82-003.
Rcvd: 15-1-82

SECTION I - RESEARCH PROTOCOL

(1) Title — Minimum Level of Non-Compliance Amongst Oral Contraceptive Acceptors in the Matlab MCH-FP Project.

(2) Principal Investigator — Brian Seaton

Co-Investigators — J. Chakraborty, Md. Yunus

(3) Starting Date — January, 1982

(4) Completion Date — Phase-1 April, 1982; Phase-2 September, 1982

(5) Total Direct Cost

Phase-1	US$	1495.00
Phase-2	US$	2405.00
Total	US$	4900.00

Incremental Cost — Nil.

(6) Scientific Program Head

This Protocol has been approved by the Community Services Research Working Group.

Signature:

Date : 31/12/81

(7) Abstract Summary

Forgetfulness, leading to irregularity, in taking oral contraceptives is common in many acceptors, regardless of their social status. This protocol seeks to document the minimum level of non-compliance amongst OC acceptors in the Matlab MCH-FP Project as an essential preliminary to more detailed studies (should they prove desirable) on the consequences of non-compliance in this population.

(8) Reviews:

(a) Research Involving Human Subjects: _____

(b) Research Review Committee: _____

(c) Director: _____

(d) BMRC: _____

(e) Controller/Administrator: _____

SECTION II - RESEARCH PROTOCOL

A. INTRODUCTION

1. Objectives:

The objective of this Limited Study is to determine the minimum level of non-compliance amongst oral contraceptive (OC) acceptors in the Matlab MCH-FP Project.

2. Background:

Correct usage of OCs requires that it be taken daily, with absolute regularity, for 21 days followed by 7 days when either no pill is taken or (as is the case with the type of OC used in the Matlab-FP Project) a placebo pill containing no active hormonal ingredients is substituted to maintain continuity. Acceptors are encouraged to take their pill at a specific time each day (e.g.just before retiring) in order to promote regularity in use. In the event that a pill in inadvertantly omitted on one day, it should be taken either as soon as the omission is recognised or together with the pill for the following day.

Non-compliance is defined as any departure from the prescribed schedule. Non-compliance may take either or both of two forms:

(i) forgetting that the daily pill has already been taken and therefore inadvertantly taking a second on the same day;

(ii) forgetting to take any pill on the scheduled day.

Non-compliance due to gross misunderstandings of the correct way to use the pill may also occur, but only rarely if the field workers are well trained and working effectively.

Forgetting to take the pill from time-to-time seems to be a common occurance amongst all acceptors, including the well-educated and highly-motivated. It may therefore be expected to be widespread

amongst the poorly-educated women of rural Bangladesh, particularly if their grasp of the concept of prophylactic medicine is poor. Provided that the omission is recognised and corrected within 24 hrs. (i.e. up to the time when the next pill would normally be taken) there is probably little adverse consequences, either in terms of endoctrinological disturbances or of risk of pregnancy. Indeed, for the purpose of this study, an omission corrected within 24 hrs. will an expected, and therefore acceptable occurance from time-to-time and will not be regarded as non-compliance.

However, omission which extend over more than 24 hrs. present a more serious problem; (i) the subject may never realise that the omission has occurred, particularly since the date-makings are printed in English and are therefore unintelligible to the majority of acceptors; (ii) the half-life of the synthetic steroids used in OCs is quite short, about 8 hrs. so long-duration irregularities in the taking of the OC may not only put the acceptor at risk of pregnancy but also distrub the endoctrinological balance of the acceptor and give rise to undesirable side-effects such as break-through bleeding (and, perhaps, other side-effects also).

There is very little information on the incedence of non-compliance amongst OC acceptors in rural Bangladesh. Western women commonly forget as many as 2-4 pills per cycle (data from expatriates living in Dacca), though these rarely constitute non-compliance within the context of this study since the omission is usually corrected within 24 hrs. with the aid of the date-marking on the packet. However, this observation suggests that similar omissions will occur in Bangladeshi women using OCs and the hypothesis is that the lower educational levels amongst rural Bangladeshi women will mean that a much higher proportion of such omissions will go un-noticed giving rise to a significant level of non-compliance.

3. Rationale

Before any in-depth studies on the consequences of such non-compliance (if it actually occurs) are contemplated it is clearly essential to establish what the level of non-compliance is in the population.

B. SPECIFIC AIMS

The specific aims of this protocol are the same as the objectives viz. to determine the minimum level of non-compliance amongst oral contraceptive (OC) acceptors in the Matlab MCH-FP project.

C. METHODS OF PROCEDURE

All OC acceptors in 2 blocks the Matlab MCH-FP Project (one MCH-FP block and one FP-only block) will be studies. Each time the acceptor is visited by the FVW (approx. every two weeks) the FVW will ask to see the OC packet and the FVW herself will count and record the number of pills remaining in the packet, together with the subject and the actual (not the scheduled) date of the visit. No other information will be collected, except for the standard admission history for Endocrinology Studies (see Appendix A) with the addition of the number of years of education of the subject.

The above data will be analysed to determine the minimum level of non-compliance. Taking the date and number of pills on the first visit (i.e. admission to the study) as the base-line, the number of pills which should remain on any given subsequent date can easily be calculated. Any discrepancy from this calculated number represents the minimum level of non-compliance. It should be noted

that only the minimum level can be determined in this study-design; for example, a non-compliance of inadvertantly taking two pills on one day could cancel a non-compliance of inadvertantly omitting to take a pill at some other time. It is impossible to identify such self-cancelling errors within the two-weeks observation interval, but the data-analysis procedures will be designed to accommodate such positive and negative non-compliance when occuring in different observation intervals. The average level of non-compliance will be calculated for each individual and for the population. The results will be stratified by the age of the subject and by the number of years of education.

The study will be for an initial period of 3 months with an option to extend the study for a further 6 months (i.e. total of 9 months) if justified by the initial results.

D. SIGNIFICANCE

There is at present virtually no information on the levels of non-compliance amongst the contraceptive users particularly in the rural areas. This study will give an indication of the level of non-compliance in the Matlab area and that information will be useful to determine whether this is a significant problem requiring more detailed study.

E. FACILITIES REQUIRED

Existing FVWs will be able to collect the required data on their regular rounds. A senior health assistant will be required to supervise and monitor the data collection and transmission to Dacca. Data sheets will be transferred weekly to Dacca for computerisation. Approximately 2 hrs./week of data-entry technician time will be

required to enter the data (consisting of approx. 200 entries; subject-id, date and no. pills; per week) onto the computer. Software for data analysis will be written by the Principal Investigator, Dr. B. Seaton or a programmer. No additional office-space or logistic support will be required.

F. COLLABORATIVE ARRANGEMENTS

No collaborative arrangements are planned for the study.

1. PERSONNEL SERVICES

Sl. No.	Name	Position	Level/ Step	Monthly Rate	Person Month	Cost Phase 1	Cost Phase 2
1A	Brian Seaton	Scientist		$ 3000	3x0.05	450	
1B	— " —	— " —		— " —	6x0.05		900
2A	Various, 40 persons	FNW		Tk 922	40x3x0.01	70	
2B	— " —	— " —		— " —	40x6x0.01		140
3A	To be named	Sen. Field Asst.		Tk 3536	3x0.25	166	
3B	— " —	— " —		— " —	6x0.25		332
4A	To be named	Data Entry Tech.		Tk 2311	3x0.05	22	
4B	— " —	— " —		— " —	6x0.05		44
5A	To be named	Programmer		Tk 5592	3x0.01	105	
5B	— " —	— " —		— " —	6x0.03		63

2. TRAVEL & TRANSPORTATION OF PERSONS

Nil — Nil

3. TRANSPORTATION OF MATERIALS

Nil — Nil

4. RENT, COMMUNICATION AND UTILITIES

a) Communication. — 25 — 50

5. PRINTING AND REPRODUCTION

a) Printing of forms	1x600 copies	10	
	1x1200 copies		20
	200 copies	10	
	400 copies		20
		20	40

6.	OTHER CONTRACTUAL SERVICES			
	a) Computer Services			
	Terminal time for data entry	@ Tk.10/hr	16	33
	Computer time (programmer)		139	78
	Terminal time (user	@ Tk 50/hr	40	80
	Lineprinter output		20	20
	b) Daily wagers			
	Boatman, Matlab.	@ Tk 20/hr	45	90
			250	310
7.	SUPPLIES AND MATERIALS			
	h) Office supplies & stationery		25	50
8.	EQUIPMENT		Nil	Nil
9.	TRANSPORT			
	a) ICDDR,B transport in Dacca		30	60
	b) Trips to Matlab		169	169
	c) Speedboat, Matlab	10 hrs/week	163	326
			362	555
10.	PATIENT HOSPITALISATION		Nil	Nil
11.	OUTPATIENT CARE		Nil	Nil
12.	LABORATORY TEST		Nil	Nil

13. CONSTRUCTION, RENOVATION, ALTERATION	Nil	Nil
14. INCOME		
Funding from BFRP/IFRP	(1000)	?
TOTAL COSTS	1495	2405

ABSTRACT SUMMARY FOR THE ETHICAL REVIEW COMMITTEE

1. A subject population of rural Bangladeshi women is required for the study in order to investigate the level of non-compliance in oral contraceptive use in such a population.

2. This study involves only the recording of the number of contraceptive pills remaining at any given time. Thus there was no potential risk to the subject whatsoever. It should be specifically noted that, apart from recording the number of pills, there will be no deviation from health care practices in relation to such subjects and in particular subject will not be encouraged to take oral contraceptive irregularly for process of the study. Indeed, they will receive the normal encouragement to continue to take the pill regularly.

3. Not applicable.

4. Data stored on the computer will be held in secured files which can be excessed only by the Principal Investigator and other authorised persons. Printed material will be kept securely in the Principal Investigator's office. No subject will be identified by name in any publication arising out of this project.

5. Since there are no risks to the subject a signed content form will not be required. Subjects will simply be told that we are conducting a study on how on contraceptive survive under field conditions in Bangladesh. Any subjects who particularly do not wish to provide the required information will not be pressurised into doing so.

Informing either the subjects or the FWWs that the purpose of the study is to test compliance will necessarily frustrate the study in one of two ways: (1) subjects may be embarrassed to admit that they have not taken their OC regularly and may give false or misleading information; (2) since the workers receive vigorous training and motivation to encourage the clients to take the OC regularly, the FWWs may feel that to report non-compliance would be to admit to fault or failure in motivating

the client and may therefore suppress or falsify non-compliance data. In view of this, permission has already been sought and given (vide memoranda dated 6.12.79) to withhold the true purpose of the study. Instead FWs and subjects will be informed that the objective of the study is to examine for pill deterioration in the field. The report form (Appendix B) will contain an additional, irrelevant (in terms of the actual purpose of the study) question on whether or not the pills appear to be crumbling, in order to give credibility to the supposed purpose of the study.

6. On entry to the study each subject will be asked a few basic pregnancy history details as set out in appendix A. On subsequent visits an interview as such will be not required. The Field Worker will simply request to see the card of contraceptive and will record the relevant information.

7. In general the subject will not receive any direct benefit by participation in the study except that in rare cases where a subject is found to have very poor compliance some follow-up and encouragement may be given by the field worker. However, the study is expected to be a considerable benefit to society as a whole by indicating the level of non-compliance of oral contraceptive use within such a population.

8. The study does not require the use of any records, organs, tissues, body fluid or other materials.

VERBAL CONSENT

STATEMENT TO BE READ TO POTENTIAL SUBJECTS

As part of its policy of ensuring that its services are maintained at the highest level the ICDDR,B is conducting a survey of oral contraceptive packets in the homes. We therefore request that you permit us to examine your packet of oral contraceptives each time we visit your house. By this minor inconvenience you will assist us in providing better services. If you do not wish to assist us in this way you are not obliged to and it will not create any problem for you if you refuse to help us.

Thank you for your cooperation.

মৌখিক সম্মতি

সম্ভাব্য জন্মদায়িনীদের উদ্দেশ্যে

"আই, সি, ডি, ডি, আর, বি" নিজেদের কর্মসূচীকে সর্বোত্তমভাবে কার্যকরি করার উদ্দেশ্যে নিজস্ব সরবরাহকৃত এবং প্রতি গৃহে ব্যবহৃত জন্মনিরোধ বটিকার প্যাকেট সমূহের জরীপ কার্য পরিচালনা করিবে ।

সুতরাং আপনাদের নিকট সবিনয় অনুরোধ এই যে আমরা যতবার আপনাদের গৃহে উপস্থিত হইবো, ততবারই আপনাদের জন্মনিরোধ বটিকার প্যাকেটটি আমাদিগকে দেখাইতে কোনরূপ দ্বিধা করিবেন না । ইহাতে আপনাদের কিছুটা অসুবিধা হইলেও আমরা আপনাদের সেবার একটা ভাল সুযোগ পাইবো । অবশ্য এভাবে আপনারা আমাদিগকে সাহায্য করিতে বাধ্য নহেন, এমনকি আপনারা যদি আমাদিগকে এ ব্যাপারে সাহায্য করিতে সম্পূর্ণ অস্বীকারও করেন তাহাতেও আপনাদের কোনরূপ সমস্যার সৃষ্টি হইবে না ।

আপনাদের সহযোগীতার জন্য অসংখ্য ধন্যবাদ ।

Database name: DPROJ

ICDDR,B COMPLETED/ONGOING PROJECT DATA INPUT SHEET

Rec. no.: 60

Input date ISO (005):

Rev date ISO (006):

Lang of text (021): EN

Investigators' name (110): [^a^b^e^f] â Seaton ĥ Brian ê GB f Principal investigator/ â Chakraborty ĥ J. ê BD f co-investigator/ â Yunus ĥ Md ê BD f co-investigator

Affiliation of principal investigator (112): [^a^b^d^e] â International Centre for Diarrhoeal Disease Research, Bangladesh â Dhaka ê BD

Other associated inst (113): [^a^b^d^e^f]

Project inf (142): [^a^b^c^d] â Minimum level of non-compliance amongst oral contraceptive acceptors in the Matlab MCH-FP project ĥ 82-003 f PHSD

Project duration - ISO (143): [^a^b^c] â 1982_0101 ^

Project status (144): [^a^b]

Policy note (150):

Call no. fl.

General note (155):

Accession no. (165): A-031940

Main descrip/ subj (300): <Contraceptive, Oral>/<Family planning>/<Compliance>/<Health services research>/<Health services accessibility>/<Health promotion>/<Maternal-child Health Centers>

Geographic descrip (302): <Bangladesh>

Local descrip/ study area (303): <Matlab>

Abstract (310):

Documentalist (430): MN

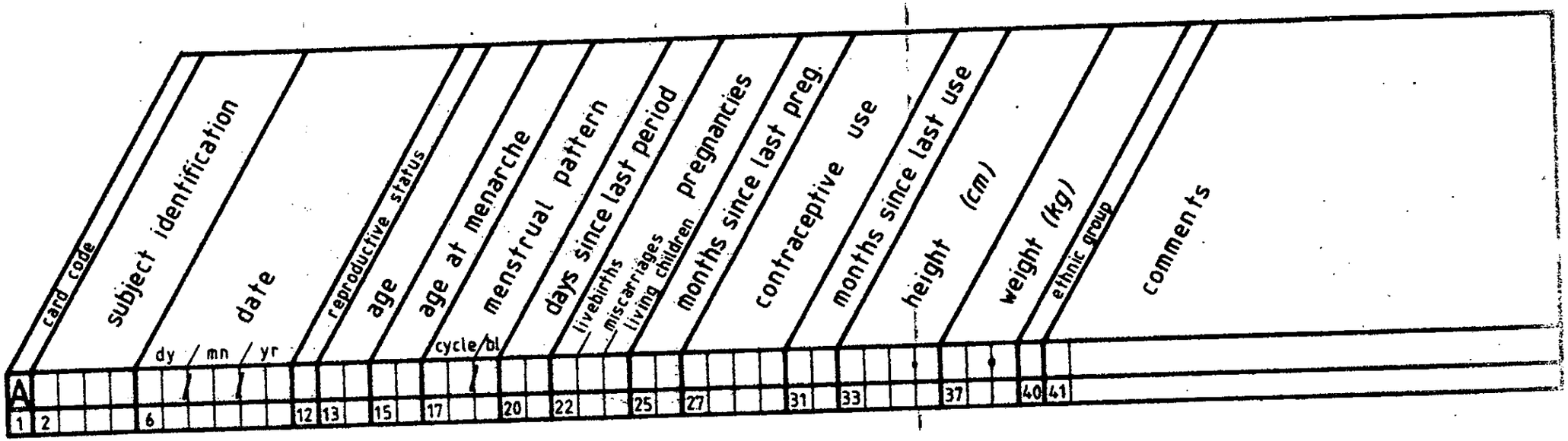
Budget (516): [^a^b^c] ^a USD ^b 4,900/=

Funding Inf note (530):

11.8.98

Checked by:

Approved by: 12/8/98



Subject's name _____

Census no. _____

ICDDR,B

Endocrinology Study

BS 2/79 A-3