ment 1.

Date 20-8-80

ETHICAL REVIEW COMMITTEE, ICDDR,B.

incipal Investigator Dr. L.N. Mutanda Trainee Investigator (if any) _____

plication No. 80-033(P) Supporting Agency (if Non-ICDDR,B) _____

tle of Study Seasonal Pattern of Vibrio cholera Biotypes in Dacca and Matlab

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

ircle 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 NA
   (b) Procedures to be followed including alternatives used — Yes No NA
   (c) Physical risks — Yes No NA
   (d) Sensitive questions — Yes No NA
   (e) Benefits to be derived — Yes No NA
   (f) Right to refuse to participate or to withdraw from study — Yes No NA
   (g) Confidential handling of data — Yes No NA
   (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure — Yes No NA
5. Will signed consent form be required:
   (a) From subjects — Yes (No)
   (b) From parent or guardian (if subjects are minors) — Yes (No)
6. Will precautions be taken to protect anonymity of subjects — Yes No
7. Check documents being submitted herewith to Committee:
   - [X] Umbrella proposal - Initially submit 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 Ctte. for review.

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

Principal Investigator Trainee

80-033 (P)
rec'd 11/8/80

SECTION I - LIMITED STUDY PROTOCOL

1) Title: SEASONAL PATTERN OF VIBRIO CHOLERA BIOTYPES IN DACCA AND MATLAB

2) Investigators: Drs. L.N. Mutanda, M.U. Khan, I. Huq and W.B. Greenough

3) Starting Date: 1st August, 1980

4) Completion Date: End of October, 1980

5) Total Direct Cost: $200

6) Scientific Program Head:

This protocol has been approved by the Disease Transmission Working Group Working Group.

Signature of Scientific Program Head WBG

Date 7/8/80

7) Abstract Summary:

A limited protocol to establish the monthly distribution of Vibrio Cholera in comparision with the non-cholera biotypes in Dacca and Matlab since 1970 is proposed. Laboratory records of both Dacca and Matlab will be reviewed, and the number of cholera and non-cholera isolates counted against the total number of diarrhoeal stools examined. The percentages obtained will be analysed versus the weather seasons.

8) Reviews:

(a) Research Involving Human Subjects: _____

(b) Research Review Committee: _____

(c) BMRC: _____

(d) Director: _____

(e) Controller/Administrator: _____

Background:

Until 1971 nearly 95% of the cholera cases were caused by the classical V.cholera Inaba. During 1972-73 there was a predominence of classical Ogawa. Subsequently both El Tor Ogawa and Inaba were reported(1).

The close association of the non-agglutinating (NAG) vibrios with diarrhoeal disease has been well established since 1964. In the experience of the International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B) over the last several years, this general group of organisms had, however, only been associated with 20-40 cases of diarrhoea annually. Only in 1975 that acute diarrhoeas associated with these vibrio-like organisms began to appear with increasing frequency(2). In Dacca, there were 167, 207, 413 cases respectively in 1975, 1976 and in the first seven months of 1977. The first studies revealed that these organisms belonged to a variety of Heiberg Groups. More than half were Group III, with small numbers in Groups I. II, V and VIII. Subsequent studies have, however, shown that the organisms belong to four distinct taxonomic groups: V.cholera non O Group 1; V.parahaemotiticus; A.hydrophilia and Group F vibrios. V.Parahaemolitius has been reported to occur in the environment thoughout the year, with a peak in the hot months(4). But whether the peak-incidence coincides with the highest isolation from diarrhoeal patients is not known. In this limited study the distribution in time of V.cholera El Tor, Vibrio NAG as a group and individually, Group F vibrios and V.parahaemoliticus since 1970 will be determined.

Objective:

This study intends to study the monthly distribution of V.cholera in comparision with that of other vibrios which have been reported to be associated with acute diarrhoea. This retrospective study will provide base-line data for a prospective investigation of the epidemiology of Vibrios other than the El Tor biotypes which have been isolated from diarrhoeal patients.

Methods of procedure:

Bacteriology records of Matlab and Dacca will be reviewed. The number of monthly vibrio isolations, together with the total number of stool specimens examined will be recorded. The percentages will be worked out manually, and analysed versus the weather seasons. Dr. Khan has the data covering the period 1970 to 1977. Only isolates of 1978 and 1979 need to be counted, and the percentages worked out.

Personnel and Budget:

Use will be made of the Immunology personnel. Two of them can count the number of isolates during the years 1978-79. Right now all are not fully utilized. Drs. Mutanda and Khan will work out the percentages, and finally compile the data. The amount of time required for this project is negligible. Thus only money for publication will be required, and this can come from the Disease Transmission Working Group Budget Code No.

References:

1. Khan, M.U., Mosley, W.H., Chakraborty, J., Sardar, A.M. and Khan, M.R. ICDDR,B Scientific Report No.16, 1978

2. Cholera Research Laboratory, Annual Report, 1977

3. Cholera Research Laboratory, Annual Report, 1979

4. Feldman, R., Seminar, ICDDR,B, 25th July, 1980