailed part of the study.

Some demographic and medical information will be collected from each mother about herself, her husband and her family. A biweekly health diary will be recorded. All information will be treated in strictest confidence.

### SECTION III - PERSONNEL

Name	Position	Percentage Time
Andrew Hall	Principal investigator	50%
Kazi Selim Anwar	Coinvestigator and Project physician (NO A)	100%
	Laboratory technician (GS4)	100%
	Laboratory technician (GS2)	100%
	Health assistant (GS4)	100%
	Health assistant (GS3)	100%
	Health assistant (GS4)	100%
	Health assistant (GS3)	100%
	Health assistant (GS3)	100%
	Data entry technician (GS4)	40%
	4 labourers (daily paid)	100%
	1 caretaker/chokidar	100%

## DETAILED BUDGET

1. Personnel	US \$	Taka
Project physician	6 000	180 000
Laboratory technician (GS4)	2 700	81 000
Laboratory technician (GS3)	2 300	69 000
Health assistant (GS4)	2 700	81 000
Health assistant (GS4)	2 700	81 000
Health assistant (GS3)	2 300	69 000
Health assistant (GS3)	2 300	69 000
Health assistant (GS3)	2 300	69 000
Data entry technician	1 000	30 000
4 daily paid labourers	3 000	90 000
Caretaker/chokidar (GS1)	1 200	36 000
Sub-total	28 500	855 000
2. Materials		
Chemicals, fixatives	5 000	150 000
Glassware	500	15 000
Plastics, tubes, buckets	4 000	120 000
Drugs	2 000	60 000
Sub-total	11 500	345 000
3. Equipment		
Olympus BH2 microscope	2 000	60 000
Bench top centrifuge	1 000	30 000
Top loading balance with digital read-out and printer	1 000	30 000
IBM/XT compatible computer and dot matrix printer	4 500	135 000
Weighing scales for children x 2	500	15 000
Scales for weighing worms	300	9 000
Height board x 2	100	3 000
Sub-total	9 400	282 000
4. Patient hospitalisation	500	15 000
5. Out-patient care	-	-
6. Local transport	500	15 000
7. International travel	-	-
8. Shipping	1 000	30 000
9. Printing forms	1 000	30 000
10. Rent and furniture for temporary field clinic in Mirpur	4 000	120 000
11. Remuneration of subjects	3 000	90 000
Sub-total	10 000	300 000
TOTAL COST OVER 18 MONTHS	59 400	1 782 000

## CONSENT FORM

### Ascaris and wormy people

[Statement to be read to Father and/or Mother of children in household and any other adults]

Many people in Bangladesh are infected with Ascaris, the large intestinal roundworm. We are beginning to study ways of controlling the disease caused by Ascaris. We would like everyone in your household to take part in our work over the next 18 months during which we will diagnose and treat roundworms three times at intervals of about 6 months.

If you agree to take part, today we will collect a faecal sample from you, your husband or wife, from all your children and from anyone else who is living here with you. After we have tested it for worms we will provide everyone with free treatment. We would also like to ask you a few questions about you and your family.

We will return in a week to give the medicine which will expel the worms from the intestine and they will pass out in the faeces. We would like everyone to collect their worms by defecating into a bucket which we will provide for each person. To avoid mixing buckets up we will only treat two or three people at a time, beginning with the youngest children. Each bucket will be of a different colour so please make sure that each person uses his or her own bucket and not someone else's; they must not get mixed up. We will come and collect the buckets after 24 hours and replace them with clean ones. We will give 15 taka to each person in your household, both children and adults, who pass all their stools and worms into the bucket.

If you or your children develop any problems after we have given the medicine please bring them to our clinic at any time, or tell one of our health assistants. If we find evidence of parasites other than roundworm we will give another medicine to treat them afterwards.

In about 6 months time, when we have treated all the people in this area, we will return to your household and test faecal samples again from everyone as you may have become infected again in the meantime. Once again we will provide treatment and ask you to collect in buckets all worms and faeces passed after treatment. Six months later, in one year from now, we will do this again for the last time. On each occasion we will give 15 taka to each person who collects all their stools and worms.

If you agree we would also like to monitor the health of all your children aged from 3 to 9 years. We will weigh and measure them once a month. A fieldworker will also come to see you twice a month to ask about the health of each child in the past two weeks. We will hold a clinic every Thursday to Sunday between 1.00 and 3.00 pm to which you can bring any of these children if they are ill. We will give you a card which you must bring to obtain treatment.

If you agree to take part on behalf of this household then please sign below or mark it with your fingerprint.

You and your family are free to drop out of this study at any time.

Signature or thumbprint  
of Head of Household or  
Representative:

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Signature of Health  
Assistant or Physician:

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Date:

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## আন্তর্জাতিক উদ্যোগ গবেষণা কেন্দ্র

### সম্মতিপত্র

সম্মতি লেখার পূর্বে নিম্নলিখিত বিবরণসমূহ সম্পূর্ণ দিতা বা মাতাকে (বা উভ্যকে) পাঠে জ্ঞাত হইবে।

বাংলাদেশের বহু প্রাক্তন কৌশল দ্বারা আক্রান্ত হয়। এই কৃষির-  
প্রতিকার করার জন্য আমরা একটা গবেষণা কাজ শুরু করিতে থাকি। আমাদের ধারণা  
অন্যে যদি এই গবেষণায় অংশ গ্রহন করেন (যা আগামী ৩৮ মাস হইতে চলবে) তাহলে  
আমরা পুর যুক্তি হ'ব। এই গবেষণায় ৬ মাস পর পর, ৩৮ মাস ব্যাপী স্রোত ও বার, আমরা  
আমাদের এই কৃষি প্রতি বৈশিষ্ট্যে নির্মাণ ও চিকিৎসা করিয়া।

আপনি যদি রাজী থাকেন, আমরা আমাদের আগামীর, আগামীর স্ত্রী  
বা স্বামীর, আগামীর বাচ্চাদের সব; যাতে আপনি আপনার স্বাস্থ্য বান করে তাদের সকলেরই  
স্বাস্থ্যে কিছুটা মনোযোগ করিয়া, সব; তা পরীক্ষা করে দেখবে যে স্রোত কৃষি আছে  
কিনা। যদি থাকে তবে বিনামূলীে আমরা তার চিকিৎসা করিয়া। অছাড়া আমরা আমাদের  
ও আগামীর পরিবারের অন্যান্যদেরকে কয়েকটা প্রকল্প করিতে চাই।

এক সপ্তাহ পর আমরা আগামীরকে একটা ভ্রমণে লইতে দিই  
যা আগামীর দেহে (অন্ত) থেকে কৃষি স্রোতকে স্বাস্থ্যে ত্বর করে দিই। আমরা  
চাই যে, আগামীর সকলেরই আমাদের দেহের স্বাস্থ্যে মনোযোগ করবেন যাতে কৃষিস্রোত  
সুস্থ হয় এবং যেতে পারে। অনেক স্বাস্থ্যে যাতে একসাথে মিলে গিয়ে বিপরীতের স্রোত  
না করে, তার জন্য আমরা স্রোত শিশু থেকে শুরু করে এক মাসে মাত্র ২/৩ জনকে চিকিৎসা  
করিয়ে। সুতরাং আগামীর দয়া করে মনোযোগ রাখুন - যাতে অন্যের স্বাস্থ্যে না নিয়ে যেন  
প্রতিরোধ দিলে তিন র; এর নিম্ন নিম্ন স্বাস্থ্যে ব্যবহার করে থাকেন। আমরা ২৪ ঘণ্টা পর  
পর এসে এইসব স্বাস্থ্যে পরিবর্তন করে নুতনটা নিয়ে থাকে। আগামীর পরিবারের যারা,  
আমাদের সব প্রশ্ন ও কৃষি এ স্বাস্থ্যে জ্ঞান করবে, তাদের প্রত্যেককেই আমরা ৩৮ টাকা করে  
দিব।

আমাদের দেওয়া ভ্রমণে যাওয়ার পর যদি আপনার বা আগামীর বাচ্চাদের  
কোন রকম অসুস্থি দেখা দেয়, তবে তাদেরকে দয়া করে আমাদের ক্লিনিকে নিয়ে আসবেন  
কিন্তু আমাদের যে কোন প্রকারে মনোযোগ করবেন। আমরা যদি প্রমাণ পাঠে যে কৌশল  
কৃষি ছাড়াও কারও কারও দেহে (আহু) অন্যান্য কৃষি ও (পরীক্ষা) রয়েছে, তবে পরবর্তীতে  
আমরা তার জন্য ও ভ্রমণে দিই।

৬. আঙ্গুর মর্ষিত যখন আমতা ও অন্যাক্ষ্য অবস্থাকে চিকিৎসা

প্রায় কৃষ্ণকায় রক্তে সুলভ, তখন আমতা আচারও আমতা বামাণ্ড আমর এবং পূর্বে  
 পত্নী আচার আমনাদের সকলের মনের নষ্টনা নিয়ে পঠীক্ষা করে দেয় - কাজে ইচ্ছিত  
 আমতা আচার এই কৃষ্ণদ্বারা আক্রান্ত হ'লে পাবেন। তবে আমতা আচার আমনাদেরকে  
 চিকিৎসা করুন। এবং আচারও বালতি, কৃষ্ণি ও মন সংগ্রহ করতে অনুমতি দেয়।  
 এবং এরও ৬ মাস পর (আজ থেকে ২৬ মাস পর) কোষ বারের মত আমনাদেরকে  
 আমতা একই নিয়মে পঠীক্ষা করুন। প্রতিবারই আমতা তাদেরকে ২২ টাকার করে দিন।  
 যারা বালতিও মনসহ কৃষ্ণি সংগ্রহ করবে।

যদি আমনদের রক্তী থাকে, তবে আমনাদের তিন থেকে সাত বছর  
 যত্নী নিশ্চদেরকে আমতা চিকিৎসারীক করুন। প্রতিমাসে একবার বা দুই ওজন ও মাস  
 দেব। এককাল পাঠে কৃষ্ণী মাসে দুইবার এই রক্তদের গাও দুই মাসের খাদ্য অধিক জামত  
 আমর। আমনদের একটা ক্লিনিক থাকবে যা প্রতি মাসেই পরিবার থেকে বৃহস্পতিবার  
 বেলা ৩টা থেকে ৩টা পর্যন্ত খোলা থাকবে। এবং সেখানে আমনদের যে কোন অসুস্থ  
 নিশ্চকে নিয়ে আমতে পাবেন। আমতা আমনদের নিশ্চদেরকে একটা কাঁচ দিন, চিকিৎসা  
 দেও হ'লে অচল্যই আমনাকে এই কাঁচটি সত্য করে জামত হবে।

আপনি যদি আমনদের পরিবারের পক্ষ থেকে এই গবেষণায় অংশ  
 নিতে রক্তী থাকেন, তবে দয়া করে নীচে-মহি করুন বা বাম বৃদ্ধাঙ্গুলীর তুপ দিন।

আপনি বা আমনদের পরিবারের যখন ইচ্ছা এই গবেষণা থেকে  
 নাম নির্ধারণ দিতে পারেন।

আমৃত অশুকাঠা বা জাকারের স্মরণ

গৃহকর্তার প্রায় বা বাম বৃদ্ধাঙ্গুলীর তুপ

তারিখ \_\_\_\_\_

## APPENDIX A

Questions to be asked of the Head of Household (if present)  
or to the wife of the head of household.

Please tell us the name, age, sex, the mother and the father of each member of the household:

Who is the head of the household?

Do you own or rent this house?

How many people live in this house?

How long have you lived here?

Construction of house - roof:  
walls:  
floor:  
electricity?  
number of rooms?  
external dimensions?

What source of water do you use for - drinking:  
cooking:  
bathing:  
washing:

Do you have your own latrine?

Do you share a latrine?

If not, where do you and your family defecate?

Do you or your husband have a paid job?

What do you or your husband do?

What is the approximate monthly income of the household?

Did you know your wife/husband before you got married?

If yes, are you related?

If yes, what was the relationship?

Is this your first marriage?

If no, what is the status of your first marriage?

Did you go to school?

If yes, what class did you reach?

Did your husband go to school?

If yes, what class did he reach?

Do any of your children go to school?

Do you ever give your children medicine for worms?

If yes: often (how often), occasionally (how often), or never?

If yes: how long ago did you last treat any of your children?

what medicine did you give?

## APPENDIX B

Questions to be asked of the mother about the general health of each of her children aged 3 to 9.

Has your child had any major illnesses during the last year, not including slight coughs and colds.

If yes, what was the illness?

If treated where did it receive treatment?

Has your child been vaccinated against any diseases?

If yes: for what?

where was it vaccinated?

do you have any vaccine cards?

Do you think that your child may have worms at the moment?

If yes, why do you think so?

Has your child ever vomited any worms or passed them in stools?

If yes, how many times have you seen worms?

Do you ever give your child medicine for worms?

If yes: often (how often), occasionally (how often), or never?

If yes: how long ago did you last treat your child?

what medicine did you give?

Does your child ever complain of the following:

- abdominal pain?
- nausea and vomiting?
- an itchy skin?
- any skin rash? If yes, what type?
- difficulty in breathing?
- asthma?
- a dry cough?
- problems after drinking milk?

We would like you to tell us about the health of your child at the moment.

Is his/her appetite: good, moderate or poor?

Is he/she growing: well, slowly or poorly?

At night does he/she sleep: well, moderately well or poorly?

Is he or she: happy and active, quiet but fairly active or irritable and inactive?

Is he or she: rarely ill, only occasionally ill, often ill?

Does your child complain of anything which we haven't asked about.

APPENDIX C

Biweekly health questionnaire.

Since we last visited you has your child been ill on any day?

If yes: what?

Was there any fever?

If diarrhoea: more than once? (more than 4 days between episodes)  
what type? Blood? Mucus? Watery?  
for how many days did it last?  
any vomiting?  
what treatment did you give him/her?  
where was the child treated?

If chest infection or cold:  
what sort of cough?

Has your child had any skin disease since we last visited you?

Has your child's appetite changed since we last visited you?  
If yes, has it increased or decreased?

Has your child been sleeping well, moderately well or not well at night.

Since we last visited you has your child passed any worms in the faeces or vomited any worms?