

The Drugs (Research) Rules, 1978

S.R.O. 1047(I)/78, dated 15th July, 1978: In exercise of the powers conferred by Section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make the following rules, the same having been previously published as required by sub-section (3) of the said section, namely :--

1. Short title and commencement: (1.) These rules May be called the Drugs (Research) Rules, 1978.
(2) They shall come into force at once,

2. Definitions: In these rules, unless there is anything repugnant in the subject or context,--

- (a) "Committee" means the Committee of Experts constituted under rule 8;
- (aa) "form" means form appended to these rules;
- (b) "Fund" means the Central Research Fund maintained by the Federal Government under sub-rule (14) of rule 19 of the Drugs (Licensing, Registering and Advertising), Rules, 1976, [\[...\]](#);
- (c) "investigator" means a person engaged in the investigation, research, development or evaluation of a drug on his own initiative or under the sponsorship of any other person or an institution;
- (d) "recipient" means a person or an institution who or which receives aid from the Fund [\[...\]](#); and
- (e) "sponsor" means a person, firm, an establishment or institution promoting research on a drug.

3. Utilisation of Fund: The Federal Government may utilise the Fund for conducting research, development .or evaluation of a drug either itself or through a search institution working under its control or disburse it among investigators or institutions for such purposes subject to such conditions as may be specified.

4. Research in drugs: The research in drugs shall be conducted at such place or places and by such person or persons as may be approved by the Federal Government and shall be categorised as under :--

- (i) other than clinical trials; and
- (ii) clinical trials.

5. Application for grant of aid: (1) An application for the grant of aid from the Fund for conducting research on a drug on aspects other than the clinical trials and for clinical trials shall be made in Form 'A' and Form 'B', respectively, [land addressed to the Secretary of the Committee \[...\]](#).

(2) The Federal Government may, before granting any aid from the Fund, cause inspection of the premises concerned end technical evaluation of the project by the Committee or any expert appointed by it for this purpose.

(3) The Federal Government may, after obtaining the advice of the Committee and subject to such conditions as it may specify in this behalf, grant such aid from the Fund to a person or an institution as it may deem fit.

6. Conditions for conducting research on aspects of other than clinical trials: (1) The research on any aspect of drugs other than clinical trial shall be conducted under the supervision of an investigator who possesses post-graduate qualification and experience in the relevant field and has sufficient background knowledge. to conduct scientific investigation.

(2) The recipient shall, at regular intervals not exceeding six months, submit the progress report to the Federal Government in respect of the investigation being conducted.

(3) No change of an investigator or in the plan for investigation shall be made without prior approval of the Federal Government.

(4) The recipient shall allow [an expert or a panel of experts](#) authorised by the Federal Government to visit the premises at which the research is being conducted and to see that the Fund is being utilised in accordance with the approved plan.

7. Conditions for research in clinical trials: (1) In addition to the conditions laid down in rule 6, research in drugs on aspect of clinical trials shall be conducted in the following stages :--

(i) Stage 1 of investigation on human beings shall consist of studies to determine single and short term multiple dosing for tolerance, side effects, toxicity, metabolism, preferred routes of administration, safe dosage range and other pharmacological actions of the drug:

Provided that these studies shall be conducted under carefully controlled circumstances on comparatively small number of subjects to prevent any serious deleterious effect on health.

(ii) Stage II of investigation shall consist of studies to determine safety and effectiveness including an effective dose range, the common side effects of the drug on both clinical and laboratory parameters and where possible the level of drug in biological fluids in relation to therapeutic response:

Provided that these studies shall be undertaken if studies in Stage I of investigation demonstrate satisfactory results and shall involve initial and limited use of the drug in the treatment or prevention of the disease for which the drug is intended and shall be administered to carefully supervised patients:

Provided further that the Federal Government may require additional pharmacological studies to be conducted concurrently on animals to indicate safety for stage II of the investigation.

(iii) Stage III of investigation shall consist of studies under controlled conditions in order to expand knowledge of potential use and hazards and shall be undertaken if the data obtained in stages I and II provide reasonable assurance of safety and effectiveness or suggest that the drug may have a potential value of conducting several trials outweighing its hazards:

Provided that these studies shall be carefully monitored and all possible precautions shall be taken to prevent unnecessary exposure of the patient to the risk.

(2) If at any stage there appears to be an unwarranted hazard in the continuation of the ongoing clinical trials, the sponsor and recipient may be asked by the Federal Government to modify or discontinue clinical trials until further pre-clinical work has been done and the investigator conducting such research shall discontinue further tests under intimation to the sponsor and the recipient in writing, a copy of which be sent to the Federal Government.

(3) Studies on children shall not be undertaken unless there is a possibility of benefit to them and adequate studies of safety and efficacy are available in adults.

(4) When any dangerous or adverse effects are observed, emergency reports shall be sent immediately by the recipient to the Federal Government so that the other investigators are informed and the studies are stopped if the hazard so warrants.

(5) The consent for use of all investigational new drugs in clinical trials for stages I and II shall be obtained in writing by the investigator but for stage III it is the responsibility of the investigator to take into consideration the physical and mental state of the patient to decide when it is necessary or preferable to obtain consent other than in writing and if written consent is not obtained, the investigator, must obtain oral consent and record the fact in the medical record of the person receiving the drug.

(6) The recipient shall keep the record of his studies carefully in respect of every drug, retain it for at least ten years after registration of that drug and produce it before the Federal Government whenever required.

8. Committee of Experts on Drug Research: (1) The Federal. Government shall set up a Committee of Experts on Drug Research to determine the priorities, to give directions in drug research, to evaluate the applications received for the grant and make allocations from the .Fund and to take or propose such actions and measures as may be necessary for ensuring effective and proper use of the Fund:

(1) The Federal Government shall constitute a Committee of Experts to advise it on the utilisation of the Fund and for such other purposes as may be necessary for the proper utilisation of the Fund.

(2) The Committee shall consist of the following members namely :--

- (a) Director-General Health who shall be its ex-officio Chairman.
- (b) Executive Director, National Institute of Health, Islamabad.
- (c) Chairman of the Pharmacy Department who shall hold office for three years by rotation. Chairman, Pharmacy Department, Peshawar University shall be the member for the first term.
- (d) Chairman of the Pakistan Council of Scientific and industrial Research or his nominee who may be directly responsible for drugs research activities in the Council.
- (e) Chairman of the Pakistan Medical Research Council, or his. nominee who may be directly responsible for drugs research activities in the Council.
- (f) A Dean of the Pharmacy Faculty who shall hold office for three years by rotation. Dean of the Pharmacy Faculty, University of Karachi, shall be the member for the first term.
- (g) A Professor of Pharmacology who shall hold office for three years by rotation. Professor of Pharmacology Allama Iqbal Medical College, Lahore, shall be the member for the first term.
- (h) One representative of the Pakistan Pharmaceutical Manufacturers' Association (PPMA) who may be well-versed with the subject and actively engaged in the planning or conducting of research on drugs.
- (i) Drugs Controller or Deputy Drugs Controller, Health. Division, Islamabad.

(3) The Federal Government may appoint a Secretary of the Committee from amongst its members.

9. Withdrawal of Fund and termination of an investigation: (1) The Federal Government may, at any stage of an investigation, withdraw the aid from the recipient and direct him and the sponsor to terminate a clinical trial under any of the following conditions, namely :-

- (i) evidence of significant hazard;
- (ii) convincing evidence that the drug is ineffective;
- (iii) submission of false data;
- (iv) omission of material information pertaining to safety and efficiency of the drug;
- (v) unsatisfactory manufacturing practices;
- (vi) failure to conduct the investigation in accordance with plan submitted and approved by the Federal Government;
- (vii) commercialization of the drug before completing clinical trial;
- (viii) failure to report serious or potentially serious adverse reaction;
- (ix) failure to meet the requirement of patient's consent; and
- (x) evidence of misuse of the Fund:

Provided that the Federal Government may, before withdrawing the aid, require the recipient and the sponsor of any drug to comply with any of the above conditions which he has failed to comply within a specified period and may, after it is satisfied that the said conditions have been complied with, allow resumption of the investigation.

FORM 'A'
[See rule 5 (1)]

Application for grant of aid for conducting research in drugs other than clinical trials

1. Name and address of the applicant.
2. Name and address of the sponsor if he is other than the applicant.
3. Title of Research project.
4. Financial implications of the project.
 - (i) Total Financial implications.
 - (ii) Present investment.

- (iii) Other sources of finance. if any
- (iv) Amount required from the Drugs Research Fund and details of its proposed utilisation.

5. Details of the Research project as follows :-

- (i) Purpose.
- (ii) Outline.
- (iii) Progress already made (if any).
- (iv) Comprehensive future Plan.
- (v) Benefits.

6. Bio-data of all investigators including Incharge of the Research project giving the name. qualifications with years and experience.

FORM 'B'
[See rule S (I)]

Application for grant of aid for conducting clinical trials

1. Name and address of the applicant.
2. Name and address of the sponsor if he is other than applicant.
3. Title of Research project.
4. Financial implications of the project:
 - (i) Total Financial implications.
 - (ii) Present Investment.
 - (iii) Other sources of finance, if any.
 - (iv) Amount required from the Central Research Fund and details of its proposed utilisation.

5. Enclose herewith--

(i) outline of the Research Project, its purpose, benefits, description of the comprehensive plans. and progress already made, if any :

(ii) information and data about the drug to be investigated including its exact composition, chemistry. pharmacology, toxicity, conditions for use in man, and pharmacy with special reference to the method of manufacture and quality control to show that adequate standards exist and a meaningful assessment can be made of the safety of the material for use in man (copies of all informational material to be supplied to the investigator should be enclosed);

(iii) results of pre.clinical investigation including animal studies directed towards defining its safety and efficacy; and

(iv) an agreement from the sponsor and the applicant that they shall notify the Federal Government and all investigators if they become aware of any adverse effect arising during the course of investigation.

Note: When an investigator himself wishes to act as sponsor conducting an investigation, the amount of information required under item 4 (ii) and (iii) may vary but should be sufficient to identify the compound under investigation together with the facts which satisfy that the substance may be justifiably administered to human beings with reasonable margin of safety.

6. Bio-data of all investigators including Incharge of the Research project giving the name, qualifications and experience.