THE GAZETTE OF PAKISTAN

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ISLAMABAD, TUESDAY, APRIL 8, 2014

PART II
Statutory Notifications (S.R.O)

Government of Pakistan
MINISTRY OF NATIONAL HEALTH SERVICES REGULATIONS AND COORDINATION

(Drug Regulatory Authority of Pakistan)

N O T I F I C A T I O N
Islamabad, the 8th April, 2014

S.R.O. 272 (I)/2013.- In exercise of the powers conferred by section 23 of the Drugs Regulatory Authority of Pakistan Act, 2012 (XXI of 2012), read with clause (a) of section 7 thereof and section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to direct that in the Drugs, Research Rules, 1978 of the Drug Act, 1976 (XXXI of 1976). The following further amendments shall be made, the same have been previously been published, as required by sub-section (3) of the said section 43, namely:-

AMENDMENTS.

In the aforesaid rules,-

(a) in rule 2, the existing provision shall be re-numbered as sub-rule (1) of that rule,-

(i) in sub-rule (1) as re-numbered hereinbefore,-

(a) for clause (b), the following shall be substituted, namely:-

"(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;";

(b) in clause (d) the word "and", at the end, shall be omitted; and

(c) after clause (e), the following new clauses (f) and (g) shall be inserted, namely:-

"(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, pharmacovigilance including drug information and poison control and development of guideline(s) for therapeutic goods etc."; and

(ii) after sub-rule (1), the following new sub-rule shall be inserted, namely:-

"(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 Drugs Regulatory Authority of Pakistan Act, 2012 (XXI of 2012).".

(b) in rule 3, the in sub-rule (1) the existing provision shall be re-numbered as sub-rule (1) of that rule and in sub-rule (1) as re-numbered hereinbefore,-

(a) after the words "conducting" the words "basic and operational" shall be inserted;

(b) after the words "research the words "award of scholarship" shall be inserted;

(c) for the words "Drug Control Section, Ministry of Health" the word "Authority" shall be substituted;

(d) for the words "Federal Government" the word "Authority" shall be substituted; and

(e) after sub-rule (1), the following new sub-rule shall be inserted, namely:-

"(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).";

(c) in rule 4,-

(i) for the words "Federal Government" the word "Committee" shall be substituted;

(ii) in clause (i) the word "and", at the end, shall be omitted;

(ii) in clause (ii), for the full stop, at the end, the words, comma and semi colon "including bio-equivalence *cum* bio-availability studies, drug discovery, market research, quality assurance, pharmacovigilance, development of standards describing pharmacopeial monographs for therapeutic goods, data base development or digitalization of drugs research;" shall be inserted; and

(iii) after clause (ii) the following new clauses shall be inserted, namely:-

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

(iv) any other category with the approval of Authority;";

(c) in rule 5,-

(i) in sub-rules (2) and (3), for the words "Federal Government" the word "Authority"; shall be substituted; and

(ii) after sub-rule (3), the following new sub-rule shall be inserted, namely:-

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

(e) in rule 6, in sub-rules (2) and (3), for the words "Federal Government" the word "Authority"; shall be substituted;

(f) in rule 7,-

(i) in sub-rule (2), for the words "Federal Government" , occurring for the first time, the word "Committee" shall be substituted and for the words "Federal Government" occurring for the second time the word "Authority" shall be substituted; and

(ii) in sub-rules (4) and (6), for the words "Federal Government" the words "Authority" shall be substituted;

(g) in rule 8,-

(i) in sub-rule (1), for the words "Federal Government" the word "Authority" shall be substituted;

(ii) for sub-rule (2), the following shall be substituted, namely:-

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

(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, 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 his 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.";

(iii) after sub-rule (2), substituted as aforesaid, the following new sub-rules (3) and (4) shall be inserted, namely:-

"(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 an institution as it may consider fit;

(d) Committee may recommend to the Authority for immediate stoppage of study and withdrawal of funds, 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 projects.

(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;

(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.";

(h) in rule 9, in sub-rule(1), for the words "Federal Government" the word "Authority" shall be substituted; and

(i) in Form A, after entry 6, the following shall be added, namely:-

"7. The detailed information shall be given in Annex-A below.

Annex-A

1.	TITLE OF THE PROPOSED PROJECT:
2.	RESEARCH DOMAIN (priority areas): □ Product Development / Improvement (new drugs, dosage forms / drug delivery system, formulations, etc) □ Process / Development / Improvement (Basic / Bulk drug manufacturing). □ Rational Drug Use (Resistance to drugs, Prescribing patterns, Drug Management and utilization, etc.) □ Drug Quality System (Drug delivery system, Drug information and Poison control system, etc.). 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. POISITION	
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 PROEJCT:			
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/INDUSTRY Signature & Date Name Title: Address: Phone Fax E-mail
Phone Fax E-mail	

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. INSTRODUCTION (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: SECHEDULE / 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) a. Available
b. Required
7C. Other funding available for the proposed studies (if any).

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).	
1. Please attach C.V. 2. Number or Publications during the last five years & page Number on the C.V. where these publications are listed. 3. 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 million)

DESCRIPTION	YEAR 1		YEAR 2		Total Amount	
	CRF	Inst. / Ind.	CRF	Inst. / Ind.	CRF	Inst. / Ind.
A. 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		-				
Subtotal:						
B. Permanent Equipments: eg						
Spectrophotometer (UV/Visible)			-			
Micropipettes (10ul, 50ul, 100ul, 500ul, 1000ul)			-			
Subtotal						
C. Expandable Supplies: eg						
Chemicals and Rats			-			
Slides preparation for Histopathology			-			
Subtotal			-			

D. Other: eg D1. Literature, documentation, information, online literature search, contingencies, postage, etc.						
Publication, literature						
Subtotal						
D2. Local Travel (Destination and Purpose)						
	-	-	-	-	-	-
Subtotal	-	-	-	-	-	-
D3. Miscellaneous						
5% of the budget			-			
Subtotal			-			
Subtotal (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 Pl and Co-Pl, 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 lumped into one.)

C. **Expendable supplies**

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

(j) in Form B, after entry 6, the following shall be added, namely:-

"7. The detailed information shall be given in Annex-B below.

Annexure-B

1. TITLE OF THE PROPOSED PROJECT:

2. **RESEARCH DOMAIN** (priority areas):

- ☐ Phase-I: Clinical Trial
- ☐ Phase-II: 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):

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4D. DEPARTMENT/ SECTION	4E. UNIVERSITY / INSTITUTION	4F. MAILING ADDRESS	
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Twelve months:	
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- Precise nature of the project.
- The proposed objectives in the light of the first two paragraphs with explanation.

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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.,

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

6B. Scientific Personnel (at the Institution)

a. Available

b. Required

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

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Pl: One month/year of basic salary @		-		-		
Co-Pl: One month basic salary for the entire duration @		-		-		
Scientific officer @ 10000/- per month		-				
Subtotal:						
A. Permanent Equipments: eg						
Spectrophotometer (UV/Visible)			-			
Micropipettes (10ul, 50ul, 100ul, 500ul, 1000ul)			-			
Subtotal						
C. Expandable Supplies eg						
Chemicals and Rats			-			
Slides preparation for Histopathology			-			
Subtotal			-			
D. Other eg D1. Literature, documentation, information, online literature search, contingencies, postage, etc.						
Publication, literature						
Subtotal						
D2. Local Travel (Destination and Purpose)						
	-	-	-	-	-	-
Subtotal	-	-	-	-	-	-
D3. Miscellaneous						
5% of the budget			-			
Subtotal			-			
Subtotal (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 & Allowances **(**All positions, other than Pl and Co-Pl, 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 lumped 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 normally 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 document, 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 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 form (CRF)	To document investigator and sponsor agreement to the protocol /amendment(s) and CRF	X	X
8.2.3	Information given to trial subject –Informed consent form (Including all applicable translations)	To document the informed consent	X	X
	- Any other written information	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	
	- Advertisement for subject recruitment (if any)	To document that requirement measures are appropriate and not coercive		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 trial-related injury will be available.	X	X
8.2.6	Signed agreement between involved parties, e.g.:	To document agreements		
	- Investigator/institution and sponsor		X	X
	- Investigator/institution and CRO		X	X
	- Sponsor and CRO			(where required)
	Investigator/institution and authority(ies) (Where required)			X
			X	X
8.2.7	Dated, documented approval/favorable opinion of IRB/IEC of the following:	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 document(s).	X	X
	- Protocol and any amendments			
	- CRF (if applicable)			

	- Informed consent form(s) - Any other written information to be provided to the subject(s) - Advertisement for subject recruitment (if used) - Subject compensation (if any) - Any other documents given approval/favorable opinion			
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 initiation of the trial in regulatory requirement(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 document 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 regulation's 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 materials. Allows tracking of product batch, review of shipping conditions, and accountability.	X	X
8.2.16	Certificate(s) of analysis of investigational product(s) shipped	To document identity, purity, and strength of investigational products of be used 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 applic-able)

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 initiation 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/amendment(s) and CRF - Informed consent form - Any other written information provided to subjects - Advertisement for subject recruitment (if used)	To document revisions 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 amendment(s) - Revision(s) of: - 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)	To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s)	X	X
8.3.4	Regulatory authority(ies) authorizations /approval/notifications where required for: - Protocol amendment(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	To document normal values and ranges that are revised during the trial (see section 8.2.11)	X	X

	procedure(s)/ tests(s) included in the protocol			
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 products	(See section 8.2.16)		X
8.3.10	Monitoring visit reports	To document site visits by, and findings of, the monitor		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 treatment, and history of subject	X	
8.3.14	Signed, dated, 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 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 identification of subjects who entered pretrial screening	X	X (where required)

8.3.21	Subject identification code list	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	
8.3.22	Subject enrollment log	To document chronological enrollment of subjects by trial number	X	
8.3.23	Investigational product(s) accountability at the site	To document that investigational product(s) have been used according to the protocol	X	X
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 sections 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 product(s) received at the site, dispensed to subjects, returned by the subjects, 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 sit	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 IRB/IEC where required, and where applicable, to the regulatory authority(ies) (see section 4.13)	To document completion of the trial	X	
8.4.8	Clinical study report (see section 5.22)	To document results and interpretation of trial	X (if applicable)	X.”.

(k) after Form B the following new Form shall be added, namely:-

"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 product?	_____	_____	_____
d	Import substitution?	_____	_____	_____
e	Export promotion?	_____	_____	_____
f	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	Answers 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 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?	_____	_____	_____
b	Is the study likely to open avenues for further studies?	_____	_____	_____
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 evaluations?	_____	_____	_____
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 equipped 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 is 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 this 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)]

(SHEIKH ANSAR AHMAD)
Director (Pharmacy Services)