SHAHEED ZULFIQAR ALI BHUTTO MEDICAL UNIVERSITY

Ethical Review Board (ERB)

(Hospital)

Application for approval of a Research Project involving Human Subjects

Date of Application: _____

1. Brief title of project:

2. Personnel involved

3. State your personal experience in this field in terms of extent and duration.

PROJECT DETAILS

4. Purpose of investigation (please indicate what information you hope to obtain, and what you believe will be the benefits).

5. Provide a concise description of what is to be done (the protocol).

6. State the potential hazards (if any), and precautions to be taken to meet them.

7. **State the degree of discomfort in terms of apprehension, pain and disturbance in terms of alteration of subject's routine.**

8. **State the likely duration of the project.**

9. **Where will the project be done?**

10. **What individual benefit (if any) will a patient have if he participates in the study?**

PATIENTS/VOLUNTEERS

11. State the number, age and type of patients/subjects likely to be involved. Have you discussed the methodology and number of subjects needed with a statistician? (If yes, please indicate with whom).

12. Do these include women who are pregnant or likely to become pregnant? How will pregnancy be excluded (if relevant)?

13. How will patients/volunteers be recruited?

14. Informed consent must be obtained in all cases: where written consent is sought, written information should be provided for the patient/volunteer, and this must be included with the application. Please indicate if consent will be:

(a) Oral

(b) Written

(c) Obtained in the presence of a disinterested 3rd person

15. Give details of any payment to be made to the patient/subject.

COMMUNICATION

16. Please indicate what (if any) information will be sought from general practitioners/other doctors, and what information will be supplied to them and in what form. Note that written information should indicate how experimenters can be contacted by telephone in emergency.

17. When a drug is being administered will the patient/subject have on his person some means of this being known in the case of a sudden illness/accident?

DRUGS

18. Please state briefly the known pharmacology of drugs to be used, indicating activity and I mportant side-effects.

SPONSORSHIP

19. Is this study being performed with commercial sponsorship, or sponsorship from some outside body (e.g. the PMRC)? If so, please state from whom.

20. If this project involves participation/sponsorship by a pharmaceutical company, has indemnification or no fault liability been obtained?

21. Is there any other form of indemnification?

22. In case of commercial sponsorship, is there any payment to be made to the experimenters/department in addition to the actual cost of the study? If so, please give details.

Signature of Principal Investigator

Name: **Designation:**

Deptt:

Tel No Office: **Mobile:**

Email:

DISHONESTY AND FALSIFICATION IN DRUG TRIALS

In November 1998, the case of Dr. James Bochsler, a retired GP, was considered by the Professional Conduct Committee of the General Medical Council, UK. The doctor did not attend.

He faced allegations of failing to obtain proper consent from patients to participate in clinical trials and falsification of trial results.

He was erased with immediate suspension, following an unsuccessful application by his solicitor to have the case adjourned or referred to the health committee.

Dr. John Ball, chairman of the PCC, concluded the case by saying, 'The integrity of clinical trials depends on the honesty of all those involved. Dishonesty by doctors participating in clinical trials is a matter of grave concern to this Committee. Scientific dishonesty producing bogus results undermines the integrity of drug trials and endangers patients who may in the future be treated with drugs which have not reliably been tested.'

Source: GMC Newsletter, Winter 1998

Note: Submitted to Ethical Review Board Office, VC Secretariat, Shaheed Zulfiqar Ali Bhutto Medical University, PIMS, G-8/3, Islamabad. Tel: 051-9107679