Attachment 1. Date 529

ETHICAL REVIEW COMMITTEE, ICDDR,B.

Principal Investigator A.S.M.H. Rahman
Application No. 80-048(P)
Title of Study Haematological and Biochemical Values of Normal Laboratory Animals

Trainee Investigator (if any) _____
Supporting Agency (if Non-ICDDR,B) _____
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 Yes No
   (b) Non-ill subjects Yes No
   (c) Minors or persons under guardianship Yes No
   } NA
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)
   } NA
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
   } NA
4. 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
   } NA
5. Will signed consent form be required:
   (a) From subjects Yes No
   (b) From parent or guardian (if subjects are minors) Yes No
   } NA
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) PILOT STUDY
   ✓ 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.

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

Rahman

80-048(P)
Recd.
30/12/80

PILOT PROJECT

1. Title: Haematological and Biochemical values of Normal Laboratory Animals
I. Rabbit II. Guinea Pig III. Rat IV Mouse

2. Principal Investigators: A.S.M. Hamidur Rahman & K.A. Al-Mahmud

3. Starting Date: August 1, 1980

4. Completion date: October 31, 1980

5. Total direct Cost

6. Scientific Program Head:

This protocol has been approved by the Nutrition Working Group

* Signature of Scientific Program Head: _____

Date: 22/12/1980

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

7. Abstract Summary:

Variations of blood constituents in normal conditions occurring in the individual class of laboratory animals is of great academic and practical importance for clinical works. Although investigations have been carried out in other countries to fix haematological standards for laboratory animals such has not been attempted in this country and no records are available of this type.

The object of the present study is to establish normal standards of haematological values of laboratory animals under Bangladesh condition.

8. Reviews;

a) Ethical Review Committee: _____

b) Research Review Committee: _____

8 Reviews:

c) Director: _____

d) BMRC: _____

e) Controller/Administrator _____

PILOT PROJECT

HAEMATOLOGICAL VALUES OF NORMAL LABORATORY ANIMALS: I. RABBIT II GUINEA PIG III RAT IV MOUSE.

Abstract Summary

Variations of blood constituents in normal conditions occurring in the individual class of laboratory animals is of great academic and practidal inportance for clinical works. Although investigations have been carried out in other countries to fix haematological values such has not been attempted in this country and no records are available of this type. The object of this study is to establish normal standards of blood values of laboratory animals raised under Bangladesh condition.

I. Population:

200 healthy rabbits of either sex with the following age groups will be taken.

a. 1 wk - 8 wk
b. 9 wk - 16 wk.
c. 17 wk - 24 wk
d. 25 wk - above

2. Potential risk

There is no significant risk to the study. All humane procedures will be restored to collect blood samples.

3. Procedrues for minimizing potential risks

Since there is no risk this section is not applicable.

4. Safeguarding confidentiality: Not applicable.

5. Informal consent: Not applicable

6. Interview information: Not applicable.

7. Potential benefits to the subject

The benefits of the study will be utilized by the investigators who want to perform nutritional and bio-medical researches on laboratory animals raised under Bangladesh condition.

8. Medical Records: Not applicable.

BUDGET SUMMARY

No direct cost for animals - sampling will be done from the existing stock of ARB. The work will include 25% of time of Dr. A.S.M.H. Rahman and 5% that of Dr. K. Al-Mahmud for a period of 90 days. A key punch operator (½ day) and a computer programmer for 3 days. One technician from each of Clinical Pathology & Biochemistry for 2 hours/day for 90 days.

As discussed with Head, Biochemistry and In charge, Pathology - no extra manpower will be needed. The tests will be performed as routine work.

Cholera Research Laboratory

Memorandum

TO Member of ~~the~~ Nutrition Working Group

FROM A.S.M. Hamidur Rahman and K. A. Al-Mahmud DATE 8.7.80

SUBJECT Pilot Project: Haematological Values of Normal Laboratory Animals. I. Rabbit II. Guinea Pig III. Rat IV. Mouse

The object of the study is to fix a base line data on the normal haematological values of the four laboratory animals reared in the Animal Resources Branch of the Centre.

Goals

1. To observe the influence of age and sex on the haematological values (Table I and II) attached.

2. To observe influence of age and sex on some of the selected values of blood chemistry (Table III & IV) attached.

Reports from Hafez et al (1965) say that food, breed and climatic conditions have great influence on the normal blood constituents of animals and there are variations in such conditions.

Selected tables to be compiled and analysed are appended.

Attachments:

TABLE - I

INFLUENCE OF AGE ON THE MEAN BLOOD VALUES OF LABORATORY ANIMALS

Age in Weeks	1-8 Wk		9-16 Wk	17 Wk - Above
	1-3	4-8		
No. in each groups	50	50	50	50
RBC 10^6 /Cu mm				
Hb G%				
PCV %				
MCV Cu/				
MCH rr				
MCHC %				
WBC 10^3 /Cu mm				
ESR mm/hr.				
DIFF. LEUCOCYTES				
Lymphocytes %				
Monocytes %				
Neutrophils %				
Eosinophils %				

TABLE - II

INFLUENCE OF SEX ON THE NORMAL HAMATOLOGICAL VALUES OF LABORATORY ANIMALS

Sex	Male	Female
No. in each group	100	100
RBC (10^6 /Cu mm)		
Hb (G%		
PCV (%)		
MCH (rr)		
MCHC (%)		
WBC (10^6 /Cu mm)		
ESR (mm/hr.)		
DIFF. LEUCOCYTES		
Lymphocytes (%)		
Monocytes (%)		
Neutrophils (%)		
Eosinophils (%)		

TABLE - III

INFLUENCE OF AGE ON THE BLOOD CHEMISTRY OF LABORATORY ANIMALS

Age in Weeks	1-8 Wk		9-16 Wk	17 Wk-Above
	1-3	4-8		
No. in each groups	50	50	50	50
Glucose mmol/l				
Urea mmol/l				
Creatinine µmol/l				
Electrolytes				
Na + mmol/l				
K + mmol/l				
Cl - mmol/l				
TCo2 mmol/l				
Refractive index				
Protein g/l				
Sp.Gr.				

TABLE - IV

INFLUENCE OF SEX ON THE BLOOD CHEMISTRY OF LABORATORY ANIMALS

Sex	Male	Female
No. in each groups	100	100
Glucose mmol/1		
Urea mmol/1		
Creatinine mmol/1		
Electrolytes		
Na + mmol/1		
K + mmol/1		
Cl- mmol/1		
TCo2 mmol/1		
Refractive index		
Protein g/1		
Sp. Gr.		