

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator DR B. SEATON Trainee Investigator (if any) _____

Application No. 82-015(P) Supporting Agency (if Non-ICDDR,B) _____

Title of Study Directory of Endocrinology Project status:
Research in S.E. Asia
 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 N/A
 - (d) Discomfort to subjects Yes No N/A
 - (e) Invasion of privacy Yes No N/A
 - (f) Disclosure of information damaging to subject or others Yes No N/A
3. Does the study involve:
 - (a) Use of records, (hospital, medical, death, birth or other) Yes No N/A
 - (b) Use of fetal tissue or abortus Yes No N/A
 - (c) Use of organs or body fluids Yes No N/A
4. Are subjects clearly informed about:
 - (a) Nature and purposes of study Yes No N/A
 - (b) Procedures to be followed including alternatives used Yes No N/A
 - (c) Physical risks Yes No N/A
 - (d) Sensitive questions Yes No N/A
 - (e) Benefits to be derived Yes No N/A
 - (f) Right to refuse to participate or to withdraw from study Yes No N/A
 - (g) Confidential handling of data Yes No N/A
 - (h) Compensation &/or treatment where there are risks or privacy is involved in any particular procedure Yes No N/A

5. Will signed consent form be required:
 - (a) From subjects Yes No N/A
 - (b) From parent or guardian (if subjects are minors) Yes No N/A
 6. Will precautions be taken to protect anonymity of subjects Yes No N/A
 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.

Brian Seaton
Principal Investigator

REF
WK 22.JA1
S-441d
1982

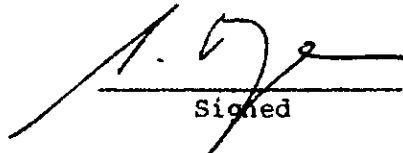
82-015(P)
1/4/82

LIMITED PROJECT

SECTION I - PROTOCOL

- 1) Title : Directory of Reproductive Endocrinology Research in S. E. Asia.
- 2) Principal Investigator : Dr. Brian Seaton
- 3) Starting Date : April 1982
- 4) Completion Date : June 1982
- 5) Total Direct Cost : \$ 1365
- 6) Scientific Program Head :

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



Signed

20/3/1982

Date

- 7) Following the S.E. Asia Regional Survey of Reproductive Endocrinological Research conducted by the Principal Investigator in 1981, a directory of research activities in S.E. Asia will be produced to facilitate exchange of research ideas and data.
- 8) Reviewers
 - a) Research Involving Human Subjects - Not applicable
 - b) Research Review Committee - Not applicable
 - c) Director _____
 - d) BMRC - Not applicable
 - e) Controller/Administration _____

SECTION II - OPERATIONAL PLAN

A. INTRODUCTION

1. Objective

The objective of this proposal is to prepare and distribute a directory of current research activity in reproductive endocrinology in S.E. Asia.

2. Background

During 1981 the Principal Investigator, assisted by Dr. Kosin Amatayakul of the Research Institute for Health Sciences (Chiang Mai University, Thailand) and funded by the Ford Foundation and IDRC, conducted a regional survey of reproductive endocrinology research in S.E. Asia. That survey collected a considerable amount of information on current research activities in the region. It also revealed that most of the workers in the region are ignorant of the activities of others due to the absence of any communication network.

The information collected on the survey could be used to construct a directory of current activities which, if circulated to persons interested, would greatly improve their awareness of current activities in the region and promote greater communication and collaboration by enabling scientists to correspond with each other directly. At the present time there is no mechanism for facilitating such communication.

3) Rationale

Reproductive endocrinology is an expensive and highly technical research field. Few countries in S.E. Asia can therefore afford more than one or two centres undertaking such research. If scientists in the region are not to be isolated but to make effective use of their resources in pursuing regional issues, it is essential that they be provided with facilities to enable them to communicate with their colleagues in other countries of the region. The provision of a directory will be one such facility.

B. SPECIAL AIMS

The objective of this proposal is to prepare and distribute a directory of current research activity in reproductive endocrinology in S.E. Asia.

C. METHODS OF PROCEDURE

1. Individual Entries

The S.E. Asia regional survey produced details of the personnel, equipment, resources and activities of approximately 30 laboratories in the region. The entry for the ICDDR,B is reproduced in Appendix-A. Copies of the entries will be sent to the respective laboratories for correction and updating as appropriate.

2. Donor Entries

An important aspect of research programs is location of the necessary funds. Donors who have an interest in supporting reproductive endocrinology research will be contacted and requested to provide the following information:-

- a) areas of research that they are willing to consider funding
- b) name or designation and address of the appropriate person to whom enquiries about possible funding should be addressed
- c) outline information about the required structure and content of requests for funding
- d) a list of projects/institutions currently being funded

(item d may be omitted if the donor feels this would be a breach of confidence - but note that the amount of funding would not be given).

3. Commercial Entries

Also important is knowing where to obtain equipment and/or reagents relevant to reproductive endocrinology research will be contacted and asked to supply information about their products. This will be done on a pro-forma basis to ensure comparability and uniformity of information (see Appendix-B). Whilst the basic information will be published free of charge to the company in a format to be decided by the PI which will be the same for all companies, companies will also be offered a limited amount of space in the directory to advertise themselves and/or their products. For such advertisements a fee will be paid to help cover the costs of preparing and distributing the directory.

A deadline will be set for receipt of all the relevant information. After that date the directory will be compiled, mimeographed, bound and circulated.

D. SIGNIFICANCE

Production of the directory will greatly facilitate the development and coordination of research in reproductive endocrinology in the region and will enhance the status of the ICDDR,B as an international centre which contribute to the development of the region.

E. FACILITIES REQUIRED

The current office-space of the PI is adequate for the purpose. Whilst the currently available secretarial assistance will be sufficient in the initial stages, some additional secretarial assistance will be needed for preparation of the final directory. This may be accomplished either by paying over-time to current employees or by hiring temporary staff on a contractual basis. Mimeography, xerox, telex and printing facilities will be required and also the assistance of the Medical Illustration to design and execute any outwork that may be necessary.

F. COLLABORATIVE ARRANGEMENTS

None

SECTION III - DETAILED BUDGET

(Apr. - June 1982 incl)

<u>1. PERSONNEL SERVICES</u>					
<u>Sl.No.</u>	<u>Name</u>	<u>Position</u>	<u>Monthly Rate</u>	<u>Person Month</u>	<u>Estd. Cost 1982</u>
1	Dr. Brian Seaton	Scientist	\$ 3000	3 x 0.1	(900) +
2	Farida Sultana	Secretary	\$ 183	3 x 0.1	55
<u>2. TRAVEL & TRANSPORTATION OF PERSONS</u>					
					nil
<u>3. TRANSPORTATION OF MATERIALS</u>					
					nil
<u>4. RENT, COMMUNICATION AND UTILITIES</u>					
c) Communication					250
<u>5. PRINTING AND REPRODUCTION</u>					
b) Special reproduction. Covers.					250
c) Publication mimeo 250 copies x 200 pages					690
d) Xerox. 533 copies @ Tk. 0.6					<u>20</u>
					960
<u>6. OTHER CONTRACTUAL SERVICES</u>					
b) Daily wagers. Typist (Overtime rates) 50 hrs @ Tk16/hr					50
<u>7. SUPPLIES AND MATERIALS</u>					
h) Office supplies and stationery					25
<u>8. EQUIPMENT</u>					
					nil
<u>9. TRANSPORT</u>					
ICDDR,B transport in Dacca					25
<u>10. PATIENT HOSPITALISATION</u>					
					nil
<u>11. OUTPATIENT CARE</u>					
					nil
<u>12. LABORATORY TEST</u>					
					nil

Section III - Detailed Budget - Page-2.

13.	<u>CONSTRUCTION, RENOVATION AND ALTERATION</u>	nil
14.	<u>INCOME</u>	nil
	Total Cost	\$ 1365

Notes

+ Dr. Seaton's salary is paid directly by ODA and does not pass through ICDDR,B accounting procedures. It is included here only to indicate the true cost of the project.

INTERNATIONAL CENTRE FOR DIARRHOEAL DISEASE RESEARCH, BANGLADESH

<u>Institution</u>	International Centre for Diarrhoeal Disease Research, Bangladesh.
<u>Postal Address</u>	PO Box 128 Dacca-2 Bangladesh
<u>Telephone</u>	300171 (10 lines)
<u>Cables</u>	CHOLERA DACCA
<u>Telex</u>	65612 ICDD BJ
<u>Chief Executive</u>	Dr W.B. Greenough III, MD Director.
<u>Staff</u>	Academic/Research staff (all disciplines) . ≈40 Technical support staff ≈500 Administrative support staff ≈100
<u>Students</u>	Post-graduate students § Under-graduate students § § The ICDDR,B is not a teaching institution in the same way as a university or medical school, but it runs a variety of training courses and research fellowships in diarrhoeal diseases and related subjects.

Reproductive Endocrinology and/or Contraceptive Technology Research Programmes

Community Services Research Working Group

<u>Scientific Research Staff</u>	Dr B. Seaton MA, DPhil, AIMLS Scientist (British Technical Cooperation Officer) Dr J.F. Phillips Ph.D. Scientist
<u>Support Staff</u>	Laboratory staff with PhD - Laboratory staff with MSc 2 Laboratory staff with BSc - Other qualified laboratory staff - Unqualified laboratory staff 2 Secretarial staff 1 Electronics technician 2

030755

International Centre for Diarrhoeal Disease Research, Bangladesh

<u>Laboratory Facilities</u>		
	β-counter	2G
	γ-counter	1S
	refrigerated centrifuge	2S+1G
	non-refrigerated centrifuge	2G
	refrigerator (4°C)	4G
	deep-freezer (<-10°C)	1D+2G
	pH meter	3G
	analytical balance (0.1mg)	2G
	ice-maker	1S
	lyophiliser	1G
	extractor/evaporator	2D
	analytical-grade water	1S+1G
	cold-room	2G
	radioisotopes laboratory	1G
	standby generator	1G
	electronics/instrument workshop	1G
	main-frame computer	1G
	micro-computer	1G+1D [§]
	programmable calculator	1D+3G

§ Micro-processor incorporated into the γ-counter.

<u>Reagents and Supplies</u>		
	anti-sera for RIA	A+K
	radioisotopes	A+K
	solvents	A
	scintillation fluid	A+P
	expendables	A
	quality control materials	W+A+P

<u>Assays</u>		
	progesterone	1000-A ^φ
	17α-hydroxyprogesterone	N
	estrone	N
	estradiol	<100-A
	estriol	N
	testosterone	<100-A
	LH	500-A
	FSH	500-A
	hCG	P
	prolactin	N
	cortisol	<100-A
	ACTH	N
	T3	N
	T4	N
	depo-medroxyprogesterone acetate ...	P

φ Primarily for assaying progesterone levels in saliva.

Name and Address of Parent Company

Telephone:

Cables:

Telex:

Name(s) and Address(es) of Subsidiary Companies or Distributors Serving S.E. Asia

(1)

Telephone:

Cables:

Telex:

(2)

Telephone:

Cables:

Telex

(3)

Telephone:

Cables:

Telex:

RIA REAGENTS

Complete Kits.	Individual Reagents				
	Antisera	Isotope	Standards	Seperating Agent	Buffer
Progesterone					
17 _a -hydroxy progesterone					
estrone					
estradiol					
estriol					
testosterone					
LH					
FSH					
hCG					
Prolactin					
cortisol					
ACTH					
T3					
T4					
others (specify)					

Miscellaneous Reagents

Inorganic chemicals, buffers	Yes/No
Organic chemicals, solvents	Yes/No
Scintillation-grade solvents	Yes/No
Scintillators	Yes/No
Scintillation cocktails	Yes/No

International Centre for Diarrhoeal Disease Research, Bangladesh

Current Research (all topics)

- Diarrhoeal disease research (i) Disease transmission
 (ii) Host defense
 (iii) Pathogenesis & therapy
- Nutrition research
- Community services research (i) Demography
 (ii) Family planning and Maternal & child health
 (iii) Effects of chronic ill-health on reproductive
 endocrinology and hormonal contraceptive use.

Recent Publications (endocrinology only)

Seaton, B. & Johnston, P.G.B

Effect of cyproheptadine on steroid hormone excretion by a young girl with Cushing's syndrome.

J. Endocrinol. 1980 87 61P

Seaton, B. & Riad-Fahmy, D.

The use of salivary progesterone assays to monitor menstrual cycles in Bangladeshi women

J. Endocrinol. 1980 87 21P

Seaton, B., Rahman, M., Ali, A. & Wahed, M.A.

Towards appropriate clinical biochemical technology for Bangladesh.

1st Bangladesh Biochemical Conference, 1980

Seaton, B. & Ali, A.

Unified clinical chemistry methodologies for developing countries.

Institute of Medical Laboratory Sciences, Triennial Conference, 1980.

Seaton, B.

Endocrinology of menstrual cycles in Bangladeshi women of low socio-economic status.

Acta Endocrinologica Conference, 1981.

Isotope Handling Equipment

β -Counters

Model No.	No. Channels	No. Vials	Special Features

γ -Counter

Model No.	No Channels	No. Vials	Special Features

Miscellaneous Equipment

Positive displacement pipettes	Yes/No
Air-displacement pipettes	Yes/No
Automatic diluters/dispensers	Yes/No
Plastic scintillation vials	Yes/No
Chemically clean tubes for RIA	Yes/No