

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator C.M. FILLMORE

Trainee Investigator (if any) _____

Application No. 83-010P

Supporting Agency (if Non-ICDDR,B) FAO

Title of Study Entry of Sommer/Lowenstein

Project status:

Final & Preliminary Analysis
(Pilot Protocol)

- New Study
- Continuation with change
- No change (do not fill out rest of form)

Indicate the appropriate answer to each of the following (If Not Applicable write NA).

Source of Population:

- (a) Ill subjects N.A. Yes No
- (b) Non-ill subjects Yes No
- (c) Minors or persons under guardianship Yes No

Does the study involve: N.A.

- (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

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 N.A. 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: NA.

- (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 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)

NA 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)

NA Informed consent form for subjects

NA Informed consent form for parent or guardian

NA Procedure for maintaining confidentiality

NA 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.

C.M. Fillmore
Principal Investigator

Trainee

SECTION - I: RESEARCH PROTOCOL

Recd: 22/3/83

1. Title: Entry of Sommer/Lowenstein Data & Preliminary Analysis
2. Principal Investigator: Capri Mara Fillmore
3. Supervisor: Dr. Stan D'Souza
4. Starting Date: 12 January 1983
5. Completion Date: 12 April 1983
6. Total Direct Cost: US\$ 750
7. Scientific Program Head:

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

* Signature of the Scientific Program Head: _____

Date: 15 Feb 1983.

* This signature implies that the Scientific Program Head takes responsibility for the planning, execution and budget for this particular protocol.

8. Abstract Summary:

Data collected by Sommer and Lowenstein December 1970 to January 1971 needs to be entered onto the computer and edited. This data contains the height, arm circumference, sex, and birthdate or approximate birthdate of about 9000 children under 11 years of age. Once this is done the data set will be analysed utilizing the NCHS anthropometric reference, utilizing Z-scores and percentiles and breaking down by specific age group and sex. The data will also be analysed in terms the distribution curve of the data and proportion of children below an arbitrary lower-limit indicator value. Then there will be an attempt to link these children with the 1970 SES data on their families.

9. Reviews:

- (a) Ethical Review Committee _____
- (b) Research Review Committee _____
- (c) Director _____

ABSTRACT SUMMARY

None of the questions for the Ethical Review Committee apply because this study involves only old data sets, and will not involve contact with any patient or population surveyed.

SECTION - II: RESEARCH PLAN

A. INTRODUCTION

1. Objective

The data of Sommer and Lowenstein are the oldest tracable anthropometric data from Matlab. By entering this data on the computer and doing this preliminary analysis, it will be possible to use the data as a baseline by which to compare more recent anthropometric studies and then relate changes in anthropometry to economic development. A secondary objective will be to work out a mid-arm circumference reference program for ICDDR,B.

2. Background

December 1970 to January 1971 Sommer and Lowenstein collected data on arm circumference and height for 0-10 year old children in 27 Matlab villages. They later analysed this "QUAC Stick" data in terms of its mortality prediction potential (Sommer and Lowenstein, 1975). The only record of this data in Bangladesh is the 1970 Matlab Census Books. A thorough investigation of Matlab anthropometric data (see "Anthropometric Data Collected in Matlab") made it clear that the Sommer and Lowenstein study is the earliest anthropometric study in Matlab for which data is still available.

As of today, there is no mid-arm circumference reference program at ICDDR,B. This program will have to be developed in order to fully analyse the data from ICDDR,B studies which included arm circumference measurements, as well as the Sommer and Lowenstein study discussed in this protocol.

The Cholera Laboratory's SES (Socio-economic Status) 1970 survey included information on occupation and education of head of household, marital status,

land holding, crop yield, and income of land leasers. Since this survey involved at least some of the families in the Sommer and Lowenstein study, it may be possible to make some linkage of the two surveys.

3. Rationale

The Sommer and Lowenstein study has the earliest available anthropometric data from Matlab, it can therefore be used as a baseline by which to compare more recent studies. This will be necessary for my FAO Research Fellowship on the "Rapidly of Response of Nutritional Status Indicators to Economic Development Efforts" which will attempt to link changes in anthropometry to economic development over the years in Matlab.

B. SPECIFIC AIM

The goal of this exercise is to put the data into a workable form which will facilitate its comparison with more recent anthropometric data. The secondary goal is to begin development of an ICDDR,B anthropometric data bank.

C. METHODS OF PROCEDURE

As of today, data from 26 of the villages have been entered on the computer from the Matlab Census Books, and I personally, randomly spot-checked about 30 of these entries to see that they were properly entered. The code sheet for this data entry is attached.

If this protocol is approved it would entail my going to Matlab to record the data from the 1970 Census Book of the 27th survey village and

bringing it to Dhaka for entry onto the computer, adding it to the data from the other 26 villages that have already been entered.

Once the data is all entered it will be edited by use of Z-scores of the NCHS anthropometric reference. The data will then be analysed by breaking down into age and sex groups and determining: 1) proportion of children below a specified and arbitrary lower-limit of the anthropometric indicator, and 2) the specified populations' distribution range of the anthropometric indicator (as recommended by WHO, 1979).

The above should be done for arm circumference as well as height, but as of yet ICDDR,B has not program for an arm circumference reference. Information providing the reference values for the arm circumference program has been requested from FAO, Rome. As a part of this protocol that program will be developed.

If it is possible, the families of the Sommer and Lowenstein anthropometric study will be linked to the 1970 Socio-Economic Status (SES) data on these same families, and again the WHO recommended determinations (1979) will be made using SES population breakdowns.

SIGNIFICANCE

It is not expected that this study in itself will represent any significant finding, as it is meant to be a baseline for the analysis of changes in anthropometric findings over the years. In order to do the Andre Mayer Fellowship research all anthropometry studies need to be analysed in the same manner so that studies done one year can be compared with studies done

another year in order for anthropometric changes to be linked to economic development.

An additional advantage in this study is that it will be the first step in establishing a documented nutritional anthropometry data bank, with easy access to any interested ICDDR,B researcher.

E. FACILITIES REQUIRED

Use of ICDDR,B computer services.

F. COLLABORATIVE ARRANGEMENT

NIL

REFERENCES

Sommer, A. and M.S. Lowenstein (1975) "Nutritional status and mortality:
a prospective validation of QUAC stick" Am. J. Clin. Nutr., 28: 287-292.

World Health Organization (1979) A Guideline for the Measurement of Nutritional
Impact of Supplementary Feeding Programmes Aimed at Vulnerable Groups
(WHO/FAP/79.1, Geneva).

Attached:

11 January 1983 Memo on Entry of Sommer's 1970 Nutrition Data.

Available on Request:

Fillmore, C.M. (1983) "Anthropometric Data Collected in Matlab"
Final Draft.

SECTION - III: BUDGET

A. DETAILED BUDGET

As Capri Mara Fillmore receives a stipend for her fellowship from FAO, there will no budget money allocated for her salary.

PERSONNEL SERVICES (Computer Services)

<u>Position</u>	<u>% Effort</u>	<u>Man Months</u>	<u>Annual Salary</u>	<u>Requirement Taka</u>
Data Entry Technician	100	2	Tk. 32,400	6,000
Programmer (National)	100	2	" 47,600	8,000

MISCELLANEOUS

Computer Time	3,000
Computer Stationery & Diskettes	1,000
	<u>18,000</u>

B. BUDGET SUMMARY

<u>Category</u>	<u>Takas</u>
Personnel Services	14,000
Miscellaneous	4,000
Total:	<u>18,000</u>

Total in Dollars (Taka 24.00/\$1.00) = \$750

Mr. Mohd. Mohsin

Capri Mara Fillmore *AK Fillmore*

11.1.1983

Entry of Sommer's 1970 Nutrition Data

As we discussed I would like the column position as follows:

1-4 Village code
5-8 Family code
9-10 Individual code
11-16 Birth date
17-22 Date of Measurement (always to be 010171)
23-25 Arm circumference
26-29 Height
30 Male = 2, Females = 1

Some of the children have age (y.o) but no birth date list their birth dates as follows:

2 y.o. = 011168
3 y.o. = 011167
4 y.o. = 011166
5 y.o. = 011165
6 y.o. = 011164
7 y.o. = 011163
8 y.o. = 011162
9 y.o. = 011161
10 y.o. = 011160

If you have any problems, please note down the I.D., number and ask me when I return on 19 January,

cc: Mr. A.H. Mostafa, Computer Manager

S. D'Souza
M. Chowdhury