DRUG REGULATORY AUTHORITY
OF PAKISTAN

The Drugs (Research) Rules, 1978

(As amended)

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.- [1][(1)] In these rules, unless there is anything repugnant in the subject or context,-

[2][(a) "Committee" means the Committee of Experts constituted under rule 8];

(aa) "form" means form appended to these rules;

[3][(b) "Fund" means the Central Research Fund collected by the authority under sub-rule (14) of rule 19 of the Drugs (Licensing, Registering and Advertising), Rules, 1976 and is maintained by the Authority;]

(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 [4][….];

(e) "sponsor" means a person, firm, an establishment, or institution promoting research on a drug;

[5][(f) "basic research" means discovery and development of new drug which include chemical synthesis, screening, lead selection, pre-clinical testing, optimization and clinical trial with special emphasis on pre-clinical screening of medicines to look for remedies required in relation to our priority national health problems. Basic research also includes research in medicinal plants and other therapeutic goods; and

(g) "operational research" means a study that may involve intervention including treatment, medication programme survey or lab operation to confirm safety, efficacy and quality of the drug using human subjects. This also include studies on rational drug, antibiotics resistance, prescribing patterns in Pakistan, drug utilization studies, management of drugs in common / serious diseases, organize monitoring for quality control, monitoring of adverse reaction of drugs, therapeutic drug monitoring, studies on cost effectiveness of drugs, drug supply system, Pharmacovigiliance including drug information and poison control and development of guidelines(s) for therapeutic goods etc."; and

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[1] Amended vide S.R.O 272(I)/2014 dated 8th April, 2014

[2] Clause (1) re-lettered as Clause (aa), new clause added vide S.R.O. 619(i)/88, dated 26th April, 1988

[3] Amended vide S.R.O 272(I)/2014 dated 8th April, 2014

[4] Words omitted vide S.R.O. 619(I)/88, dated 26th April, 1988

[5] Inserted vide S.R.O 272(I)/2014 dated 8th April, 2014

(2) The words used but not explained in these rules shall have the same meanings as are assigned to them in the Drugs Act, 1976 (XXXI of 1976) and the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012).".]

3. Utilization of Fund.- [6][(1)] The [7][Authority] may utilize the Fund for conducting [8][basic and operational] research, [9][award of scholarship], development or evaluation of a drug either itself or through a search institution working under its control or disburse it among investigators or institution for such purposes subject to such conditions as may be specified [10][and for that matter, it may also utilize the fund to [11][upgrade and] establish Drugs Research and Testing Laboratories and a unit in the [12][Authority], for evaluation and monitoring of the research proposals and projects and management of the fund.]

[13][(2) The utilization of Fund shall be in accordance with accounting procedure of Authority and the same may be monitored by a sub-committee of Authority comprising of Director (Pharmacy Services), Director (Budget and Account) and Director (Administration).]

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 [14][Committee] and shall be categorized as under:-

(i) other than clinical trials ; [15][…]

(ii) clinical trials, [16][including bio-equivalence cum bio-availability studies, drug discovery, market research, quality assurance, Pharmacovigiliance, development of standards describing pharmacopeial monographs for therapeutic goods, data base development or digitalization of drugs research;

(iii) award of scholarship to conduct research on projects as approved by the Authority; and

(iv) Any other category with the approval of Authority.]

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, [17][and addressed to the Secretary of the Committee] [18][….].

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[6] Amended vide S.R.O 272(I)/2014 dated 8th April, 2014
[7] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[8] Inserted vide S.R.O 272(I)/2014 dated 8th April, 2014
[9] Inserted vide S.R.O 272(I)/2014 dated 8th April, 2014
[10] Words added by S.R.O. 150(I)/98, dated 14th February, 1998
[11] Words inserted by S.R.O. 219(I)/2005, dated 15 Feb, 2005
[12] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[13] Added vide S.R.O 272(I)/2014 dated 8th April, 2014
[14] Subs. Vide S.R.O 272(I)/2014 dated 8th April, 2014
[15] Omitted vide S.R.O 272(I)/2014 dated 8th April, 2014
[16] Inserted vide S.R.O 272(I)/2014 dated 8th April, 2014
[17] Words omitted vide S.R.O. 1063(I)/83, dated 17th November, 1983
[18] Words omitted vide S.R.O 619(I)/88, dated 26th April, 1988

[19][(2) The [20][Authority] may, before granting and aid from the Fund, cause inspection of the premises concerned and technical evaluation of the project by the Committee or any expert appointed by it for this purpose.

(3) The [21][Authority] 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 any institution as it may deem fit.]

[22][(4) The Committee shall evaluate the projects in accordance with the check list specified in Form C.]

6. Conditions for conducting research on aspects of other than clinical trials.- (1) The research on any aspect of drugs other than clinical trials 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, submits the progress report to the [23][Authority] 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 [24][Authority].

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

7. Conditions for research in clinical trials.- (1) In addition to the conditions laid down in rule 6, research in drugs in respect of the 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 drugs:

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 effect 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:

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[19] Subs. Ibid.
[20] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[21] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[22] Added vide S.R.O 272(I)/2014 dated 8th April, 2014
[23] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[24] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014

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 Stage I and II provide reasonable assurance of safety and effectiveness or suggest that the drug may have a potentials value of conducting several trials outweighing its hazard:

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 [25][committee] 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 [26][Authority].

(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 [27][Authority] 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.

(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 [28][Authority] whenever required.

[29]**[8. Committee of Experts on Drug Research.-** (1) The [30][Authority] shall constitute a Committee of Experts to advise it on the utilization on the fund and for such other purposes as may be necessary for the proper utilization of the fund.

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

[25] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[26] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[27] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[28] Subs vide S.R.O 272(I)/2014 dated 8th April, 2014
[29] Subs vide S.R.O 619(I)/88, dated 26th April, 1988
[30] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014

[31][(a) The Director Pharmacy Services who shall be its *ex-officio* Chairman;
(b) Deputy Drug Controller, Pharmacy Services of the Authority, who shall be *ex-officio* Secretary of the Committee;
(c) Chairman of the Pakistan Council of Scientific and Industrial Research or his nominee not below the rank of BPS-19 who shall directly be responsible for drug research activities;
(d) Chairman, Pakistan Medical Research Council or shall nominee not below the rank of BPS-19 who shall directly be responsible for drug research activities.
(e) Chairman, Higher Education Commission or his nominee not below the rank of BPS-19 who shall directly be responsible for drug research activities;
(f) one Professor of Pharmacy from each Province to be nominated by the Federal Government on the recommendations of the respective Provincial Government;
(g) one expert in biotechnology not below the rank of BPS-19 to be nominated by the Biotechnological Commission of Pakistan;
(h) a co-opted expert in the field related to a specialty case before the committee to be nominated by the Chairman of the committee on Drug Research.]

[32][…]

[33][(3) The Committee shall also develop a code of conduct for itself.

(4) The procedure of the committee shall be as follows:-

(a) the Committee shall evaluate applications received for grant in aid and may recommend allocation out of the fund and propose such conditions as may be necessary for ensuring effective and proper utilization of the fund;

(b) before recommending any aid from the Fund, cause inspection of the premises concerned and technical evaluation of the project by the committee or any expert appointed by it for this purpose;

(c) Committee may give advice for such condition as may be specified for grant of such aid from the fund to a person or any institution as it may consider fit;

(d) Committee any recommend to the Authority for immediate stoppage of study and withdrawal of fund, if any dangerous or adverse effects are observed upon emergency reports received by the recipient;

(e) Committee may recommend an honorarium for the evaluator or technical and supporting team of the Authority for evaluating the research project;

(f) Committee may monitor and evaluate or investigate complaints received from any quarter so as to propose action to the Authority in respect of any contraventions of these rules;

[31] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014
[32] Omitted vide S.R.O 272(I)/2014 dated 8th April, 2014
[33] Added vide S.R.O 272(I)/2014 dated 8th April, 2014

(g) Committee may call any person for personal hearing to adduce evidence before the committee in order to dispose of the complaint received by the Authority;

(h) Committee may adapt, review guidelines with the prior approval of the Authority for regulating the drug research;

(i) Committee may update national guidelines for research in line with the internationally published guidelines for the country and recommend to the Authority for its adaptation;

(j) in the absence of the Chairman, committee may elect one of the members to preside over the meeting;

(k) the Chairman himself or on the directions of the Chief Executive Officer of Drug Regulatory Authority of Pakistan, may call meeting of the committee;

(l) the Committee may co-opt any expert to give his opinion on a specialized matter before it for consideration or may refer the matter to him for expert opinion; and

(m) the Committee shall recommend to the Authority draft regulations to be made for the conduct of its business.]

9. Withdrawal of Fund and termination of an investigation.- (1) The [34][Authority] 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 or 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;

[34] Subs. vide S.R.O 272(I)/2014 dated 8th April, 2014

(ix) failure to meet the requirement of patient's consent; and

(x) evidence of misuse of the Fund:

Provided that the [35][Authority] 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.

[35] Insurted vide S.R.O 272(I)/2014 dated 8th April, 2014

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 utilization.
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.
7. [36][The detailed information shall be given in Annex-A below.

Annex-A

1. TITLE OF THE PROPOSED PROJECT:
2. RESEARCH DOMAIN (priority areas): o Product Development / Improvement (new drugs, dosage forms / drug delivery system, formulations, etc) o Process/ Development / Improvement (Basic / Bulk drug manufacturing). o Rational Drug Use (Resistance to drugs, Prescribing patterns, Drug Management and utilization, etc) o Drug Quality System (Drug delivery system, Drug information and Poison control system, etc). Major Area: Minor area:
3. ABSTRACT OF THE PROJECT:

[36] Added vide S.R.O No. 272(I)/2014 dated 8th April, 2014

4. PRINCIPAL INVESTIGATOR NAME (full with no initials):			
4A. AREA OF SPECIALIZATION		4B. HIGHEST DEGREE/YEAR	4C. POSITION
4D. DEPARTMENT/ SECTION	4E. UNIVERSITY / INSTITUTION	4F. MAILING ADDRESS	
4G. Telephone: (area code, number and extension) Fax (area code, number) email:			
5. Co-Principal Investigator (full with no initials):			
5A. AREA OF SPECIALIZATION:	5B. HIGHEST DEGREE/ YEAR	5C. POSITION	
5D. SECTION / UNIT	5E. UNIVERSITY / INSTITUTION	5F. OFFICIAL MAILING ADDRESS	
5G. Telephone: (area code, number and extension) Fax (area code, number) email:			
PROPOSED DURATION OF PROJECT (in months)	PROPOSED STARTING DATE		
SIX MONTHLY TARGET OF ACHIEVEMENTS FOR THE ENTIRE DURATION OF THE PROJECT			
Six months:			
Twelve months:			
Eighteen months:			
Twenty four months: (and so on)			
TOTAL FUNDS REQUIRED Rs.	9A. SHARE OF THE INSTITUTION Rs.	9B. GRANT –IN-AID FROM CRF REQUESTED Rs.	
SIGNATURE OF PRINCIPAL INVESTIGATOR Date	SIGNATURE OF PRINCIPAL INVESTIGATOR Date		

ENDORSEMENT OF THE HEAD OF INSTITUTION (Vice-chancellor / Rector of University/ Chief Executive)	ENDORSEMENT OF THE HEAD OF PARTNER/INDSUTRY

Signature & Date Name Title: Address	Signature & Date Name Title: Address
Phone Fax Email	Phone Fax Email

PROJECT DETAILS

1. Project summary

Describe the proposed research using (about 250) words.

2. PROPOSED GOALS / OBJECTIVES (please identify quantifiable goals) Please clearly identify the output in the form of a product or process, system, need or relationship to the pharmaceutical / health sector. Enumerate GOALS/ OBJECTIVES :

3. INTRODUCTION (not to exceed one page)

The introduction should indicate: • The scientific and / or commercial basis on which the project is based. • Precise nature of the project. • The proposed objectives in the light of the first two paragraphs with explanation.

4A. BACKGROUND AND METHODOLOGY OF THE PROPOSED RESEARCH (not to exceed two pages)

A comprehensive and upto-date justification. Whether the project will lead to: Finding a solution to a national health care problem/ Capacity building in health or pharmacy services/ Benefit to the patient / Commercialization of a product/ Import substitution / Export promotion etc.,

4B. RESEARCH PLAN: SCHEDULE / PHASING (Preferably with a time-chart not to exceed one page)

4C. REFERENCES (cited in 3,4A & 4B; not to exceed two pages)

6. PROJECT PARTNERS (information on Industry)

Please give a brief introduction of the collaborating Partners, if any. Also state how and where the Partner's budgetary contribution will be utilized.

7. FACILITY AND FUNDING

7A. Facilities: equipment available for the research project in the host university / institution & the collaborating organization. 7B. Scientific Personnel (at the Institution) Available
b. Required
7C. Other funding available for the proposed studies

8A. PRINCIPAL INVESTIGATOR

A brief resume of research accomplished in the last 05 years. Please specify title of the research proposal(s), duration, and funding source(s) and award amount(s)
Please attach C.V. Number or Publications during the last five years & page Number on the C.V where these publications are listed Number of research projects completed & page number _____ of CV where this information appears of CV National:_____ International:_____ Basic:_____ Applied:_____

8B. CO-PRINCIPAL INVESTIGATOR

A brief resume highlighting achievement / experience, specially / concerned with the present proposal.

9A. ESTIMATED BUDGET FOR THE PROPOSED RESEARCH PERIOD (Rs. In millions)

DESCRIPTION	YEAR 1		YEAR 2		Total Amount	
	CRF	Inst/ Ind	CRF	Inst / Ind	CRF	Inst/ Ind
Salaries and honorarium eg						
Pl: One month / year of basic salary @		-		-		
Co-Pl One month basic salary for the entire duration @		-		-		
Scientific officer @ 10000/- per month		-				
Sub-total:						
Permanent Equipments: eg						
Spectrophotometer (UV/Visible)			-			
Micropipettes (10ul, 50ul, 100ul, 500ul, 1000ul)			-			
Sub-total			-			
Expandable Supplies: eg						
Chemicals and Rats			-			
Slides preparation for Histopathology			-			
Sub-total			-			
Other: eg D1 Literature, documentation, information, online literature search, contingencies, postage, etc.						
Publication, literature						

Sub-total						
D2. Local Travel (Destination and Purpose)						
	-	-	-	-	-	-
Sub-total	-	-	-	-	-	-
D3. Miscellaneous						
5% of the budget			-			
Sub-total			-			
Sub-total (D1 + D2 + D3): 60000 + 49750= 109750			-			
Grand Total (A+B+C+D+E):						
Total Budget CRF + Institution + Industry components						

10B. JUSTIFICATION (Please justify your request in a background of the existing facilities available at the host institute.)

A. Salaries and Allowances (All positions, other than P1 and Co-P1, must be fully justified. Please give qualifications / requirements of each of the new full-time positions requested for in the Proposal.)

B. Permanent Equipment (Please identify major items (over Rs. 25,000). Major pieces of equipment costing over Rs. 0.1 million must be fully justified. Minor items (under Rs. 25,000) may be limped into one.)

C. Expendable supplies

D. Other Costs. (Travel must be justified.)"

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FORM 'B'

[see rule5(1)]

Application for grant of aid for conducting clinical trails

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 Central Research Fund and details of its proposed utilization.
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 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 investigator if they become aware of any adverse effect arising during the course of investigation.

(Note.- When an investigator himself wishes to act as sponsor for 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.

[37][7. The detailed information shall be given in Annex-B below.

[37] Added vide S.R.O No. 272(I)/2014 dated 8th April, 2014

Annexure-B

1. TITLE OF THE PROPOSED PROJECT:

2. RESEARCH DOMAIN (priority areas):

- Phase-I: Clinical Trial
- Phase-I1: Clinical Trial
- Phase-III: Clinical Trial
- Phase-IV: Clinical Trial
- Bio-equivalence Studies
- Bio-availability Studies
- Any other bio study

Major Area: Minor area:

3. ABSTRACT OF THE PROJECT:

4. PRINCIPAL INVESTIGATOR NAME (full with no initials):

4A. AREA OF SPECIALIZATION		4B. HIGHEST DEGREE/YEAR	4C. POSITION
4D. DEPARTMENT/ SECTION	4E. UNIVERSITY / INSTITUTION	4F. MAILING ADDRESS	
4G. Telephone: (area code, number and extension) Fax (area code, number) email:			

5. Co-Principal Investigator (full with no initials):

5A. AREA OF SPECIALIZATION:	5B. HIGHEST DEGREE/ YEAR	5C. POSITION
5D. SECTION / UNIT	5E. UNIVERSITY / INSTITUTION	5F. OFFICIAL MAILING ADDRESS
5G. Telephone: (area code, number and extension) Fax (area code, number) email:		

6. PROPOSED DURATION OF PROJECT (in months)	7. PROPOSED STARTING DATE

8. SIX MONTHLY TARGET OF ACHIEVEMENTS FOR THE ENTIRE DURATION OF THE PROJECT

Six months:	
Twelve months:	

Eighteen months:		
Twenty four months: (and so on)		
9. TOTAL FUNDS REQUIRED Rs.	9A. SHARE OF THE INSTITUTION Rs.	9B. GRANT –IN-AID FROM CRF REQUESTED Rs.

SIGNATURE OF PRINCIPAL INVESTIGATOR Date	SIGNATURE OF PRINCIPAL INVESTIGATOR Date
ENDORSEMENT OF THE HEAD OF INSTITUTION (Vice-chancellor / Rector of University/ Chief Executive) Signature & Date Name Title: Address	ENDORSEMENT OF THE HEAD OF PARTNER/INDSUTRY Signature & Date Name Title: Address
Phone Fax Email	Phone Fax Email

PROJECT DETAILS

1. Project summary

Describe the proposed research using (about 250) words.

2. PROPOSED GOALS / OBJECTIVES (please identify quantifiable goals)

Please clearly identify the output in the form of a product or process, system, need or relationship to the pharmaceutical / health sector. Enumerate GOALS/ OBJECTIVES :

3. INTRODUCTION (not to exceed one page)

The introduction should indicate: ▪ The scientific and / or commercial basis on which the project is based. ▪ Precise nature of the project. ▪ The proposed objectives in the light of the first two paragraphs with explanation.

4A. BACKGROUND AND METHODOLOGY OF THE PROPOSED RESEARCH (not to exceed two pages)

A comprehensive and upto-date justification. Whether the project will lead to: Finding a solution to a national health care problem/ Capacity building in health or pharmacy services/ Benefit to the patient / Commercialization of a product/ Import substitution / Export promotion etc.,

4B. RESEARCH PLAN: SCHEDULE / PHASING (Preferably with a time-chart not to exceed one page)

4C. REFERENCES (cited in 3,4A & 4B; not to exceed two pages)

5. PROJECT PARTNERS (information on Industry)

Please give a brief introduction of the collaborating Partners, if any. Also state how and where the Partner's budgetary contribution will be utilized.

6. FACILITY AND FUNDING

6A. Facilities: equipment available for the research project in the host university / institution & the collaborating organization.

6B. Scientific Personnel (at the Institution)

Available

b. Required

6C. Other funding available for the proposed studies (if any)

7A. PRINCIPAL INVESTIGATOR

A brief resume of research accomplished in the last 05 years. Please specify title of the research proposal(s), duration, and funding source(s) and award amount(s)

Please attach C.V.

Number or Publications during the last five years & page Number on the C.V where these publications are listed

Number of research projects completed & page number _____ of CV where this information appears of CV

National:_____

International:_____

Basic:_____

Applied:_____

7B. CO-PRINCIPAL INVESTIGATOR

A brief resume highlighting achievement / experience, specially / concerned with the present proposal.

8A. ESTIMATED BUDGET FOR THE PROPOSED RESEARCH PERIOD (Rs. In million)

DESCRIPTION	YEAR 1		YEAR 2		Total Amount	
	CRF	Inst/ Ind	CRF	Inst / Ind	CRF	Inst/ Ind
Salaries and honorarium eg						
Pl: One month / year of basic salary @		-		-		
Co-Pl One month basic salary for the entire duration @		-		-		
Scientific officer @ 10000/- per month		-				
Sub-total:						
Permanent Equipments: eg						
Spectrophotometer (UV/Visible)			-			
Micropipettes (10ul, 50ul, 100ul, 500ul, 1000ul)			-			
Sub-total			-			
Expandable Supplies: eg						
Chemicals and Rats			-			
Slides preparation for Histopathology			-			
Sub-total			-			
Other: eg D1 Literature, documentation, information, online literature search, contingencies, postage, etc.						
Publication, literature						
Sub-total						
D2. Local Travel (Destination and Purpose)						
	-	-	-	-	-	-
Sub-total	-	-	-	-	-	-
D3. Miscellaneous						
5% of the budget			-			
Sub-total			-			
Sub-total (D1 + D2 + D3): 60000 + 49750= 109750			-			
Grand Total (A+B+C+D+E):						
Total Budget CRF + Institution + Industry components						

8B. JUSTIFICATION (Please justify your request in a background of the existing facilities available at the host institute.)

A. Salaries and Allowances (All positions, other than P1 and Co-P1, must be fully justified. Please give qualifications / requirements of each of the new full-time positions requested for in the Proposal.)

B. Permanent Equipment (Please identify major items (over Rs. 25,000). Major pieces of equipment costing over Rs. 0.1 million must be fully justified. Minor items (under Rs. 25,000) may be limped into one.)

C. Expendable supplies

D. Other Costs. (Travel must be justified.)"

Explanatory Note for guidance regarding Essential Documents for the conduct of a Clinical Trial

8.1 Introduction:

Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of GCP and with all applicable regulatory requirements.

Essential Documents also serve a number of other important purposes. Filling essential documents at the investigator / institution and sponsor sites in a timely manner can greatly assist in the successful management of a trial by the investigator, sponsor and monitor. These documents are also the ones that are usually audited by the sponsor's independent audit function and inspected by the regulatory authority(ies) as part of the process to confirm the validity of the trial conduct and the integrity of data collected.

The minimum list of essential documents that has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normal be generated (1) before the clinical phase of the trial commences, (2) during the clinical conduct of the trial and (3) after completion or termination of the trial. A description is given of the purpose of each documents, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Trial master files should be established at the beginning of the trial, both at the investigator/ institution's site and at the sponsor's office. A final close-out of a trial can only be done when the monitor has reviewed both investigator/ institution and sponsor's files and confirmed that all necessary documents are in the appropriate files.

Any or all of the documents addressed in this guidance may be subject to and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies).

8.2 Before the Clinical Phase of the Trial Commences:

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Located in Files of Investigator / Sponsor Institution	
8.2.1	Investigator's brochure	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2	Signed protocol and amendments if any and sample case report from (CRF)	To document investigator and sponsor agreement to the protocol/ amendment(s) and CRF	X	X
8.2.3	Information given to trial subject.- Information consent form (Including all applicable translations) - Any other written information - Advertisement for subject recruitment (if any)	To document the unformed consent To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent. To document that requirement measures are appropriate and not coercive	X X X	X X
8.2.4	Financial aspects of the trial	To document the financial agreement between the investigator / institution and the sponsor for the trial	X	X
8.2.5	Insurance statement (where required)	To document that compensation to subject(s) for trail-related injury will be available.	X	X
8.2.6	Signed agreement between involved parties, e.g. - Investigator/institution and sponsor - Investigator /institution and CRO - Sponsor and CRO Investigator/ institution and authority(ies) (Where required)	To document agreements	X X X	X X (where required) X X
8.2.7	Dated, documented approval/favorable opinion of IRB/IEC of the following: - Protocol and any amendments	To document that the trial has been subject to IRB/IEC review and given approval / favorable opinion. To identify the version number and date of the	X	X

	- CRF (if applicable) - Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject requirement (if used) - Subject compensation (if any) - Any other documents given approval / favorable opinion.	documents(s)		
8.2.8	- Institutional review board/ independent ethics committee composition	To document that the IRB/IEC is constituted in agreement with GCP	X	X (where required)
8.2.9	Regulatory authority(ies) authorization/ approval notification of protocol (where required)	To document appropriate authorization;/approval notification by the regulatory authority(ies) has been obtained prior to institution of the trial in regulatory requirements(s)	X (where required)	X (where required)
8.2.10	Curriculum vitae and / or other relevant documents evidencing qualifications of investigator(s) and sub investigators	To document qualification and eligibility to conduct trial and / or provide medical supervision of subjects	X	X
8.2.11	Normal value(s)/range(s) for medical/ laboratory/technical procedure(s) and/ or test(s) included in the protocol	To documents competence of facility to perform required test(s), and support reliability of results	X	X
8.2.12	Medical/Laboratories/technical Procedure/test - Certification or - Accreditation or - Establishment quality control and or external quality assessment or - Other, validation (where required)	To document competent of facility to perform required test(s), and support reliability or results	X (where required)	X
8.2.13	Sample of label(s) attached to investigational product container(s)	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects		X
8.2.14	Instructions for handling of investigational product(s) and trial-related materials (if not included in protocol or investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational products and trial-related materials	X	X
8.2.15	Shipping records for investigational product(s) and trial-related materials	To document shipment dates, batch numbers, and method of shipment of investigational product(s) and trial-related material. Allows tracking of	X	X

		product batch, review of shipping conditions, and accountability.		
8.2.16	Certificate(s) of analysis of investigational product(s) shipped	To document identity purity and strength of investigational products of be use in the trial.		X
8.2.17	Decoding procedures for blinded trials.	To document how in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subject's treatment.	X	X (third party if applicable)
8.2.18	Masters randomization list	To document method for randomization of trial population		X (third party if applicable)
8.2.19	Pretrial monitoring report	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20	Trial intimation monitoring report	To document that trial procedures were reviewed with the investigator and investigator's trial staff (may be combined with 8.2.19)	X	X

8.3 During the Clinical Conduct of the Trial

In addition to having on file the above documents, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

	Title of Document	**Purpose**	**Located in Files of Investigator/ Sponsor Institution**	
8.3.1	Investigator's Brochure updates	To document that investigator is informed in a timely manner of relevant information as it becomes available	X	X
8.3.2	Any revisions to: - Protocol/amendments(s) and CRF - Informed consent from - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	To document revisisions of these trial-related documents that take effect during trial	X	X
8.3.3	Dated. Documented approval/ favorable opinion of institutional review board (IRB)/independent ethics committee (IEC) of the following: - Protocol amendments(s) - Revision(s) of	To document that the amendment(s) and / or revision(s) have been subject to IRB/IEC review and were given approval / favorable opinion. To	X	X

	- Informed consent form Any other written information to be provided to the subject Advertisement for subject recruitment (if used) - Any other documents given approval/favorable opinion - Continuing review of trial (see section 3.1.4)	identify the version number and date of the documents(s)		
8.3.4	Regulatory authority(ies) authorizations / approval / notifications where required for: - Protocol amendments(s) and other documents	To document compliance with applicable regulatory requirements	X (where required)	X
8.3.5	Curriculum vitae for new investigator(s) and /or sub investigators	(See section 8.2.10)	X	X
8.3.6	Updates to normal value (s)/range(s) for medical laboratory/technical procedure(s)/test(s) included the protocol	To document normal values and ranges that are revised during the trial (see section 8.2.11	X	X
8.3.7	Updates of medical / laboratory/ technical procedures/tests - Certification or - Accreditation or - Established quality control and/ or external quality assessment or - Other validation (where required)	To document that tests remain adequate throughout the trial period (see section 8.2.12)	X (where required)	X
8.3.8	Documentation of investigational product(s) and trial-related materials shipment.	(See section 8.2.15)	X	X
8.3.9	Certificate(s) of analysis for new batches of investigational product	(See section 8.2.16)		X
8.3.10	Monitoring visit reports	To documents site visits by, and findings of, the monitor	X	X
8.3.11	Relevant communications other than site visits - Letters - Meeting notes - Notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting	X	X
8.3.12	Signed informed consent forms	To document that consent is obtained in accordance with GCP and protocol and date prior to participation of each subject in trial. Also to document direct access permission (see section 8.2.3)	X	
8.3.13	Source documents	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical	X	

		treatment, and history of subject.		
8.3.14	Signed, date, and completed case report forms (CRFs)	To document that the investigator or authorized member of the investigator's staff confirms the observations recorded.	X (copy)	X (original)
8.3.15	Documentation of CRF corrections	To document all changes/ additions or corrections made to CRF after initial data were recorded	X (copy)	X (original)
8.3.16	Notification by originating investigator to sponsor or serious adverse events and related reports	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with 4.11)	X	X
8.3.17	Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) / IEC(s) of unexpected serious adverse drug reactions and of t other safety information	Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s)/IEC(s) of unexpected serious adverse drug reactions in accordance with 5.17 and 4.11.1 and of other safety information in accordance with 4.11.2 and 5.16.2	X (where required)	X
8.3.18	Notification by sponsor to investigators of safety information	Notification by sponsor to investigators of safety information in accordance with 5.16.2	X	X
8.3.19	Interim or annual reports to IRB/IEC and authority(ies)	Interim or annual reports to IRB/IEC in accordance with 4.10 and to authority(ies) in accordance with 5.17.3	X	X (where required)
8.3.20	Subject screening log	To document that investigator / institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator / institution to reveal identity of any subject	X	X (where required)
8.3.21	Subject identification code list	To document that investigator/ institution keeps a confidential list of names of all subject allocated to trial numbers on enrolling in the trial. Allows investigator institution to reveal identity of any subject	X	
8.3.22	Subject enrollment log	To document chronological	X	
8.3.23	Investigational product(s) accountability	To document that	X	X

	at the site	investigational product(s) have been used according to the protocol		
8.3.24	Signature sheet	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs	X	X
8.3.25	Record of retained body fluids/tissue sample (if any)	To document location and identification of retained samples if assays need to be repeated	X	X

8.4 After Completion or Termination of the Trial:

After completion or termination of the trial, all of the documents identified in section 8.2 and 8.3 should be in the file together with the following:

	Title of Document	**Purpose**	**Located in Files of Investigator/ Sponsor Institution**	
8.4.1	Investigational product(s) accountability at site	To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational products(s) received at the site, dispensed to subject, returned by the subject, and returned to sponsor.	X	X
8.4.2	Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or at site	X (if destroyed at site)	X
8.4.3	Completed subject identification code list	To permit identification of all subject enrolled in the trial in case follow-up is required List should be kept in a confidential manner and for agreed upon time	X	
8.4.4	Audit certificate (if required)	To document that audit was performed (if required) (see section 5.19.3(e))		X
8.4.5	Final trial close-out monitoring report	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X
8.4.6	Treatment allocation and decoding documentation	Returned to sponsor to document any decoding that may have occurred		X
8.4.7	Final report by investigator/ institution to	To document completion of	X	

	IRB/IEG where required, and where applicable, to the regulatory authority(ies) (see section 4.13)	the trial		
8.4.8	Clinical study report (see section 5.22)	To document result and interpretation of trial	X (if applicable)	X

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[38][Form C

[see rule 5(4)]

Note:- Evaluator/ Reviewers are required to comment on the following headings of the proposed study (N.B. Please write N.A. where it is not applicable).

A. INTRODUCTION

1.	What is the actual scientific research problem to be investigated by the researchers? (HYPOTHSIS)			
		YES	**NO**	**NA**
2.	Whether project will lead to:			
a.	Find solution to a problem of national importance?	_____	_____	_____
b.	Capacity building/	_____	_____	_____
c.	Commercialization of a	_____	_____	_____
d	product?	_____	_____	_____
e.	Import substitution?	_____	_____	_____
f.	Export promotion?	_____	_____	_____
	What else?	_____	_____	_____
3.	Whether the project:			
a.	Has a testable hypothesis?	_____	_____	_____
b.	Has it properly been delineated and defined?	_____	_____	_____
c.	Has justification been provided?	_____	_____	_____
d.	Answer the problem posed?	_____	_____	_____
4.	Whether literature review of the proposed research is adequate and up-to-date? If not, indicate important references, which should be consulted by the investigator(s).	_____	_____	_____
5.	Has any related work been done by the investigator(s)?	_____	_____	_____
6.	Whether the research	_____	_____	_____

[38] Added vide S.R.O No. 272(I)/2014 dated 8th April, 2014

	proposal involves any duplication of the work already done or under study? If so, indicate as to how it can be avoided.			
7.	Whether the project is likely to be completed within the stipulated time? If not, indicate probable time justified.	_____	_____	_____
8.	Whether the project involves duplication of the work already done in the country or currently under way? If so, indicate as to how it can be avoided.	_____	_____	_____
B.	**OBJECTIVES**	**YES**	**NO**	**NA**
a	Are the objectives given relevant to the problem?	_____	_____	_____
b	Are the objectives manageable within the given resources and time?	_____	_____	_____
C	**IMPORTANCE OF WORK**	**YES**	**NO**	**NA**
a	Whether the findings / results of the research work would be significant enough to be published/ patented?	_____	_____	_____
D	**METHODOLOGY**	**YES**	**NO**	**NA**
a	Has the methodology/ work plan for the study been given reproduced?	_____	_____	_____
b	Have the sampling techniques been described?	_____	_____	_____
c	Is the selection of subjects properly made?	_____	_____	_____
d	Is the sample size proposed for study adequate for statistical evaluation?	_____	_____	_____
e	Are the proposed data instruments (Performa etc.) properly designed to give required information?	_____	_____	_____
f	Have methods of tabulation and analysis been given?	_____	_____	_____
E	**BUDGET**	**YES**	**NO**	**NA**
1.	Have the budget details been given?	_____	_____	_____
2.	Has proper justification been	_____	_____	_____

	given for each item in the budget?			
3.	Whether in the project budget.	_____	_____	_____
a	Staff requested for the proposed project is essential and compatible with the tasks involved?	_____	_____	_____
b	Parent institution is adequately equppped to implement the project efficiently?	_____	_____	_____
c	Equipment asked for is essential and costs involved reasonable? If not to what extent if can be modified?	_____	_____	_____
d	Funds requested under other heads are realistic. If not, what amount if recommended?	_____	_____	_____
4	Do you think that the budget asked for is reasonable?	_____	_____	_____
5	Whether the project has adequate	_____	_____	_____
F	**RECOMMENDATIONS**	**YES**	**NO**	**NA**
a	Do you recommend the study for funding?	_____	_____	_____
b	Do you approve the proposed budget?	_____	_____	_____
c	It not, what should be appropriate level of funding?	_____	_____	_____

[No.F.6-1/2013-Director (Pharmacy services).]]

[No.F, 14-2/78-QC]